From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 5/26/2022 12:10:51 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
CC: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]
Subject: Re: REVIEW REQUEST, 2PM TODAY: PR, FDA Flexibilities, Collaboration to Yield Millions of Bottles of Specialized Medical Infant Formula in Coming Months to Increase U.S. Supply

Thank you! I plan to put in front of Rob after hearing … as long as my phone doesn't die.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, May 26, 2022 12:09:56 PM
To: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: RE: REVIEW REQUEST, 2PM TODAY: PR, FDA Flexibilities, Collaboration to Yield Millions of Bottles of Specialized Medical Infant Formula in Coming Months to Increase U.S. Supply

Looks fine to me. Janet W

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Thursday, May 26, 2022 11:48 AM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: REVIEW REQUEST, 2PM TODAY: PR, FDA Flexibilities, Collaboration to Yield Millions of Bottles of Specialized Medical Infant Formula in Coming Months to Increase U.S. Supply
Importance: High

Dr. Califf and Dr. Woodcock,

Today, we're aiming to issue a press release regarding 500,000 additional cans of specialized medical formula manufactured by Danone's Nutricia business that will be headed to the U.S. The press release includes a proposed quote attributed to Dr. Califf and is attached here for your urgent review, if possible by 2pm today.

Agency/Office: Infant Formula IMG/OFPR/CFSAN
Subject: FDA Flexibilities, Collaboration to Yield Millions of Bottles of Specialized Medical Infant Formula in Coming Months to Increase U.S. Supply
Deadline for comments: **REQUESTING BY 2:00PM, THURSDAY 5/26**
Planned release date: Thursday, May 26
Driving event: About 500,000 additional cans of specialized medical formula manufactured by Danone's Nutricia business will be headed to the U.S.

Many thanks,
Tara

Tara G. Rabin
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-3157 / Cell: (b) (6)
Tara.Rabin@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 2/23/2022 9:59:11 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Rawlings, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae46d13993dc46e190ae70b61e1d4871-KRawling]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: Schedule & Read Ahead for Thursday, February 24, 2022
Attachments: 00-02.24.2022-Calendar.pdf; 0930-OPLIA Biweekly Meeting Agenda_02.24.2022.docx; 1630-OFPR Biweekly Meeting Material_02.24.2022.pdf

Your first meeting is scheduled for *8:45 AM [Small OC Executive Team].* Your final meeting is scheduled for *4:30 PM [Biweekly OFPR Check-In with the Commissioner].*

8:45-9am Small OC Executive Team

9:00-9:30am DESK TIME

9:30-10:00am Biweekly OPLIA Meeting with the Acting Commissioner
Materials: Agenda attached

10:00-10:30am Biweekly 1:1: MChuk/Woodcock

10:30-11:30am DESK TIME

11:30-11:45am Biweekly Check-In: EJefferson/Dr. Woodcock

11:45am-12:30pm LUNCH

12:30-1:00pm Commissioner Informational Briefing: COVID (Part I)
Materials: Forthcoming

1:00-1:30pm Monthly Meeting: JSigg/MKeller/JWoodcock

1:30-3:00pm DESK TIME

3:00-3:30pm ORA ETO Pre-Brief

3:30-4:30pm DESK TIME

4:30-5:00pm Biweekly OFPR Check-In with the Commissioner
Materials: Attached

MEETING MATERIALS:

- **Attached**

OEA/OMA READING:

- **None**

Jakea Copeland
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Desk Phone: (301) 796-7050
Email: Jakea.Copeland@fda.hhs.gov

Bi-Weekly OFPR Check-In

2/24/2022

(b) (5)

(b) (5)

(b) (5)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/24/2022 3:53:33 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
CC: Tierney, Julia [Julia.Tierney@fda.hhs.gov]
Subject: RE: Infant Formula Update #5 - Recall, Supply Chain Implications, & Potential Mitigation Measures

Thanks very helpful. Makes sense to divide up activities. JW

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Thursday, February 24, 2022 3:15 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Infant Formula Update #5 - Recall, Supply Chain Implications, & Potential Mitigation Measures

Yes. See below in blue.

1. For the Abbott products that are uniquely or solely made at the Abbott Sturgis facility, determine if they can be produced elsewhere. Formulas that meet nutritional needs of specific sub-populations (e.g., EleCare) should be
(b) (5) [redacted]

2. Quickly obtain and assess loss in production volume/products from Abbott's Sturgis plant and determine to what extent production losses from Sturgis can be offset by increased production at other Abbott production facilities.
Same as above

3. For any amounts/products that Abbott cannot offset through increased production at their other facilities, determine if the losses in Abbott production can be offset by increased production by other manufacturers.
(b) (5) [redacted]

4. Determine if WIC can extend the waiver to allow WIC recipients to purchase alternate brands beyond the March 31 deadline/extension.
(b) (5) [redacted]

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, February 24, 2022 2:18 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Infant Formula Update #5 - Recall, Supply Chain Implications, & Potential Mitigation Measures

Thanks Frank. Are the specific action items you note being undertaken? Who is doing them? Thx jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Thursday, February 24, 2022 1:20 PM
To: Califf, Robert (b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Subject: Infant Formula Update #5 - Recall, Supply Chain Implications, & Potential Mitigation Measures

FOOD SAFETY UPDATE

U.S. FOOD & DRU ADMINISTRATION

From the Office of Food Policy and Response

Internal, Privileged, & Confidential

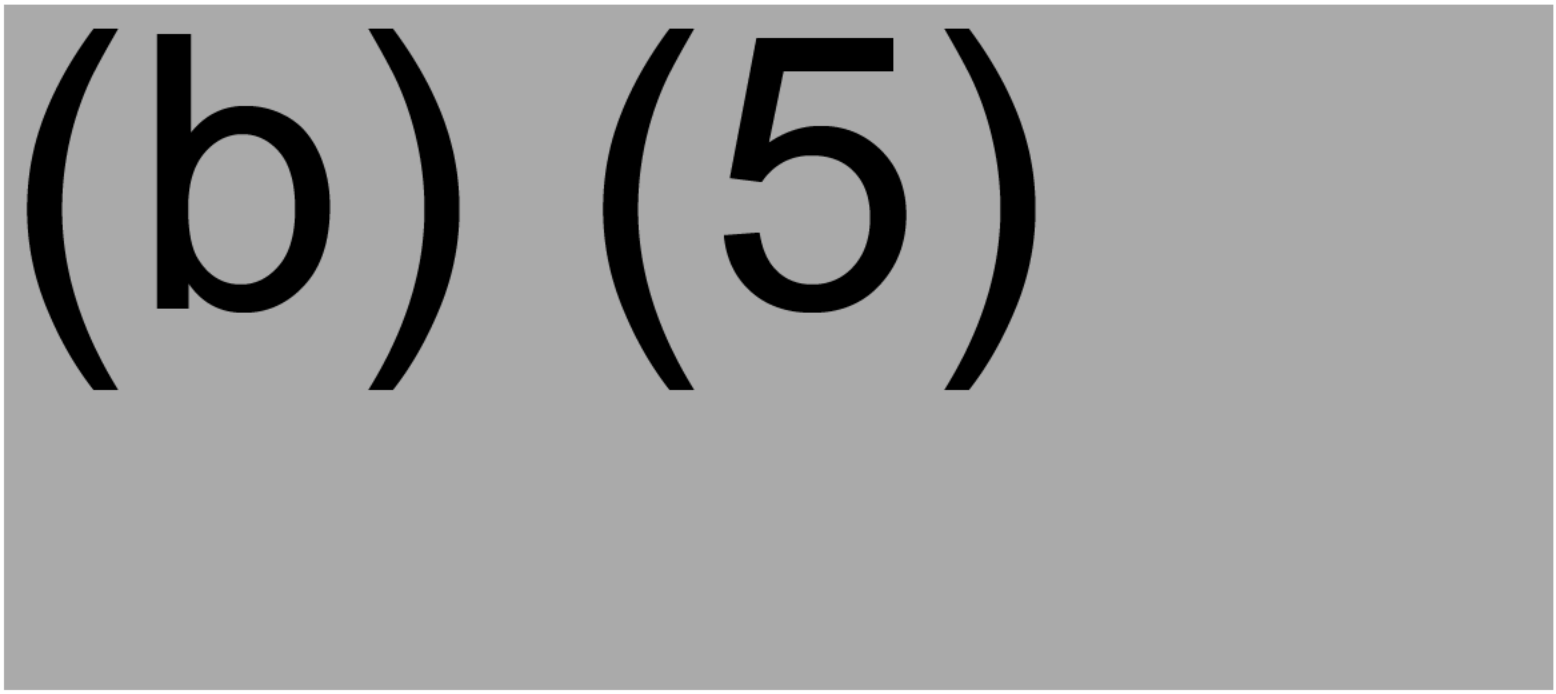
Below is a quick summary of the potential supply chain impacts of the Abbott infant formula recall. It's largely based on information we've been able to gather by talking to numerous retailers (Ahold USA, Kroger, Publix, Walmart) that collectively operate approx. 10,000 retail outlets across the country, as well as from feedback provided by FMI from info provided by their members.

Recall Data and Information Provided by Abbott

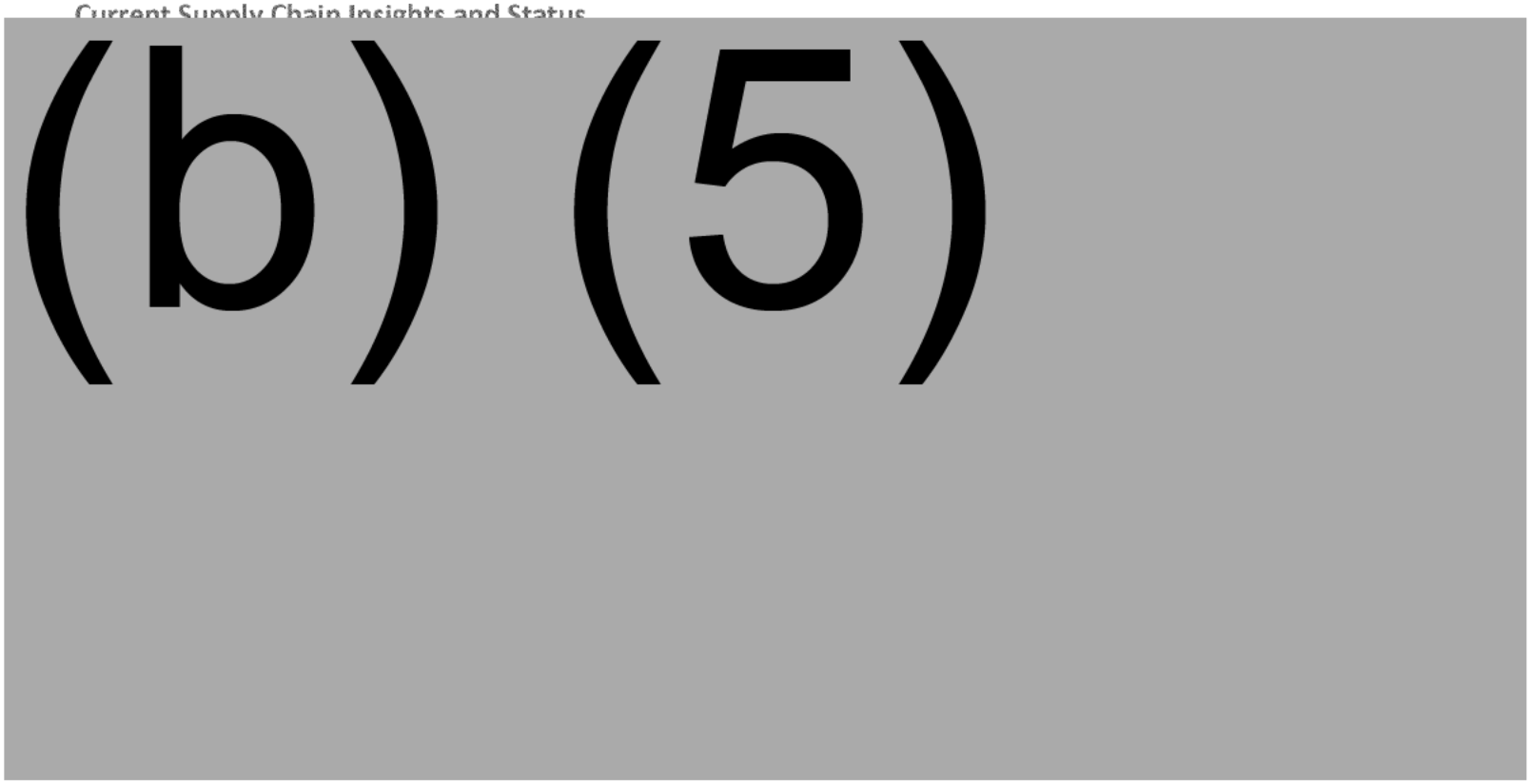
(b) (5)

Recall Execution by Retailers

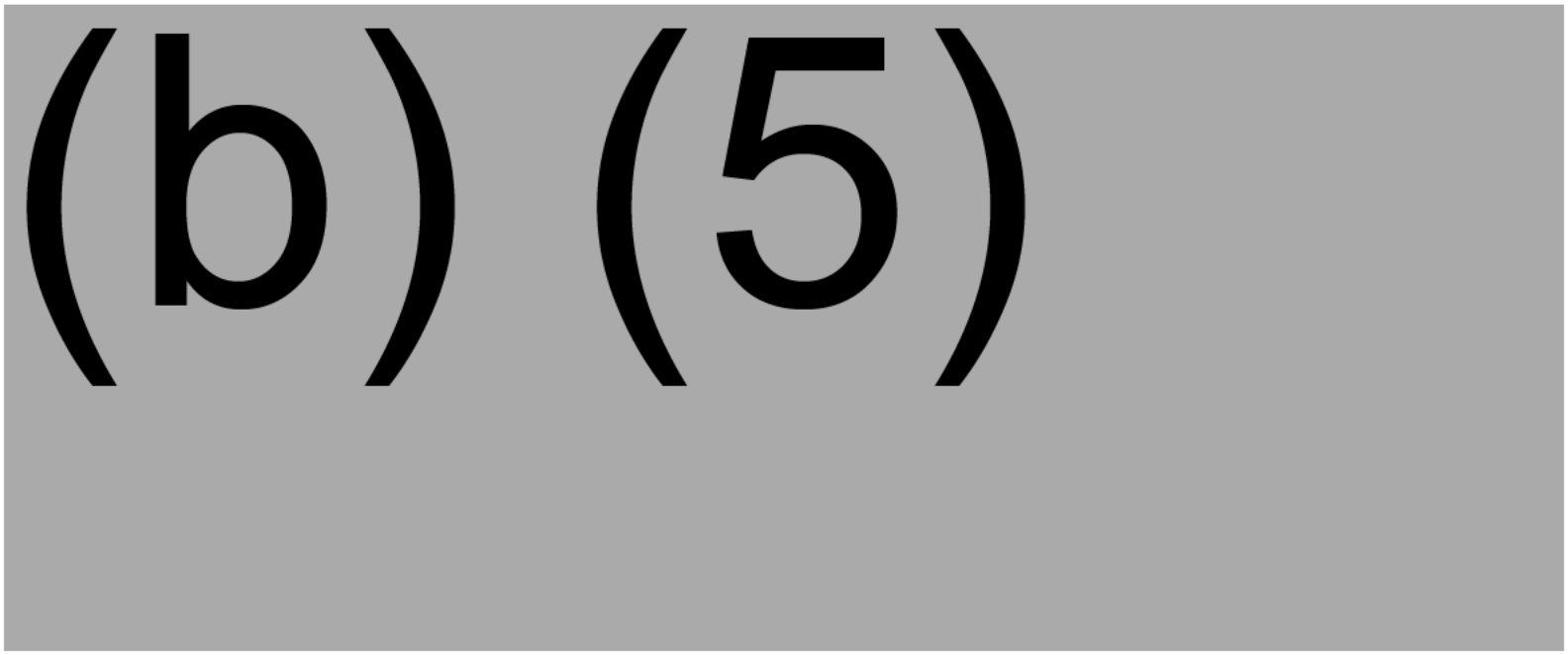
(b) (5)



Current Supply Chain Insights and Status



Outlook, Replenishment, and Mitigation Measures



This remains and evolving situation. As usual, we'll keep you updated of any noteworthy developments.

Frank Yiannas
Deputy Commissioner, Food Policy & Response
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20993
Tel: 301-796-4665
frank.yiannas@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/25/2022 4:09:28 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: Update: Infant Formula Communications planned for 5:00 p.m. TODAY

Thanks Erica. jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Friday, February 25, 2022 3:50 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dickinson, Elizabeth (FDA) <Elizabeth.Dickinson@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Update: Infant Formula Communications planned for 5:00 p.m. TODAY

Good afternoon all,

In advance of our check-in at 5:00 p.m., I wanted to share:
- The updated CORE advisory **[FINAL]**
- Latest draft of the Consumer Update we worked to quickly pull together today that is nearing final clearance from CFSAN, OFPR and ORA. It will go to Pete Beckerman in OCC around ~4:15 p.m. (he is standing by to review).

Key updates in comms:
- New language on our work to address supply chain issues
- Cross-linkage to CDC website (they posted new information yesterday)
- Language for consumers who participate in the WIC program. Tara is coordinating with USDA comms to ensure they are aware of today's posting and the new language updates.
- A more consumer-friendly Q&A on what the recall entails, what FDA is doing and what consumers should know.

The CORE advisory is scheduled to post at 5:00 p.m. TODAY. We are working to get the Consumer Update caught up to the CORE post, with the goal of pushing today as well. Will keep you posted.

Please let us know if you have any questions.

Thank you,
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov

Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/28/2022 4:26:43 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Draft OC Infant Formula Evaluation Plan

Haven't heard back yet. Will do. wj

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Monday, February 28, 2022 3:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Subject: RE: Draft OC Infant Formula Evaluation Plan

Thank you. Made two further edits – (b) (5) Let me know what you hear.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, February 28, 2022 10:07 AM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Subject: RE: Draft OC Infant Formula Evaluation Plan

See attached. I am going to check on the workload in the ombudsman's office. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Friday, February 25, 2022 6:55 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Subject: Draft OC Infant Formula Evaluation Plan

Hi Dr. Woodcock and Julie,

Please see attached a draft OC Infant Formula Evaluation plan for comment/feedback. I am particularly interested in views on the evaluation points on page 2. That will be the roadmap for the facilitator. I'm doing more thinking on the precise members of the eval team and who to have facilitate.

Tristan Colonius, DVM, MPA, DACVPM
Acting Deputy Chief of Staff
Office of the Commissioner
O: 301.796.2624 | M: (b) (6)

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/4/2022 8:28:12 AM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: FYSA - DeLauro Letter to OIG on Infant Formula

We should make sure these points are all covered in our internal look. jw

---

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Thursday, March 3, 2022 5:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FYSA - DeLauro Letter to OIG on Infant Formula

Flagging Rep. DeLauro's letter to OIG requesting an audit of the Abbott infant formula recall. OIG issued a report on food recalls generally in 2017 that led to a congressional hearing.

Tristan Colonius, DVM, MPA
Acting Deputy Chief of Staff
240.701.8476

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/10/2022 8:31:36 AM
To: Baer, Gerri [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dff3ad85ef047108db7d78fd1ce7893-Gerri.Baer]; Massaro, An [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45eac3f386c648c7b898f0341ca9ea12-An.Massaro]
Subject: RE: Infant formula recall

I'll get back to you soon. Need to coordinate everyone. Probably early afternoon. jw

From: Baer, Gerri <Gerri.Baer@fda.hhs.gov>
Sent: Thursday, March 10, 2022 8:27 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Massaro, An <An.Massaro@fda.hhs.gov>
Subject: Re: Infant formula recall

Hi Janet,
Absolutely. What time would you like to talk?
Thanks for reaching out.
Gerri

Get Outlook for iOS

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 10, 2022 8:26:01 AM
To: Baer, Gerri <Gerri.Baer@fda.hhs.gov>; Massaro, An <An.Massaro@fda.hhs.gov>
Subject: FW: Infant formula recall

Connecting. So you could be available today? jw

From: Green, Dionna <Dionna.Green@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 6:31 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Infant formula recall

Good evening Janet,
OPT's neonatologists (Gerri Baer and An Massaro) have been peripherally tracking this topic and would be happy to join a discussion tomorrow and be of assistance.
Best,
Dionna

Dionna Green, MD, FCP | Director, Office of Pediatric Therapeutics
Office of Clinical Policy and Programs | Office of the Commissioner
US Food and Drug Administration
10903 New Hampshire Avenue, White Oak Building 32 Room 5152
Silver Spring, MD 20993
Office: (301) 796-1543 | Work Cell: (b) (6)
Email: Dionna.Green@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 6:28 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Green, Dionna <Dionna.Green@fda.hhs.gov>
Subject: RE: Infant formula recall

Thanks Janet. We do have a pretty good sense for which of these products might have comparable products from other manufacturers, but what we don't know is how much exists in the supply chain (so if babies are switched, we could run out of the comparable products). And in some cases we do not believe there are comparable products at all (as an example, Calcilo for disorders of mineral metabolism, Williams Syndrome, hypercalcemia), so we are likely looking at risk mitigation. Happy to discuss.

Susan

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 6:11 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Green, Dionna <Dionna.Green@fda.hhs.gov>
Subject: Infant formula recall

FDA is working on a recall of infant formula made by Abbott at a single plant for potential bacterial contamination. Unfortunately this plant also makes a variety of special formulas for rare metabolic diseases. These have not been recalled and are of unknown risk. CFSAN does not know how many alternatives exist for these and whether they are available. They need help from knowledgeable pediatric endocrinologists and maybe neonatologists.

These formulas are medically necessary and can't be removed unless alternatives exist. Some mitigation measures are available and are posted by CDC. I suggested possibly an IND might be helpful as these infants are under medical supervision and the formulas stocked in pharmacies.

CFSAN needs help in finding out how many infants may be involved and what alternatives might exist and what steps we can take. Does CDER and OPT have people who are versed in this area? I'd like to get a discussion together tomorrow. Thanks. Jw

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/10/2022 8:14:14 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Infant Formula Recall Briefing for EC

Sounds fine. jw

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 10:39 PM
To: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: Infant Formula Recall Briefing for EC

That seems fine to me if you think is the best path forward. Do you feel that the briefers are well synced and prepared?

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 10:29:49 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Infant Formula Recall Briefing for EC

Hi all –

We wanted to follow up regarding tomorrow's infant formula recall briefing with E&C.

This is an initial briefing with E&C that will be focused on facts of the situation and actions taken by FDA and CDC in response. Earlier this week, we had a similar briefing with Senate Ag Committee Majority staff that was led by Caitlin Boon, Michael Rogers, and Stic Harris that went well.

Tomorrow's briefing with E&C is unique in that it will also include CDC. Joining from CDC will be Megin Nichols, Acting Deputy Division Director for Foodborne, Waterborne, and Enteric Diseases, as well as Laura Gieraltowski, Jennifer Rittenhouse Cope from the same division. We believe that there is alignment currently with the CDC and FDA briefers.

Given that this is a joint briefing and that we have already held our prep where we planned out the cadence and briefing roles jointly with CDC, we would advise that we proceed with the current plan for purposes of tomorrow. However, we would like to have Dr. Woodcock on future additional briefings to be able to provide her feedback on what resources or authorities would have been helpful in addressing this situation.

Unless there are any objections, we can let the briefers know in the AM that we will proceed as planned. Also, happy to discuss further if that would be helpful.

Thanks,
Kim

Kimberlee Trzeciak
Associate Commissioner for Legislative Affairs
Office of Legislation
U.S. Food and Drug Administration
M: (b) (6)
kimberlee.trzeciak@fda.hhs.gov
FDA U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/10/2022 9:54:41 AM
To: Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: RE: Meeting at 11:30

Thanks so much. jw

From: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Sent: Thursday, March 10, 2022 9:54 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Smpokou, Patroula <Patroula.Smpokou@fda.hhs.gov>; Baer, Gerri <Gerri.Baer@fda.hhs.gov>; Massaro, An <An.Massaro@fda.hhs.gov>
Subject: RE: Meeting at 11:30

Absolutely.

Best,
Jacque

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 10, 2022 9:53 AM
To: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Smpokou, Patroula <Patroula.Smpokou@fda.hhs.gov>; Baer, Gerri <Gerri.Baer@fda.hhs.gov>; Massaro, An <An.Massaro@fda.hhs.gov>
Subject: Meeting at 11:30

Jacque, could you set up a meeting at 11:30 today for the above people and me? Subject: infant formula. Susan, should others be invited? Caitlin Boone? If so let Jacque know. Thanks all. jw

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 1/27/2022 5:03:45 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: RE: CBS Infant Formula Story

Certainly agree. jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Thursday, January 27, 2022 5:03 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: CBS Infant Formula Story

This is a perfect example….we shouldn't learn about infant formula challenges through the news…..the type of supply chain report I just shared would help us detect signals before they become news stories.

FY

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Thursday, January 27, 2022 5:00 PM
To: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Hansen, Patricia A <Patricia.Hansen@fda.hhs.gov>
Cc: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: CBS Infant Formula Story

Hi,

I've been trying to do news scans for food supply stories, and just came across this one from earlier in the week. It's a lengthy segment from CBS Mornings.

https://www.cbsnews.com/news/baby-formula-supply-parents-shortage/

Has ONFL had contact with the infant formula manufacturers/INCA this week? Any further intel on this issue? I know we had already seen an uptick in packaging changes. Anything else new?

Thank you,
Caitlin

Caitlin Boon, Ph.D.
Associate Commissioner for Food Policy and Response
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
(b) (6)
Caitlin.Boon@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/10/2022 6:58:15 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Metabolic infant formulas

Thx I will be following up tomorrow and maybe pass the torch to you. Needed me today to get this in gear but seems people are with the program now. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Thursday, March 10, 2022 5:57 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Metabolic infant formulas

Let me know if there's anything I can do to help on this during your leave.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 10, 2022 12:21 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: Metabolic infant formulas

Just met with the combined expertise from CFSAN, CDER and CPT (neonatologists and pediatric endocrine/metabolic experts) on these specialty formulas. Bottom line, consensus is that for most of them, risk of not getting the right formula outweighs any risk of contamination. Caitlin Boone is working to get the data on alternatives and their availability—not very likely as these are very specialized, made in surges, and Abbott had at least 30% of the market. Also transition very difficult for these infants and typically takes weeks. Currently these products were not recalled except for a lot implicated in an infection, and new product is being held at the Abbott facility. Health Canada tells us that they are approaching shortage there and will import product to compensate.

Our plan is the following. We will call the specialty societies both nutritionists and medical, including AAP, today, notify them of the situation and provide them with the mitigation information that is on the CDC website that we collaborated on (involves boiling water and putting the formula in). Susan Mayne will work with the group on developing the talking points. By tomorrow Erica this will probably get out and so Susan will also contact you about more general messaging. We still don't have information on all alternatives and Caitlin Boone is working to get that and put in a spreadsheet. We also will risk rank these by medical need, some infants will get extremely ill in days if not getting the right formula. I am going to talk to Peter Beckerman and Amanda Edmonds about ways we can make these available—for example, could we have INDs?

We likely will have to release finished product from the plant and maybe let them go into production again. CDER does this for medically necessary products, we can have enhanced testing and oversight. It is not likely that we will have an adequate supply from alternative sources anytime soon.

Of course we still don't have a definitive link between the plant and reported infections, but I think there is a lot of circumstantial evidence. Recall of formulas with alternatives was prudent, but this situation is different. I will stay on this until we have a fleshed-out plan. jw

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/10/2022 6:54:16 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: Metabolic infant formulas

Thx Erica.jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Thursday, March 10, 2022 6:01 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: Metabolic infant formulas

Hi all,

I wanted to circle back on Dr. Woodcock's email since we've been working with CFSAN behind the scenes. CFSAN and OCC cleared talking points that we will use to update our comms—the CORE consumer advisory, press release (update the blue box at the top) and consumer update. We will get into clearance ASAP. The plan is to post the updated materials tomorrow with this new information.

Confirming that CFSAN completed calls with the Society for Inherited Metabolic Disorders, AAP and Genetic Metabolic Dietitians International.

CFSAN also shared with me that:

- These formulas and medical foods are not sold in traditional retail stores. These products often require a prescription and have limited distribution through specialty distribution channels.
- Many of the products do not have identical alternatives and even for products that may have alternatives it's challenging to switch children to a different specialty formula as children can get ill.

(from Medline inborn errors of metabolism definition https://medlineplus.gov/ency/article/002438.htm)

- As noted below, the program is expecting Health Canada to update its website today. We will keep an eye on the website to see what information they provide.

More to come.
Erica

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 10, 2022 12:21 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: Metabolic infant formulas

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formula outweighs any risk of contamination. Caitlin Boone is working to get the data on alternatives and their availability—not very likely as these are very specialized, made in surges, and Abbott had at least 30% of the market. Also transition very difficult for these infants and typically takes weeks. Currently these products were not recalled except for a lot implicated in an infection, and new product is being held at the Abbott facility. Health Canada tells us that they are approaching shortage there and will import product to compensate.

Our plan is the following. We will call the specialty societies both nutritionists and medical, including AAP, today, notify them of the situation and provide them with the mitigation information that is on the CDC website that we collaborated on (involves boiling water and putting the formula in). Susan Mayne will work with the group on developing the talking points. By tomorrow Erica this will probably get out and so Susan will also contact you about more general messaging. We still don't have information on all alternatives and Caitlin Boone is working to get that and put in a spreadsheet. We also will risk rank these by medical need, some infants will get extremely ill in days if not getting the right formula. I am going to talk to Peter Beckerman and Amanda Edmonds about ways we can make these available—for example, could we have INDs?

We likely will have to release finished product from the plant and maybe let them go into production again. CDER does this for medically necessary products, we can have enhanced testing and oversight. It is not likely that we will have an adequate supply from alternative sources anytime soon.

Of course we still don't have a definitive link between the plant and reported infections, but I think there is a lot of circumstantial evidence. Recall of formulas with alternatives was prudent, but this situation is different. I will stay on this until we have a fleshed-out plan. jw

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/14/2022 6:16:52 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: RE: Proposed issues for Special Purpose Tactics Call

Thanks, I understood. Just so we are all on the same page. jw

---

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Monday, March 14, 2022 12:55 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Proposed issues for Special Purpose Tactics Call

I think you may have misunderstood me. There is no debate on the importance of these products and trying to do all that we can to mitigate shortages.

I was just re-affirming that we're glad we're being transparent about why these products were not part of the original or expanded recall. We had been advocating for the transparency and rationale for a while.

FY

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 14, 2022 11:34 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: RE: Proposed issues for Special Purpose Tactics Call

Well my understanding is that the subspecialty peds medical and nutrition groups have been contacted and told about the mitigation efforts and that FDA comms has reactive. No recall of these products should be done unless alternatives are firmly established, as the risk of not having them is much greater than the risk of the contamination. We also will have to consider allowing shipping and even production from the plant with appropriate mitigation measures if shortages occur. Janet W

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Monday, March 14, 2022 9:55 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: Proposed issues for Special Purpose Tactics Call

Internal-Deliberative-Confidential

Janet

Thanks for your help late last week. Caitlin told me your involvement helped provide momentum, as we had been checking-in with the nutrition and special tactics team regularly and asking for updates, but weren't getting much.

FY

From: Boon, Caitlin
Sent: Monday, March 7, 2022 1:07 PM

To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Subject: Proposed issues for Special Purpose Tactics Call

Internal-Deliberative

I think a special purpose tactics call is the appropriate next step. In particular, we would like to ask that the group discuss the following and come back to leadership to provide a download of the discussions and recommendations for the path forward. Items for consideration/discussion:

1. Considering the full weight of the food safety evidence collected to date, is there a need to expand the recall or consumer advisory to include other powdered products made at Sturgis, MI (i.e., metabolic products). Since the initial decision, we have learned a lot more about the status of this plant and the range of dates in which potential contamination took place.
2. Considering the additional information we have now about comparable products, does this change the risk calculation for the scope of a recall or consumer advisory? We now have a clearer understanding of how many comparable products may exist for certain metabolics, and some may have more alternatives than what we originally understood. We recognize that all infants may not be able to switch to a different product, but alternatives could be an option for at least a portion of the population.
3. Consider whether we should have targeted communication for those sub-populations that may not have an alternate product available, but for whom carefully following the CDC preparation instructions could add additional protection. This was a question raised last week, but I have not heard an outcome from any discussions that took place.

Given the complicated nature of these discussions we may also want to ask that a communications/stakeholder engagement SME be added to the call. For example, if we were to decide that communications were needed on preparation instructions, we would likely want to work closely with AAP and patient support groups to get the message out.

Thank you,
Caitlin

Caitlin Boon, Ph.D.
Associate Commissioner for Food Policy and Response
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
(b) (6)
Caitlin.Boon@fda.hhs.gov

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Monday, March 7, 2022 12:46 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin

<Caitlin.Boon@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Subject: RE: IEC

Agree.

Caitlin will send a list of things we'd like for them to consider and report-out on, after their deliberations.

FY

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/10/2022 1:04:04 PM
To: Robert Rutkowski (b) (6)
Subject: RE: [EXTERNAL] Regulate Novel, Potentially Hazardous Nanomaterials in Infant Formula

Thank you for writing. We will evaluate the petition and take appropriate action. Janet Woodcock

-----Original Message-----
From: Robert Rutkowski (b) (6)
Sent: Thursday, February 10, 2022 12:43 PM
To: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; FDA Office of Media Affairs <FDAOMA@FDA.HHS.GOV>
Cc: Keith Abouchar <keith.abouchar@mail.house.gov>
Subject: [EXTERNAL] Regulate Novel, Potentially Hazardous Nanomaterials in Infant Formula

Janet Woodcock
Acting Commissioner
via Caitlin Pennington, Executive Assistant Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
caitlin.pennington@fda.hhs.gov, janet.woodcock@fda.hhs.gov, FDAOMA@fda.hhs.gov

Re: Regulate Novel, Potentially Hazardous Nanomaterials in Infant Formula

Dear Commissioner:

Yesterday, Center for Food Safety and International Center for Technology Assessment formally petitioned the Food and Drug Administration (FDA) to regulate nanomaterials in infant formula. The groups request that FDA immediately take the steps necessary to properly regulate nanoscale ingredients and prohibit all engineered nano ingredients in formula until they are demonstrated to be safe for infants.

FDA has known for five years that many U.S. infant formulas contain nanochemical additives that the agency has not approved. It is time for FDA to act to make infant formula safe from these toxic additives.
Europe keeps them out of infant formula–we should too.

Compared to their bulk material counterparts, nanomaterials can have fundamentally different health and environmental impacts which creates new oversight challenges for regulatory agencies. The risks of nanomaterials in infant formula–although not well understood–are alarming in light of existing studies about toxicity, chemical reactivity, and nanomaterials' greater capacity to penetrate biological membranes, as infants are particularly vulnerable to food safety risks due to their developing immune systems.

A study conducted by Arizona State University found nanomaterials in infant formula manufactured by four companies: Gerber, Enfamil, Well Beginnings, and Similac. The materials are mostly used for their brightening/whitening, anti-caking, and flow-enhancing properties.

FDA must ensure infant formulas are safe and meet certain nutritional requirements. Before any infant formula can be sold, the manufacturer must first register with FDA and provide a notice. Once a formula is on the market, any changes to the contents of the formula must be reported to FDA.

FDA should enact new regulations directed at the agency's oversight of nanomaterials, including that any infant formula undergo rigorous testing for the presence of nanomaterials and that the products be labeled as containing nanotechnology. Additionally, FDA should declare all currently available infant formulas containing engineered nanoparticles as adulterated and issue a recall. Lastly, use of nanomaterials in infant formula should not be approved using the "Generally Recognized as Safe" (GRAS) loophole.

Recently, various agencies of the European Union, including the European Food Safety Agency (EFSA), have raised serious health questions about both the nano and the bulk forms of certain chemicals, such as hydroxyapatite and titanium dioxide, which are found in infant formulas in the U.S. An EFSA panel recently concluded that titanium dioxide can no longer be considered safe as a food additive due to concerns over genotoxicity.

Full petition:
https://www.centerforfoodsafety.org/files/2-9-22-cfs_nano-infant-formula-petition_57739.pdf

Yours sincerely,
Robert E. Rutkowski

cc:
Legislative Correspondence Team
1705 Longworth House Office Building
Washington DC 20515
Office: (202) 225-4131
Fax: (202) 225-4300
keith.abouchar@mail.house.gov

(b) (6)

From: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Sent: 3/17/2022 3:33:01 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: Re: Can we have a 10 min call on our favorite topic-infant formula?

I'm available after 6 if anyone needs to talk

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Thursday, March 17, 2022 10:40:08 AM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Can we have a 10 min call on our favorite topic-infant formula?

Rob, looks like noon-12:30 or 2:30-3 work for you if you don't mind talking over lunch, not sure what Janet's day looks like. FYI we're supposed to touch base on comms strategy with the larger group at 11:30

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Thursday, March 17, 2022 10:28 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Can we have a 10 min call on our favorite topic-infant formula?

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/24/2022 11:49:32 AM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Oversight Letter to RMC on Infant Formula Recall

Thanks. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Thursday, March 24, 2022 10:58 AM
To: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: Oversight Letter to RMC on Infant Formula Recall

Hey y'all – Flagging this Krish request since it was just mentioned on the interview – FYSA.

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Thursday, March 24, 2022 10:53 AM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>
Subject: Oversight Letter to RMC on Infant Formula Recall

Hi all –

I wanted to flag an incoming oversight request from Rep. Krishnamoorthi on the infant formula recall that came in this morning.

We will work on a response but wanted to make sure you were aware. Below are the key requests from the letter:

To assist the Subcommittee in its review of this matter, we request that you provide the following information by April 7, 2022:

1. Why did FDA wait until February 17, 2022, to issue a warning to consumers not to use certain powdered infant formula produced at the Abbott Nutrition facility in Sturgis, Michigan?

2. What steps, if any, is FDA taking to ensure that it more quickly inspects facilities, and issues consumer warnings, after reports of foodborne illnesses linked to particular facilities?

We also request that you provide all documents and communications, from September 1, 2021, to the present, by April 7, 2022, related to the following topics:

1. Reports from Minnesota health authorities regarding *Cronobacter sakazakii* or *Salmonella* Newport infections traced back to the facility; and

2. FDA's steps to address the reported infections at the facility.

Let us know if you would like to discuss further.

Thanks,
Kim

Kimberlee Trzeciak
Associate Commissioner for Legislative Affairs

Office of Legislation
U.S. Food and Drug Administration
M: (b) (6)
kimberlee.trzeciak@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/29/2022 8:31:17 AM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: RE: Final Proposal - Infant Formula IMG Memo and Org Chart

Thanks Frank. jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, March 29, 2022 6:53 AM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Fwd: Final Proposal - Infant Formula IMG Memo and Org Chart

FYI only - no action needed.

We're looking to stand up the more formal Infant Formula IMG we discussed. Should be stood up some time this week.

As you will see below, adequately socially w all food program elements and vast majority of their input addressed.

Any questions, please let me know.

Frank

Get Outlook for iOS

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, March 29, 2022 4:31 AM
To: Russo, Mark
Cc: Boon, Caitlin; Smith-Dulley, Jasmine *
Subject: Final Proposal - Infant Formula IMG Memo and Org Chart

Mark:

Attached is the updated memo to stand up the infant formula IMG, along with the proposed organizational charts. We reviewed them with ORA and CFSAN, and included the vast majority of their suggestions.

Please let me know what you think the next steps are to get this going. While we're still hopeful that this might turn out to not be as large as some think it will be, nevertheless, we'd like to try to stand this up this week.

Lastly, i also think perhaps the memo should be co-authored by you and me.

Thanks again for your help Mark. You and your team have been wonderful to work with.

Frank Yiannas
Deputy Commissioner, Food Policy & Response
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20993
Tel: 301-796-4665
frank.yiannas@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/29/2022 9:08:19 AM
To: Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: HHS Briefing on Infant Formula

(b) (5)
jw

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Tuesday, March 29, 2022 8:36 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: HHS Briefing on Infant Formula

Good morning. Attached are the draft slides for Thursday's briefing with HHS and CDC. Will plan to make any necessary changes to the deck after this meeting and then route it through clearance. I kept the evaluation slide very high level and welcome any feedback you have there. Thanks!

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 28, 2022 11:48 AM
To: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: HHS Briefing on Infant Formula

Happy to do this. jw

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Monday, March 28, 2022 11:43 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: HHS Briefing on Infant Formula

Forgot to note that the briefing is scheduled for Thursday, March 31st 11:30-12:30 and we have a prep meeting with CDC tomorrow at 11:30. Holds have been placed on your calendar already.

From: Tobias, Lindsay
Sent: Monday, March 28, 2022 11:40 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: HHS Briefing on Infant Formula

Good morning, Dr. Woodcock. (b) (6) While you were away, HHS asked us to provide a briefing on the infant formula recall. The briefing will be for Sarah, Lisa and Kimberly Espinosa. FDA's primary speakers will include the folks who have been doing the Hill briefings: Caitlin Boon, Stic Harris, and Mike Rogers. CDC will also be on the call. In brainstorming the agenda, we wanted to tee up the possibility of having you discuss the OC Evaluation

plan. If you're interested in doing this, I can add a slide or two (high level only) to the current deck. Here's the tentative run-of-show:

- Opening remarks (Frank?)
- Discussion of Cronobacter and lack of reporting (Stic & CDC)
- Current situation at Abbott (Michael Rogers)
- Supply chain (Caitlin)
- Authorities, budget, Congressional interest (Caitlin)
- *Next steps/evaluation plan (Janet//TBD)*

Please let us know your thoughts and/or if you need any additional information.

Thank you!

Lindsay R. Tobias
Special Assistant to the Chief of Staff

Office of the Commissioner
Office of the Chief of Staff
U.S. Food and Drug Administration
Tel: 301-796-6743
Cell: (b) (6)
Lindsay.Tobias@fda.hhs.gov
U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/30/2022 7:54:49 AM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: RE: [EXTERNAL] Abbott

Thanks. jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, March 29, 2022 8:59 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] Abbott

Rob:

FYI – we received the following note, that has a cooperative tone, from Abbott's CEO this evening.

We're going to huddle with OCC in the morning to get their advice before we respond, but I wanted you to be aware that their CEO has reached out to us in a collaborative tone.

Will keep you updated. More to come.

Frank

From: Ford, Robert B <Robert.Ford@abbott.com>
Sent: Tuesday, March 29, 2022 7:40 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Subject: [EXTERNAL] Abbott

Director Mayne and Deputy Commissioner Yiannas,

I had intended to write to you after my team had submitted our 483 responses related to our powder infant formula facility in Sturgis, MI. The objective of that communication was to express my regret for the concern and disruption the situation has caused parents and caregivers, as well as to ensure you that we are taking this situation very seriously and I am involved in overseeing corrective action. As you are no doubt aware, the situation has changed and we have been presented with a draft consent decree. The message that came through from your lawyers was heard—the FDA wants a process that will reassure the public. We are committed to the same objective. To that end, I would like the opportunity to meet with you and your team, to share with you our approach to changes at the facility, to gain a better understanding of the agency's objectives (as we have only heard them through the lawyers) and to begin to explore common ground in the approach to our processes and the oversight of those processes.

I appreciate the importance of these issues, as well as the need for the products manufactured at Sturgis and I am prepared to bring my team and come to DC to meet with you at your earliest opportunity.

I stress again, I am committed to providing parents, healthcare professionals and the FDA with renewed confidence in the quality of our manufacturing at Sturgis. This is a top priority for me and I hope we can come to an understand of how we will move forward.

Robert Ford
Chairman & CEO
Abbott

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 4/17/2022 9:59:59 AM
To: 'Califf, Robert' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: RE: Update on AEG Decision on Special Metabolic Products

Haha, autocorrect strikes again. Wasn't raining EtOH. jw

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Saturday, April 16, 2022 6:39 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Re: Update on AEG Decision on Special Metabolic Products

Hopefully you were driven, not drunken!

rmc

From: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Date: Saturday, April 16, 2022 at 6:37 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Cc: Julie Tierney <Julia.Tierney@fda.hhs.gov>
Subject: Re: Update on AEG Decision on Special Metabolic Products

Hope you got it in I was drunken inside by t-storm

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Saturday, April 16, 2022 2:31:54 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Re: Update on AEG Decision on Special Metabolic Products

Np; was just preparing for a call with Ashish. I think we're on the same wave length.
Will copy you on a note (b) (6) asap.

rmc

From: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Date: Saturday, April 16, 2022 at 2:30 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Cc: Julie Tierney <Julia.Tierney@fda.hhs.gov>
Subject: Re: Update on AEG Decision on Special Metabolic Products

Sorry did not see jw

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Saturday, April 16, 2022 10:52:05 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Re: Update on AEG Decision on Special Metabolic Products

Agree; Janet—can you hop on a zoom this morning. I'm talking with Ashish this afternoon and I wanted to run something by you, Peter and Patrizia.

rmc

From: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Date: Saturday, April 16, 2022 at 10:49 AM
To: Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Robert Califf <(b) (6) @fda.hhs.gov>
Cc: Julie Tierney <Julia.Tierney@fda.hhs.gov>
Subject: RE: Update on AEG Decision on Special Metabolic Products

Sound like the right path. Thank you. Jane tW

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Saturday, April 16, 2022 10:00 AM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Update on AEG Decision on Special Metabolic Products

Internal/confidential/deliberative

Hello,

The AEG met yesterday afternoon and landed on the below path forward for the held special metabolic products.

FDA will present a proposal to Abbott for the company to undertake a prioritized release of metabolic products in shortage based on additional sampling of each batch to minimize the risk of a contaminated product being distributed. The plan would envision only a limited supply of product being released so long as sampling does not return positive results (E.g. a two month supply). If a sample is found to be positive, FDA will work with the firm to re-evaluate whether any product from that batch will be released.

This enhanced sampling will greatly – but not entirely - reduce the risk of contaminated product going out. Therefore, FDA will pair this mitigation step with communications on handling and preparation instructions to parents to whom this product might be released, as well as important stakeholders like pediatricians. This will include a "kill step" as well as handling instructions aimed to prevent cross-contamination, to further mitigate the risk of exposure to an infant.

If Abbott agrees to FDA's proposal, testing batches prior to release can take time. On a case-by-case basis, in the setting of an individual infant or child who cannot obtain any nutritional support (since these are single source nutrition products), the benefits of providing an immediate supply from Abbott's specialty/metabolic line to that individual infant or child might outweigh the risk of potential contamination without the information from finished product testing. FDA will therefore also inform Abbott that, should these circumstances arise, FDA would work with the company on a case-by-case basis to release product even if the enhanced testing is not complete.

OMA/IMG are working on communications material for this, including instructions on how to reconstitute and safely handle formula.

Tristan Colonius, DVM, MPA, DACVPM
Acting Deputy Chief of Staff

Office of the Commissioner
O: 301.796.2624 | M: (b) (6)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 4/22/2022 9:58:06 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Special metabolic product update

Thx jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Friday, April 22, 2022 5:49 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: Special metabolic product update

Internal/confidential/deliberative

Hello,

OFPR spoke with Abbott at 4 pm on the program's proposal for metabolic products. We owe HHS an update so wanted to update y'all here first. I Here's the cliff notes of where I understand things stand:

1. Abbott concurred with our *Cronobacter* testing plan for the infant metabolic products. We are asking them to proceed on testing. They will use a contract lab.

2. Abbott is willing to work with us on any case by case urgent requests for access that come in prior to testing results. And it is very possible some of these could occur given testing will take some time.

(b) (5)

Tristan Colonius, DVM, MPA, DACVPM
Acting Deputy Chief of Staff
Office of the Commissioner
O: 301.796.2624 | M: (b) (6)

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 4/14/2022 2:51:06 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Ad Hoc Infant Formula AEG Special Focus Meeting

Yes you should. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Thursday, April 14, 2022 2:50 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: Ad Hoc Infant Formula AEG Special Focus Meeting

Do you think Julie should be on the AEG as well (or me for this one since she is (b) (6))?

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, April 14, 2022 2:49 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Subject: Re: Ad Hoc Infant Formula AEG Special Focus Meeting

Thanks. Good to hear. Jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Thursday, April 14, 2022 1:27:31 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Subject: Ad Hoc Infant Formula AEG Special Focus Meeting

Janet

I wanted to give you a quick heads up. The Infant Formula IMG has been doing outstanding work. In particular, the Food Safety and Supply Chain sub-units, have provided a consensus recommendation on how to proceed with a phased release, under specific conditions, of the specialty metabolic products currently on hold by Abbott.

As such, we are planning to call an ad-hoc AEG meeting tomorrow to present the IMG's recommendation. I realize it's not a lot of notice, but we want to move swiftly.

The IMG is in the process of extending the meeting invitations to AEG members, but I wanted to let you know personally that the meeting request is forthcoming.

I think we're at a good place.

Frank Yiannas
Deputy Commissioner, Food Policy & Response
U.S. Food and Drug Administration
10903 New Hampshire Ave.

Silver Spring, Maryland 20993
Tel: 301-796-4665
frank.yiannas@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/16/2022 9:59:44 AM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: Quick comms update on infant formula

Happy to do. jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 9:58 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: Quick comms update on infant formula

Hi all –

I just had a call with Frank and Caitlin Boon. So there is currently an ongoing call with the company as we speak, but judging by the 15 page response we received to the findings we shared with them, we anticipate they are going to push back hard on not doing a recall on their end. And probably make a stink publicly, which we can manage.

(b) (5) [redacted]

(b) (5) [redacted].

Let me know if you all have any questions. Happy to share any materials I receive (b) (5) [redacted].

Thanks,
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 4/20/2022 2:05:34 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: FOR REVIEW: Infographic on reducing cronobacter risk when prepping infant formula

Nice. jw

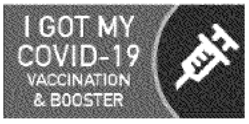
From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Wednesday, April 20, 2022 12:54 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: FW: FOR REVIEW: Infographic on reducing cronobacter risk when prepping infant formula
Importance: High

FYI. This is what I mentioned a couple weeks ago that the team was developing at CDC's request.

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Executive Assistant: Kristen.Tugwell@fda.hhs.gov (temporary)



From: Staton, Anna <Anna.Staton@fda.hhs.gov>
Sent: Wednesday, April 20, 2022 7:55 AM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FOR REVIEW: Infographic on reducing cronobacter risk when prepping infant formula
Importance: High

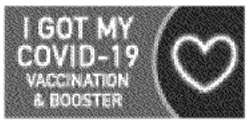
Hi Erica and Heidi,

Attached is the draft infographic we developed in consultation with many FDA and CDC SMEs. The light blue text at the bottom will link to this page: Infant Formula Preparation and Storage

It's with OCC now for review. Could you please let us know by **COB today** if you see any red flags? Apologies for the short notice, but we might be down to wire here because it still needs to be made 508 compliant, which will take a few hours. (Erica, unfortunately we didn't have the bandwidth to do a video. Getting the group to just agree on language was a labor intensive process.)

Many thanks,
Anna

Anna Staton, MPA
Deputy Director
Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration
Phone: 301-796-5758 & (b) (6)
Anna.Staton@fda.hhs.gov



From: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Sent: 4/28/2022 9:03:03 PM
To: Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]
Subject: Fwd: Heads up. FYI. Jw

From: McBride, Maren <Maren.McBride@fda.hhs.gov>
Sent: Thursday, April 28, 2022 11:54:40 AM
To: Califf, Robert <(b) (6) .@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Subject: Heads up

We wanted to flag that during the House Ag-FDA Subcommittee hearing today on the FY23 USDA Budget Request, Full Committee Chair Rosa DeLauro (D-CT) expressed concern with FDA's slow response to infant formula, and noted that a whistleblower who had worked for Abbot Nutrition provided her a report regarding numerous allegations of wrongdoing. We were able to capture a rough transcript of her remarks below. You can watch her remarks at about 57mins into the hearing at: https://www.youtube.com/watch?v=U0GcNSEV-BI.

- I recently acquired a disturbing report that was produced by a whistleblower who worked at the Abbot facility that produced infant formula recalled by the FDA.
- To my knowledge the Secretary has not seen this report.
- I bring it to your attention Secretary given your commitment to child nutrition.
- Abbot is the exclusive supplier for state WIC agencies.
- In Sept. 2021 FDA learned of a potential link between a rare and deadly foodborne pathogen and powdered infant formula manufactured by Abbot Laboratories.
- This week I received a 34-page report from a former employee at the plant that produced the contaminated formula which led to hospitalizations and dead of two babies.
- The report lays out numerous allegations of wrong doing such as falsifications of records, failure to maintain accurate maintenance records, shipping product with fill weights lower than what was on the label, releasing untested formula, hiding information during 2019 FDA audit, failure to take corrective actions once company knew of issues, an atmosphere of retaliation, to name a few.
- Parents thrust that formula will be safe and healthy. It should be the most regulated of any product.
- I'm deeply concerned about the practices at this facility and apparent failure to implement and enforce internal controls at this facility.
- We need to know when the company was aware of this failure and the alleged attempt to hide this info from the FDA.
- I'm equally concerned FDA reacted far too slowly to this report. It was submitted to FDA Oct. 19, 2021.
- FDA did not interview the whistleblower until late Dec. 2021.
- According to news reports, FDA didn't inspect the plant until Jan. 31, 2022, and recall not initiated until Feb. 17, 2022.
- Why did the FDA not spring into action? Why did it take 4 months to pull this formula off store shelves? How many infants were feeding on that contaminated formula during that time? How many additional illnesses and deaths were there due to the FDA's response?
- I've asked the HHS inspector general to look into this.
- I can assure you this committee will carry out its oversight role to prevent it from every happening again.
- I encourage you and the USDA to review contracts with Abbott. If Abbott can not guarantee the safety of formula purchased for the WIC program, the fed gov't should not be in business with them.

- I look forward to working with you on this.
- I ask that the report be added to the record.

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From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 4/29/2022 3:17:03 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: [EXTERNAL] Whistleblower warned FDA about formula plant months before baby deaths

Wow, nice work if you can get it. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Friday, April 29, 2022 3:16 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: [EXTERNAL] Whistleblower warned FDA about formula plant months before baby deaths

Frank has a comms person who used to work for (b) (5) Just an interesting fact in all this.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, April 29, 2022 3:13 PM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: [EXTERNAL] Whistleblower warned FDA about formula plant months before baby deaths

Did not see. Thanks. Hopefully Melissa's review will get all the facts straight. Wonder who told them this. wj

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Friday, April 29, 2022 2:53 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: [EXTERNAL] Whistleblower warned FDA about formula plant months before baby deaths

Don't know if you saw this specific paragraph in this story…

Both the CFSAN director Susan Mayne, and Judy McMeekin, the head of the Office of Regulatory Affairs, the division that oversees all of FDA's inspectional activities, were sent a copy of the whistleblower disclosure, but it apparently was not sent to Frank Yiannas, deputy commissioner for food policy and response. Yiannas was not informed about the whistleblower warning the agency had received in October until February, according to a source familiar — raising significant questions about the agency's internal communication regarding the incident.

From: POLITICO Pro <alert@email.politicopro.com>
Sent: Thursday, April 28, 2022 11:25 AM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: [EXTERNAL] Whistleblower warned FDA about formula plant months before baby deaths

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/16/2022 10:53:14 AM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: RE: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

(b) (5) [redacted] jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 10:43 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

Internal, Confidential

Agree. We plan to address.

Right now, (b) (5) [redacted]

We'll strengthen this going forward. We also need to work w CDC to make Cronobacter a reportable disease by the States.

I hope this illustrates why you've been hearing me focus so much on outbreak improvement process. Dole timeline and now this one reveal the opportunities for enhancement here.

Unfortunate that the our external outbreak review was fought so strongly internally, and as a result took so long to complete. The only way to get better is to acknowledge opportunities for improvement…rather than being defensive.

I've been doing this Janet for over 30 years for organizations much larger than FDA. Based on my experiences, I think "outbreak response" should be elevated to an enterprise risk for food….it's that important. Few places were public will be less forgiving and where they expect is to be fast and be right.

Frank

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 10:30 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: RE: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

Perhaps we can talk sometime about this reporting to district offices and so forth. They are our intake point for non-reportable illnesses that are possibly food related? Another timeline where we might take a look. The organism is so pathogenic in infants, needs to set off immediate alarm bells. Although I realize the vehicle may not be food necessarily. jw

---

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 10:24 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

Thanks for the support.

Frank

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 8:27 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: RE: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

I think this is the right path to urge the company and then go public. jw

---

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 6:40 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Fwd: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

On way back to DC on flight. Arrive at 9 am, in case you would like to discuss by phone.

If discussion needed sooner, I know you can call Mayne, but would recommend including Caitlin too.

Thanks

FY

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From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, February 15, 2022 8:04:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Romano, Lisa M. <Lisa.Romano@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>

Subject: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

FOOD SAFETY UPDATE

U.S. FOOD & DRUG ADMINISTRATION

From the Office of Food Policy and Response

Internal, Privileged, & Confidential

We want to provide you with a brief update on the *Cronobacter* sakazakii illnesses associated with powdered infant formula as a suspect vehicle, as this remains an evolving situation.

Epi Status

- The epi status remains unchanged from the first update.

- There remain 4 cases of infant illnesses reported to various FDA district offices between Sept 2021 to January 2022. All of the cases are reported to have consumed powdered infant formula (IF) produced in Abbott's facility in Sturgis, MI.

- Three (3) of the cases were ill due to *Cronobacter sakazakii* and one (1) due to Salmonellosis. All 4 cases were hospitalized and 1 resulted in a death attributed to *Cronobacter*.

- For more details, see attached Food Safety Update #1.

Investigation Status

- On January 31, FDA initiated an inspection at the Abbott Nutrition facility in MI in response to five consumer complaints received from September 2021 to January 2022;
  * 4 complaints relaying illnesses in infants consuming Abbott powdered infant formula and
  * one informant relaying questionable practices with the firm's manufacturing processes (OCI notified).

- On February 1, FDA initiated environmental sampling in the firms powdered infant formula manufacturing areas collecting 160 swabs; all in Zone 2. No Zone 1 samples were collected during the initial environmental investigation as the firm had not disassembled equipment such as dryers.

- To date, **4 environmental subs have been confirmed positive for C. sakazakii**. From those 4 subs, **11 isolates of C. sakazakii have been whole genome sequenced with multiple genotypes being detected**.

- As of today, there has not been a match to the limited clinical isolates available from CDC.

- An additional **14 isolates of C. sakazakii are pending WGS** and they too will be analyzed to determine if they match clinical isolates.

- Abbott independently found two positives for C. sakazakii on sister swabs taken at the same time as FDA sampling. FDA received isolates from these samples on 2/15/22 and is initiating WGS.

- The inspection is ongoing at the firm. Current initial inspection observations identified significant Good Manufacturing Practice concerns, such as cracks in dryers used for other dried infant products.

- On February 14, FDA contacted the manufacturer to relay the confirmed C. sakazakii isolates from environmental sampling at their Sturgis facility. The firm relayed they were not amenable to a recall or market withdrawal.

- Today, February 15, FDA spoke further with the firm to repeat the request for a recall of all products produced since November 2020, and to inform the firm that FDA plans to issue a consumer advisory as early as tomorrow (2/16/22). We have asked for a response on the request for recall by tomorrow (2/16) at noon EST.

- The firm continues to hold all powdered products produced between January 4 to present (the last clean in place cycle) that are still stored at the production facility.

Next Step

- FDA will issue our routine Outbreak Investigation Table on Thursday, 2/16/22. In the table, consistent with our routine practice, we will list that FDA is conducting an investigation into multiple C. sakazakii cases.

- Also, if Abbott declines to initiate a voluntary recall, FDA plans to issue a public Consumer Advisory tomorrow that warns consumers who have the Abbott brand Similac formula to avoid using products with specific lot codes and dates produced in Abbott's facility in Sturgis, Mi.

- CFSAN is also keeping the WIC Program up to date on our actions since 60% of infants in the WIC Program are using Abbott formulas and this may have implications for state WIC programs.

- FDA is also preparing a briefing paper to provide situational awareness to the White House Supply Chain Taskforce.

- FDA will return to the Sturgis facility, taking more samples including Zone 1 samples.

As usual, we will keep you updated on any noteworthy developments as the investigation continues.

Frank Yiannas

Deputy Commissioner, Food Policy & Response

U.S. Food and Drug Administration

10903 New Hampshire Ave.

Silver Spring, Maryland 20993
Tel: 301-796-4665

frank.yiannas@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/4/2022 7:59:51 AM
To: DiPaola, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e6114e2a610423996e62a920add4e82-LDIPAOLA]
Subject: Yes, I have read this notice, understand my obligations, and agree to comply with the instructions. I have relevant documents: PLEASE RESPOND: Abbott Nutrition/Infant Formula Litigation Hold

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/4/2022 12:57:13 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: RE: (b) (6), (b) (7)(C), (b) (7)(D)

Thanks. jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Wednesday, May 4, 2022 12:54 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Subject: FW (b) (6), (b) (7)(C), (b) (7)(D)

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Janet

FYI – as you'll be leading the review, incoming on (b) (6), (b) (7)(C), (b) (7)(D) related to Abbott's Sturgis facility.

We'll ensure prompt follow-up. The IF IMG is working.

FY

From: vanTwuyver, Sheila <Sheila.vanTwuyver@fda.hhs.gov>
Sent: Wednesday, May 4, 2022 11:45 AM
To: Infant Formula FDA IMG Operations <InfantFormulaFDAIMGOperations@fda.hhs.gov>
Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>
Subject: FW: (b) (6), (b) (7)(C), (b) (7)(D)

Good morning, IMG OPS,

This morning I referred an (b) (6), (b) (7)(C), (b) (7)(D)

(b) (6), (b) (7)(C), (b) (7)(D)

V/r,

Sheila

Sheila van Twuyver
National Consumer Complaint Coordinator
FDA, Office of Emergency Operations
OC/OO/OSEM/OEM
Mobile: (b) (6)
Office: 612-758-7227
Sheila.vantwuyver@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/9/2022 7:41:15 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: WH press briefing on infant formula today

Thx jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, May 9, 2022 6:52 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: WH press briefing on infant formula today

Rob and Janet –

We had ~20 minutes today to get the WH simplified talking points on our efforts on supply chain challenges for infant formula. Jen stayed on message.

Here is what we sent for your reference:

Ensuring that parents and caregivers have access to powdered infant formula is a top priority for the FDA right now. Efforts include working with manufacturers of infant formula products to help address the current supply chain issues, especially with regard to specialty and metabolic products.

- The infant formula industry is working intensely to maximize their production to meet new demands. Efforts have included optimizing their lines and product sizes to increase capacity; prioritizing product lines that are of greatest need, particularly for specialty formulas; expanding hours of operation for manufacturing plants; and expediting the importation of product produced abroad.

The agency is also working to help manufacturers ensure that while they are meeting the demand, it's critical that safe product is on the market.

- The FDA is exercising flexibility and expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- They have also emphasized a streamlined import entry review process that will allow infant formula products to come into the U.S. from overseas.

The FDA will continue to closely monitor the availability of all types of infant formula and assess the potential impact of various supply mitigation steps. We will consider all tools at our disposal to support the supply of infant formula products.

###

Separately, we have an aggressive comms plans this week to get the word out on all the work underway at FDA on this issue. Will share momentarily.

Erica

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Monday, May 9, 2022 5:41 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Jen covered our TPs in the briefing today

https://youtu.be/EC4eaBqULME?t=3389

Michael Felberbaum
Assistant Commissioner for Media Affairs

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b) (6)
michael.felberbaum@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/11/2022 3:56:54 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
CC: Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: FYSA--Appropriations Briefing Request on IF

I would like to be. (b) (6) , can do Monday but not Fri. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Wednesday, May 11, 2022 3:56 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: FYSA--Appropriations Briefing Request on IF
Importance: High

Janet – see below. Would you want to participate and pitch our resource needs? OCA thinks this briefing will get scheduled for Monday.

From: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Sent: Wednesday, May 11, 2022 2:43 PM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: FYSA--Appropriations Briefing Request on IF
Importance: High

Hey Tristan—
Just wanted to flag that we have received a request from all four corners approps for a briefing as soon as possible on infant formula shortages. They have been hearing from Members on both sides of the aisle and are eager to meet with us. They are looking to understand what's happening at the plant, status with production, shortage issue, timelines, and how they can help us, resources or otherwise. Checked in with Andi and Kim, and we feel we need to do this briefing as well. I'm reaching out to CFSAN/OFPR to inquire about availability.

Per the convo at the this morning's leg check-in, let me know if you think JW would like to be looped in as well. Perhaps another opportunity to chat about fy23, modernization, etc.

Let me know if easier to chat. Thanks!
KK

Kate Klimczak
(b) (6)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/11/2022 5:27:39 PM
To: Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: RE: JW TWEETS: Infant formula

Looks good, thanks. jw

From: Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Sent: Wednesday, May 11, 2022 5:17 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Garcia, Megan <Megan.Garcia@fda.hhs.gov>; Taiwo, Wumi <wumi.taiwo@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Subject: JW TWEETS: Infant formula

Hi - below is a tweet for your review regarding the recent infant formula press release. This is the link to the FDA tweet for context: https://twitter.com/US_FDA/status/1524478868572233728

Thank you,
Val

===

@DrWoodcockFDA
I know that parents are eager to ensure they have enough infant formula for their babies, but please remember to buy only what you need. This is top priority for FDA and we are doing everything we can to ensure parents and caregivers have what they need. **[QRT @US_FDA]**

===

Valarie Thorpe
Social Media Advisor

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: (b) (6)
Valarie.Thorpe@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/10/2022 3:08:30 PM
To: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: RE: URGENT REVIEW REQUEST: PR, FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products

Fine with me. jw

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Tuesday, May 10, 2022 12:34 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: URGENT REVIEW REQUEST: PR, FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products
Importance: High

Dr. Califf and Dr. Woodcock,

As soon as possible today, OMA is aiming to issue a press release that provides important updates on steps FDA is taking to improve the supply of infant and specialty formula products. The press release includes a proposed quote attributed to Dr. Califf and is attached here for your urgent review, if possible by 1:30pm, as we are hoping to issue this afternoon. Happy to answer any questions and thank you in advance for your expedited review.

Agency/Office: Infant Formula IMG/OFPR/CFSAN
Subject: FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products
Deadline for comments: 1:30pm, Tuesday, May 10
Planned release date: Tuesday, May 10
Driving event: Infant formula supply chain FDA progress updates

Best,
Tara

Tara G. Rabin
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-3157 / Cell: (b) (6)
Tara.Rabin@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/16/2022 10:13:57 PM
To: Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Romano, Lisa M. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9653957f210f4febb1c12c64207346d4-LROMANO]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Prater, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=291b4eab842148baba96df3bd8c31058-DPRATER]; Farrar, Jeff A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c862ce01b6714d4c9c5057306240469e-Jeff.Farrar]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]
Subject: RE: Food Safety Update #3 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

I believe that the previous positive by the firm should provide enough additional grounds to mandate a recall should the firm balk tomorrow. Janet W

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 9:33 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Romano, Lisa M. <Lisa.Romano@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Subject: Food Safety Update #3 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

FOOD SAFETY UPDATE

U.S. FOOD & DRUG ADMINISTRATION

From the Office of Food Policy and Response

Internal, Privileged, & Confidential

We want to provide you with a brief update on the *Cronobacter* sakazakii illnesses associated with powdered infant formula as a suspect vehicle, as this remains an evolving situation.

Actions Today

- Two additional calls were held with the firm today to collect additional information on the possible scope of contaminated products and to encourage the firm again to implement a recall. The firm has yet to agree to a recall despite numerous environmental positives for C. sakazakii in the facility from FDA sampling and from the firm's own sampling, along with significant Good Manufacturing Practice deficiencies. This evening, a draft Consumer Advisory was shared with Abbott Nutrition to further encourage the firm to initiate a recall prior to issuance of the FDA Consumer Advisory tomorrow.

- FDA also learned that Abbott Nutrition discarded a previous production lot of powdered infant formula due to contamination with Cronobacter.

- FDA investigators are conducting additional swabbing of recently disassembled equipment in the Sturgis, MI facility.

- WGS continues for isolates from sub samples that were confirmed positive earlier in the week.

- Discussions continued with the WIC Program to prepare for the forthcoming announcement.

- FDA transmitted a briefing paper to the White House Supply Chain Taskforce to provide situational awareness.

Next Steps

- A draft Consumer Advisory is currently in clearance and will issue tomorrow. The advisory will inform consumers to avoid powdered infant formula from the Sturgis, MI facility with expiration dates after June 2022, and will

include brands and specific label codes information to assist consumers in identifying the product manufactured at the Sturgis facility.

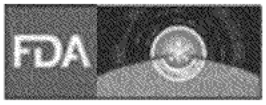
- A press release is also being prepared for issuance tomorrow.

- We are preparing for further coordination with external groups such as the American Academy of Pediatrics to amplify messaging and prepare providers to give individualized advice to patients that may need to change feeding practices.

- We are preparing to do early morning outreach to retail stakeholders (e.g., Food Marketing Institute and National Grocers Association) to request that retailers implement measures to reduce hoarding (e.g., restricting the quantities of infant formula that can be purchased in a single shopping event).

As usual, we will keep you updated on any noteworthy developments as the investigation continues.

Caitlin Boon, Ph.D.
Associate Commissioner for Food Policy and Response
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
(b) (6)
Caitlin.Boon@fda.hhs.gov



From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/17/2022 8:32:50 AM
To: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: FYI - PR, FDA Announces Investigation of Bacterial Infections Possibly Associated with Certain Powdered Infant Formula

I realize we will have to change this but looks overall right. jw

---

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 11:10 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: FYI - PR, FDA Announces Investigation of Bacterial Infections Possibly Associated with Certain Powdered Infant Formula

Dr. Woodcock,

Attached as a FYI is a copy of the press release regarding FDA's investigation of *Cronobacter sakazakii* and *Salmonella* Newport infections potentially linked with the consumption of powdered infant formulas produced at Abbott Nutrition's Sturgis, Michigan facility. The press release includes placeholder language to insert should the company agree to voluntarily recall. OMA will adjust the press release, as appropriate, per final CFSAN/OFPR conversations with the firm tomorrow morning. Happy to answer any questions.

Best,
Tara

Tara G. Rabin
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-3157 / Cell: (b) (6)
Tara.Rabin@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/12/2022 10:05:04 PM
To: 'Califf, Robert' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: RE: [EXTERNAL] Re: IRi Data - Powdered Infant Formula Availability

Totally agree. I noted that the Hill communication used the Data Assembly numbers. If they look at Abbott SKUs then clearly they will be off base. jw

---

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Thursday, May 12, 2022 10:00 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: IRi Data - Powdered Infant Formula Availability

The sooner we get the facts out, the better.

rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>
Date: Thursday, May 12, 2022 at 9:00 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Subject: FW: [EXTERNAL] Re: IRi Data - Powdered Infant Formula Availability

FYI – IRi is acknowledging the out of stock rates referenced in news articles is inaccurate.

From: Davey, Krishnakumar <Krishnakumar.Davey@iriworldwide.com>
Sent: Thursday, May 12, 2022 8:48 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: [EXTERNAL] Re: IRi Data - Powdered Infant Formula Availability

Frank, happy to help.

Erica, happy to connect with you and chat about how our methodology is very robust and how the other one in the news is not correct. We can do it tomorrow, 11-12 noon eastern or after 4 pm eastern. Let me know.

Krishnakumar (KK) S. Davey
President, Client Engagement

C +1 (b) (6)
E Krishnakumar.Davey@IRIworldwide.com

IRIworldwide.com

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Date: Thursday, May 12, 2022 at 8:45 PM
To: Davey, Krishnakumar <Krishnakumar.Davey@iriworldwide.com>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: IRi Data - Powdered Infant Formula Availability

KK

Thanks again for all of the help you've been to me and my team on powdered infant formula availability.

As you know, there's been quite a bit of news regarding out-of-stocks based on a data provider that uses a methodology that is not as robust as the IRi methodology. By way of this email, I'd like to introduce you to **Erica Jefferson** at the FDA who is leading communication efforts.

I think it would be useful for her to hear from you what the IRi data is telling us and why it's so different from the rates being reported by some outlets.

Erica – KK is quite the expert, so I'm sure he'll be helpful.

Thanks

Frank

IRi

Krishnakumar (KK) S. Davey
President, Client Engagement

C +1 (b) (6)
E Krishnakumar.Davey@IRIworldwide.com

IRIworldwide.com

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/12/2022 2:24:51 PM
To: Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]
Subject: RE: this afternoon's check-in

That's fine. Just heard from Julie that the "supplemental" would be to buy infant formula, so no budget drill. jw

---

From: Safford, Melissa <Melissa.Safford@fda.hhs.gov>
Sent: Thursday, May 12, 2022 2:21 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: this afternoon's check-in

Are there items you'd like to discuss? I'm happy to connect, but I don't have anything urgent to share if you'd like to use the time for more time-sensitive conversations.

Melissa Safford

Senior Advisor
Office of the Commissioner
(b) (6)
melissa.safford@fda.hhs.gov
U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/12/2022 1:27:59 PM
To: Desai, Vid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91b722d8adf748aaa8e91f77ad37a272-Vidyut.Desa]
Subject: RE: An idea for Safety Surveillance

I'm hoping we can get a lot of money from Congress given this infant formula problem. jw

---

From: Desai, Vid <Vid.Desai@fda.hhs.gov>
Sent: Thursday, May 12, 2022 10:58 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: An idea for Safety Surveillance

I came across the following story and quote from Peter Marks. Its accurate and I have heard many people make similar references.

FDA's IT Systems Are '20 Years Behind' Industry Standard, Official Says | MedPage Today

Our safety surveillance needs are complex with many external data sources ranging from partners like USDA 9for food), to CDC/NIH for the healthcare side and there are even some external data sources from VA, CMS etc that come into play.

I have not come across any Enterprise disciplined benchmarking of the current data flows (and systems) with a view to seeing how we can optimize and modernize this area. I'm thinking of the type of process benchmarking Eagle Hill has done for the inspections work led via the ETO. Similar to inspections, I think there are bits and pieces that may be benchmarked but no holistic view of the entire ecosystem. The Smart Era of food safety also ties in with such surveillance activity. Its all aligned with the ETO Safety Surveillance business capability. While there are many variations across the centers on the safety data, I think we need to have a common data (lake) approach as there are many events that require us to be able to analyze the data across the enterprise. So my recommendation is for such systems to be planned/designed on an enterprise basis but executed and managed in a federated manner.

We have some money left from COVID Supplement 6. There is a lot of enthusiasm for allocating it to the RUF or AETION etc. to do some RWD/RWE type activity. Instead of that, I wonder if we can use some of that funding to benchmark the safety surveillance ecosystem and then work within the FDA or even with the HHS on how to optimize/improve this. I suspect this will get complex as we will need to engage many other HHS OPDIV partners etc. who may come with their own agendas. However, this is so core to our safety mission that its worth prodding and looking for opportunities to improve.

Let me know if this has any merit and worth pursuing and discussing. I think it may result in something more useful than what RUF or AETION may deliver as RWD/RWE activities...

Thanks
-Vid

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/12/2022 10:08:12 PM
To: Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]
Subject: RE: E&C Mark-up Summary

Thx Sure don't want to make a misstep, it is just sooo important. jw

---

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Thursday, May 12, 2022 10:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: E&C Mark-up Summary

We are still working on this. E&C Majority said they are pushing to add before Full Committee next week (b) (5)

They have asked (b) (5) .

We do plan to raise this during our E&C and Senate briefings tomorrow on infant formula, and Dr. Califf will raise in his call with Rep. Upton.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, May 12, 2022 9:26 AM
To: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Subject: RE: E&C Mark-up Summary

Yes we really need to press, can use infant formula as an example. Although we got an increase in FTE it takes many months under title 5 to hire and positions not filled. jw

---

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Thursday, May 12, 2022 9:05 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: E&C Mark-up Summary

Not included yet. They are having discussions about adding next week as a part of the AINS.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, May 12, 2022 8:09 AM
To: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Subject: RE: E&C Mark-up Summary

Where is hiring in this? jw

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Wednesday, May 11, 2022 7:30 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Safford, Melissa

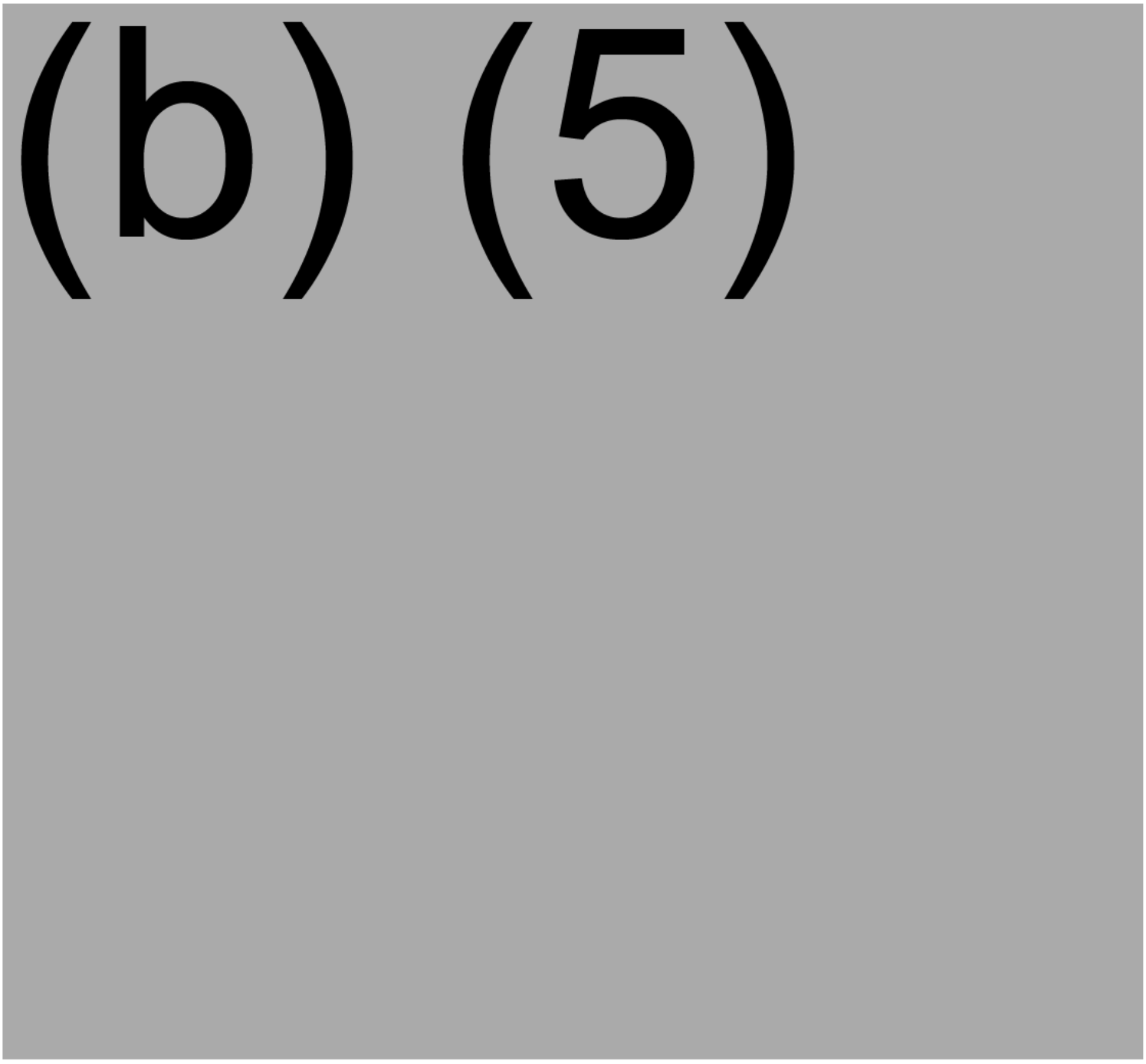
<Melissa.Safford@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>
Subject: E&C Mark-up Summary

Internal, Deliberative

Hi all -

I wanted to provide you with an update on E&C's markup of the user fee package. It passed the Subcommittee 30-0, but there was considerable debate that we thought might be helpful to share.

A key message from Chairman Pallone during the markup was that the Committee does not intend to change its timeline for markup so any policy that is not bipartisan or consensus before next week will be unable to move as a part of the user fee package.



Happy to discuss further, or provide additional information if helpful.

Thank you,
Kim

Kimberlee Trzeciak
Associate Commissioner for Legislative Affairs
Office of Legislation
U.S. Food and Drug Administration
M: (b) (6)
kimberlee.trzeciak@fda.hhs.gov
U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/13/2022 9:57:18 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Urgent Appropriations IF Questions for possible Supplemental

Yes just keep me informed, I don't want to slow anything up. Of course, we need longer-term resources but probably some additional now could help with current crisis. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Friday, May 13, 2022 9:53 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: Urgent Appropriations IF Questions for possible Supplemental
Importance: High

Do you want to weigh in on this resource request? Moving over this weekend so will be fast turnaround.

DeLauro asking for immediate and long term resource needs for an infant formula supplement they will move next week. Unfortunately, their focus seems on immediate need. There's perhaps also an intermediate need to think of – we will probably be in a precarious place for a few months of formula so just one more glitch or event in the system while we are recovering if Abbott comes back on line could create a new crisis.

From: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Sent: Friday, May 13, 2022 5:53 PM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Cc: McBride, Maren <Maren.McBride@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Urgent Appropriations IF Questions for possible Supplemental
Importance: High

Maren and I just spoke with House majority/minority on a potential infant formula supplemental, as well as Senate Minority. As I'm sure you all have seen in press, there may be an emergency supplemental related to infant formula on the house floor next week.

House approps is are looking to provide funds to FDA for IMMEDIATE needs to improve the infant formula shortage. A couple ideas/questions they had:

1. Does ORA need funding for greater oversight of formula imports coming into the IMF?
2. Does FDA need funding to go after bad actors selling adulterated products?
3. Are their new manufactures interested in producing infant formula? Or concern that too much product could start being produced flood the market?
   a. Would it be helpful for a government entity (FDA or otherwise) to guarantee purchase of infant formula?
4. Does ORA need funding to conduct inspections of additional facilities in the U.S. or internationally that could start producing infant formula?
5. What's the timeline for getting the Sturgis, MI plant up and running?
6. One the plant is able to begin production, how long till they produce and ship their first batch of formula?
7. Is there another facility(s) currently producing or planning to start producing specialized metabolic formulas?

(b) (5)

Key question needing an answer this weekend for Martha: does CFSAN, OFPR or ORA have any funding needs that could immediately impact the short of infant formula? We can pitch the longer term investments but they really want immediate needs to have impact within weeks.

Tristan, I know you've been pulling together significant amounts of information on this so starting with you, but please let me know if we should reach out to Frank, Judy and Susan and their teams to get these questions answered this weekend, or perhaps some we already have answers to that we can share quickly!

Happy to chat if helpful. Sorry for the late Friday ask..
Kate

Kate Klimczak
(b) (6)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 9:13 PM
To: Boon, Caitlin; Yiannas, Frank; Tierney, Julia; Colonius, Tristan; Raza, Mark; Beckerman, Peter; McMeekin, Judith; Rogers, Michael; Romano, Lisa M.; Mayne, Susan; Stearn, Douglas; Musser, Steven M; Harris, Stic; Goldman, David; Prater, Donald; Farrar, Jeff A.; Fristedt, Andi; Roth, Lauren; Jefferson, Erica; Rebello, Heidi; Rabin, Tara G.; Dooren, Jennifer
Subject: RE: Food Safety Update #3 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

I believe that the previous positive by the firm should provide enough additional grounds to mandate a recall should the firm balk tomorrow. Janet W

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 9:33 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Romano, Lisa M. <Lisa.Romano@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Subject: Food Safety Update #3 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

Internal, Privileged, & Confidential

We want to provide you with a brief update on the *Cronobacter* sakazakii illnesses associated with powdered infant formula as a suspect vehicle, as this remains an evolving situation.

Actions Today

- Two additional calls were held with the firm today to collect additional information on the possible scope of contaminated products and to encourage the firm again to implement a recall. The firm has yet to agree to a recall despite numerous environmental positives for C. sakazakii in the facility from FDA sampling and from the firm's own sampling, along with significant Good Manufacturing Practice deficiencies. This evening, a draft Consumer Advisory was shared with Abbott Nutrition to further encourage the firm to initiate a recall prior to issuance of the FDA Consumer Advisory tomorrow.

- FDA also learned that Abbott Nutrition discarded a previous production lot of powdered infant formula due to contamination with Cronobacter.

- FDA investigators are conducting additional swabbing of recently disassembled equipment in the Sturgis, MI facility.

- WGS continues for isolates from sub samples that were confirmed positive earlier in the week.

- Discussions continued with the WIC Program to prepare for the forthcoming announcement.

- FDA transmitted a briefing paper to the White House Supply Chain Taskforce to provide situational awareness.

Next Steps

- A draft Consumer Advisory is currently in clearance and will issue tomorrow. The advisory will inform consumers to avoid powdered infant formula from the Sturgis, MI facility with expiration dates after June 2022, and will include brands and specific label codes information to assist consumers in identifying the product manufactured at the Sturgis facility.

- A press release is also being prepared for issuance tomorrow.

- We are preparing for further coordination with external groups such as the American Academy of Pediatrics to amplify messaging and prepare providers to give individualized advice to patients that may need to change feeding practices.

- We are preparing to do early morning outreach to retail stakeholders (e.g., Food Marketing Institute and National Grocers Association) to request that retailers implement measures to reduce hoarding (e.g., restricting the quantities of infant formula that can be purchased in a single shopping event).

As usual, we will keep you updated on any noteworthy developments as the investigation continues.

Caitlin Boon, Ph.D.
Associate Commissioner for Food Policy and Response
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
(b) (6)
Caitlin.Boon@fda.hhs.gov

From: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Sent: 5/15/2022 3:26:34 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: Re: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

Thx. Jw

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Sunday, May 15, 2022 3:00:20 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: Re: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

In the interest of time, we will move these to HHS and incorporate any tweaks you may have later.

From: Felberbaum, Michael
Sent: Sunday, May 15, 2022 2:09:39 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: RE: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

Thanks. Yes, there was some extraneous language that I've now deleted. It now reads:

(b) (5)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, May 15, 2022 2:05 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: Re: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

Looks fine to me. Second sentence of fourth para of import announcement seems to be missing something. Jw

---

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Sunday, May 15, 2022 1:52:30 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

Good afternoon Dr. Califf,

Sharing drafts of the infant formula importation and consent decree press releases for review at your earliest convenience. We'd like to get this to HHS as soon as possible today.

Thanks!

Michael
Michael Felberbaum
Assistant Commissioner for Media Affairs

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b) (6)
michael.felberbaum@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/16/2022 1:35:26 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Abbott

Yes, and I was clear, just hoped that we didn't send mixed messages. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Monday, May 16, 2022 12:05 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Abbott

What he just said was much more clear than when he mentioned it earlier.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 16, 2022 12:04 PM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Re: Abbott

Right. Did you hear better what Frank said?

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Monday, May 16, 2022 12:00:05 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Abbott

I just double checked with Pete. They voluntarily ceased. Now of course, if they had tried to restart and we were concerned, we would have tried to take action to halt.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 16, 2022 11:59 AM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Re: Abbott

They put the right info in the chat. I couldn't tell but I thought Frank said they did not shut down voluntarily. Jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Monday, May 16, 2022 11:57:30 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Abbott

Yes. Both the recall and production cease are voluntary.

Also, we inspected them in Sept 2021. I do not know why ORA said 2019 or that they didn't have this information in front of them.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 16, 2022 11:56 AM

To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Abbott

Did a voluntary shutdown. Jw

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/16/2022 12:57:32 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Abbott

Ok good, would not want to give the wrong impression. We would have had to go to court for an injunction if they had refused. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Monday, May 16, 2022 12:05 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Abbott

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Subject: RE: Abbott

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Sent: Monday, May 16, 2022 11:56 AM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Abbott

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From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/17/2022 8:48:50 AM
To: Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
CC: Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]; Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]
Subject: RE: Letter from Senator Burr on Infant Formula

Maybe a partial response would be good, since some of these questions might require a lot of research and others are fairly straightforward. jw

---

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Monday, May 16, 2022 7:03 PM
To: Califf, Robert <(b) (6)@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Flahive, James <James.Flahive@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: Letter from Senator Burr on Infant Formula

Hi all -

For your awareness, I wanted to send along the letter below that just came in from Senator Burr to Dr. Califf regarding FDA's response to infant formula supply challenges, our knowledge about said supply challenges, and our lack of decisive action. I have excerpted his questions below for ease of reference.

Senator Burr has requested a response by May 20. OL will work with OFPR, ORA, and CFSAN to respond as quickly as we can, but recognize with everything that is going on right now that the May 20 deadline is not realistic.

Happy to discuss further, but we will get to work.

Thank you,
Kim

1. Infant formula shortages began in 2020 and increased sharply in July of 2021.5 What specific actions did FDA take in the Fall of 2021 to mitigate the shortage of infant formula and specialty formulas?

2. When did FDA first learn of potential risks of shortages to the infant formula supply?

3. What are the specific dates on which the agency became aware of challenges with the manufacturing of infant formula? Please provide each instance by date and facility. How soon did FDA follow up with each facility experiencing manufacturing challenges and what were the actions FDA has taken to facilitate mitigating the aforementioned challenges?

4. What does FDA use to determine that a product is a critical medical food? How does this status impact FDA's work on inspections and review of product submissions?

5. What are the specific reasons that the manufacturing lines for amino acid and other formulas remain down? What is preventing the plant in Sturgis, Michigan from resuming operation? How soon does FDA anticipate this facility reopening and resuming production?

6. What are the specific actions FDA is taking in their efforts to work with the other suppliers of infant formula? Are there suppliers with additional manufacturing capacity that could scale up to help meet the current demand for infant formula? If so, what are the actions FDA is taking to support such manufacturing scale up?

7. Are there alternative products appropriate for purposes of substitutions to the formula products in shortage? If so, what are the actions FDA is taking to fast track any alternative products or appropriate substitutions?

8. How many submissions for new infant formulas and new infant formula manufacturers are currently under review at the FDA?

a. How long has each submission been under review?

b. What is FDA's plan, in calendar days, to take action on each of these submissions?

9. What are FDA's restrictions on the import of infant formula from overseas?

a. How is FDA working to facilitate the importation of overseas product?

b. Can the FDA issue temporary waivers of labeling requirements for overseas products? When will those waivers be issued?

10. What are the regulatory differences related to safety requirements regarding infant formula manufactured and available in countries overseas, namely the United Kingdom, Australia, New Zealand, Japan, Israel, Switzerland, South Africa, the European Union, and the European Economic Zone? What are the regulatory differences, including safety, for formula products manufactured and available in Mexico, Chile, Ireland, and the Netherlands?

11. What are the steps FDA is taking to prioritize getting new domestic products on shelves?

12. How is FDA working with other federal agencies to alleviate the current infant formula shortages?

13. What are remaining barriers to relief of the U.S. shortage of infant and specialty formulas?

Kimberlee Trzeciak
Associate Commissioner for Legislative Affairs
Office of Legislation
U.S. Food and Drug Administration
M: (b) (6)
kimberlee.trzeciak@fda.hhs.gov
FDA U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/17/2022 5:15:09 PM
To: 'Califf, Robert' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: RE: Infant Formula Supp Breakdown

It would be better to get base funding rather than this supplemental. Hope it does not abrogate our appropriation. jw

---

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, May 17, 2022 5:13 PM
To: McBride, Maren <Maren.McBride@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: Re: Infant Formula Supp Breakdown

I hope we can get the tech $$ in there somehow. Important to integrate 21 Forward into the broader enterprise plan. Having the right technology will be essential to optimize our human work.

rmc

From: Maren McBride <Maren.McBride@fda.hhs.gov>
Date: Tuesday, May 17, 2022 at 3:49 PM
To: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>, "Hattis, Daniel" <Daniel.Hattis@fda.hhs.gov>, James Tyler <James.Tyler@fda.hhs.gov>
Cc: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Robert Califf <(b) (6) @fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, Judith McMeekin <Judith.McMeekin@fda.hhs.gov>, "Klimczak, Katherine" <Katherine.Klimczak@fda.hhs.gov>, Andi Fristedt <Andi.Fristedt@fda.hhs.gov>
Subject: RE: Infant Formula Supp Breakdown

Hi Frank—I certainly understand your concern. I think it is too early to say definitely what the bill intends to fund. The notes below are just a summary of what was mentioned and I don't think by any means the final product. I will check in with House staff to get their sense and try to nail down more details at the staff level. Further, we will be working with the Senate to address our concerns with the House version (assuming the Senate has a desire to take it up which I'm not confident of currently) and I will make sure this is discussed and pressed if in fact the House ultimately decides not to fund it.

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 3:36 PM
To: McBride, Maren <Maren.McBride@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>

Subject: FW: Infant Formula Supp Breakdown
Importance: High

Maren, Dan, and Jay:

I'm seeing that we're only getting one time funding ($1.5M) in the Infant Formula Supplemental for data and the 21 Forward Supply Chain Monitoring platform for the first year. And nothing else thereafter.

In subsequent years (long-term), there's additional funding $12 M for Infant Formula Review Staff of New infant formulas to markets in CFSAN and $10.65 M for 35 FTE in ORA for inspections.

While both of these are great, the funding definitely discounts one of the most important factors in managing a supply chain crisis – data and insights.

In fact, even if we can do more new formula reviews and more inspections, if production is disrupted, we need an ongoing ability to monitor supply chains.

Is there any way we can appeal? I think it's real lack of understanding of root issues to prevent and more effectively manage a re-occurrence.

Our repeated declines on the 21 Forward platform during previous budget requests over the past few years definitely hindered our ability in this incident. For example, we had to rush to put contracts in place to obtain infant formula supply chain data out of OFPR's small and limited budget, because the program was tracking at the level of real-world supply chain data.

Thanks for advocating for the better supply chain data and analytics. **Food security is national security**. I think we've all seen how true that statement is.

Frank Yiannas
Deputy Commissioner, Food Policy & Response
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20993
Tel: 301-796-4665
frank.yiannas@fda.hhs.gov

From: Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 3:03 PM
To: Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>; Baker, Matthew <Matthew.Baker@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Gribbins, Myer <Myer.Gribbins@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Wade, Jennifer <Jennifer.Wade@fda.hhs.gov>; Christin, Charlotte - OC <Charlotte.Christin@fda.hhs.gov>; Zimdahl, Nina <Nina.Zimdahl@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Poloni, Morgan <Morgan.Poloni@fda.hhs.gov>; Imber, Stephen <Stephen.Imber@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>

Cc: McBride, Maren <Maren.McBride@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Subject: IF Supp Breakdown

Hi all. Based on what OCA heard at today's Rules Committee markup, the $28M appears to fund the following pieces. I've used the table we provided to the Committee and highlighted what seems to be funded. Please note that it remains unclear whether there is a path through the Senate.

The following was specifically stated:

- $23 million is for infant formula staffing needs at ORA and CFSAN;
- $3 million is to ORA for addressing health fraud, state partnerships, laboratory methods development, improving IT systems, addressing consumer complaints, and building databases to track formula on the online marketplace;
- $1.5 million is for infant formula supply chain monitoring and assessment activities; and
- $500,000 is to CFSAN for surveillance of the infant formula marketplace.

Here's how it seems to compare to what we provided.

OFPR	CFSAN	ORA	Total
$1.2M for 21 Forward Food Supply Chain Continuity System, including additional data purchases	$1.0M Implementation Support for Infant Formula Enforcement Discretion Guidance	$1.0M for Health Fraud enhancements for online surveillance	
$0.3M for Infant Formula Supply chain Assessment (2 contract SMEs for 4 months)	$0.5M for Social Media Data Capture and Analysis to Identify Unsafe Infant Formula Products.	$1.5M with our state partners to expand current contracts/grants	
		$0.25M for lab methods development	
Total: $1.5M	**Total: $1.5M**	**Total: $2.75M**	**Total: $5.75M**

Long-Term:

OFPR	CFSAN	ORA	HQ	Annual Total
$5.0M for 21 Forward Food Supply Chain Continuity System, including additional data sources and processing capabilities	$12.0M for Infant Formula Staffing Needs	$10.65M to support 35 FTEs across the 3 areas above, including $500K in operating for increased costs for foreign operations	$0.275M for 1 FTE in the Office of Chief Counsel to provide legal support for increased workload	
	$5.0M for Data Analytics and IT Infrastructure	$2.0M for data analytics and consumer complaint modifications (enterprise wide)		
Total: $5.0M	**Total: $17.0M**	**Total: $12.65**		**Total: $34.925**

FDA

Daniel Hattis | *Team Lead, Foods and Veterinary Medicine*
Office of Congressional Appropriations

Office: (301) 796-1377
Cell: (b) (6)
daniel.hattis@fda.hhs.gov

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/17/2022 11:50:19 AM
To: Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bdaa04f42f0afb9dd6abf39793a-Daniel.Hatt]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: For review: IF Updates to RMC Oral Testimony

Looks fine. I'd use (b) (5) throughout, most (b) (5) don't buy infant formula! jw

---

From: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 11:23 AM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: For review: IF Updates to RMC Oral Testimony

Good morning—

As you all know, per the Subcommittee, Thursday's FY23 budget hearing will also now cover infant formula.

I have updated Dr Califf's oral testimony to include infant formula and provide an update on this week's announcements. I'm requesting any feedback from this group before we provide it to Dr Califf for final review and sign-off. We aim to provide the updated oral to Dr Califf this evening for his final review tonight/tomorrow before Thursday's hearing.

Pages 1 – 3 contain the IF formula updates, which are highlighted. The text has generally been pulled from previously cleared materials/TPs to facilitate clearance. The remaining FY23 Budget related text is generally unchanged from the

Senate hearing though I have shortened it a little bit to accommodate the new IF text and still meet the Committee's five minute limit. Please note I have left a placeholder in case the IF supplemental moves in the House before Thursday's hearing.

Thank you, and please let me know if you have any questions or concerns.
Thanks,
Kate

Kate Klimczak
(b) (6)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/17/2022 8:30:10 AM
To: Rob Califf [(b) (6) @fda.hhs.gov]
Subject: FW: One pager
Attachments: 20220517 Infant Formula One Pager.docx

I agree we need a platform but this is based on Palantir so it is very expensive. I will consult with Vid and company on the best way to go. jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 7:57 AM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>
Subject: FW: One pager

Thanks Rob. All sounds food. And thanks for leading from the from the front on this difficult situation.

One more thing I'd suggest get added to the top of long term fixes:

- Invest and fully build out the **21 Forward Platform**. Supply chain problems are usually data problems, as we've seen in this case. We've been asking for this since the beginning of the pandemic, but it has yet to be adequately funded. Food security is national security. In this instance, we've had to run out and buy data sets on the spot that, in my view, that FDA foods should be monitoring all that time, esp the more critical ones, in relations to the food commodities we oversee.

Even with all the other great things you mention in the long term, if we don't do this, we'll be back at square one....making phone calls abd making assumptions that are not data/evidence based on how to fix it.

Respectfully

Frank

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, May 17, 2022 7:43 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>
Subject: One pager

Friends,

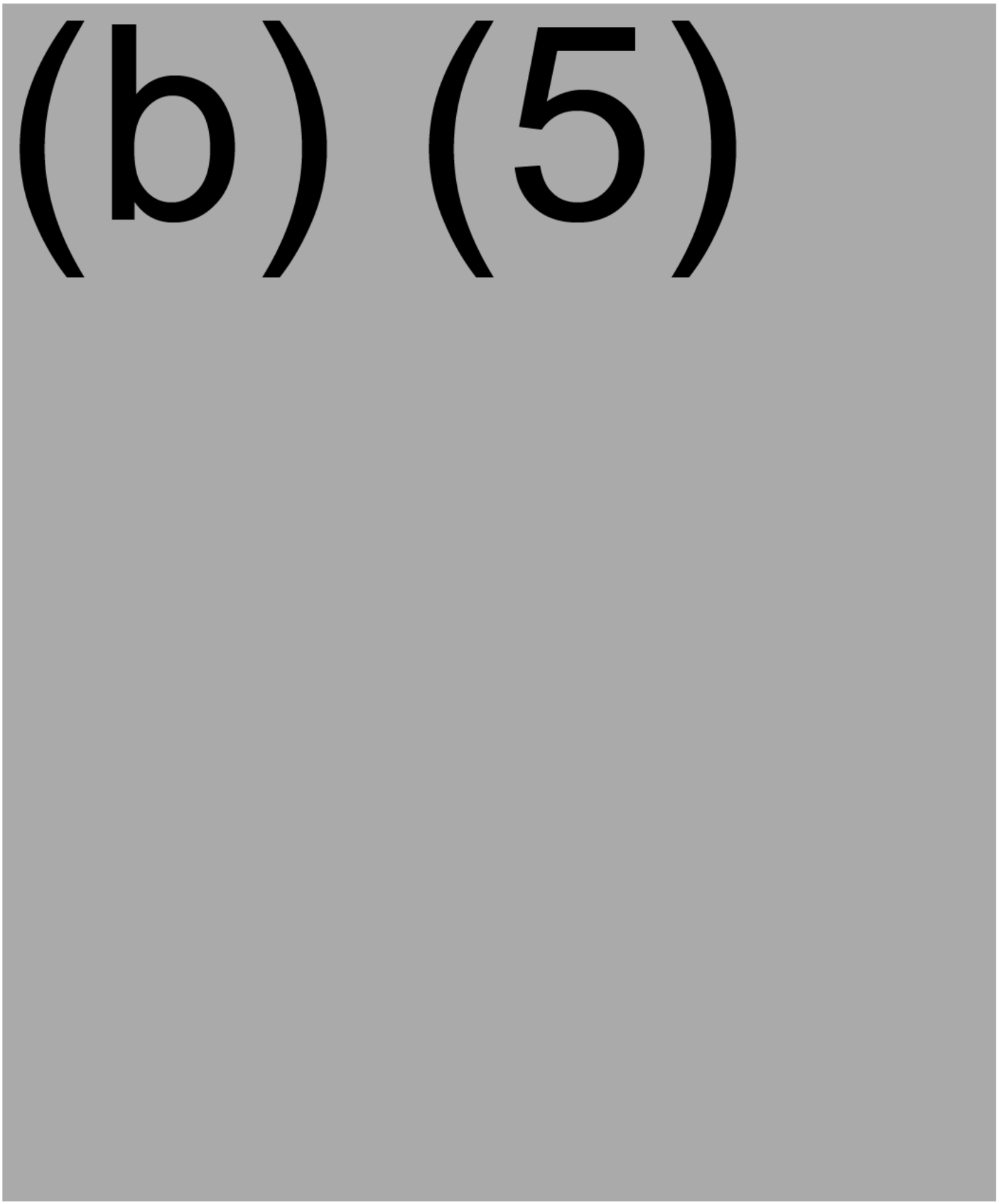
Quite a day yesterday. I saw a team in high gear putting it all out for many days to get these key elements in place. I've tried to distill our key strategy down to one page based on what you've told me.. I realize that each

element has many tactical components that will take a huge amount of work by people who are already at the max. If this is off course or there are major additional steps, please let me know, and feel free to edit.

I have seen what you are capable of doing, and its impressive.

rmc

(b) (5)



From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/17/2022 11:23:20 AM
To: McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
Subject: RE: IF supp info/update

Thx jw

From: McBride, Maren <Maren.McBride@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 10:31 AM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>; Baker, Matthew <Matthew.Baker@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Wade, Jennifer <Jennifer.Wade@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Subject: IF supp info/update
Importance: High

Folks- Today at 12 House Rules will meet to discuss the IF supplemental. We will keep you posted.

Text of supp also attached. FDA will get $28M to address current shortage but also to put towards the longer term build out. Available for 1.5 years. Path in Senate not 100% clear at this point.

The Committee on Rules will also meet **during its meeting today** on the following emergency measure, with consideration not beginning before **12:00 PM EDT**:

- H.R. 7790—Infant Formula Supplemental Appropriations Act, 2022

The Committee stands in recess, and will reconvene on **Tuesday, May 17, 2022** at **10:00 AM EDT** in **H-313, The Capitol** to consider the following measures:

- H.R. 350—Domestic Terrorism Prevention Act of 2022
- H.R. 7688—Consumer Fuel Price Gouging Prevention Act *[Rule Markup Only]*

The Committee on Rules will meet **Monday, May 16, 2022** at **3:00 PM EDT** in **H-313, The Capitol** on the following measures:

- H.R. 7309—Workforce Innovation and Opportunity Act of 2022
- H.R. 7688—Consumer Fuel Price Gouging Prevention Act
- H.R. 6531—Targeting Resources to Communities in Need Act of 2022 *[Rule Markup Only]*
- S. 2938—To designate the United States Courthouse and Federal Building located at 111 North Adams Street in Tallahassee, Florida, as the "Joseph Woodrow Hatchett United States Courthouse and Federal Building", and for other purposes. *[Rule Markup Only]*

**PLEASE NOTE:

- Members intending to join the proceeding virtually should notify the Committee's majority staff as soon as possible in order to receive instructions for connecting via the Cisco WebEx platform.

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/20/2022 9:42:56 AM
To: Levine, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14635ebee4ab4367aa606702393a1b78-HHS-Rachel.]
CC: Tierney, Julia [Julia.Tierney@fda.hhs.gov]
Subject: Need your help

Infant formula problem spiraling. May expect shortages especially in WIC. (b) (5) . I'm at (b) (6) jw

From: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Sent: 5/23/2022 1:39:17 PM
To: Desai, Vid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91b722d8adf748aaa8e91f77ad37a272-Vidyut.Desa]
Subject: Fwd: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

---

From: Tyler, James <James.Tyler@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:32 PM
To: Woodcock, Janet
Cc: Tootle, William; Tierney, Julia
Subject: FW: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

Here is more detail from OFPR. See below. OFPR indicates that there are other options and that they have discussed other options with ODT (last year?), but nothing that they can implement quickly and be responsive to the White House et al.

From: Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:27 PM
To: Tyler, James <James.Tyler@fda.hhs.gov>
Subject: RE: Send Me A Detailed Breakout of the $1M for 21 Forward that you need
Importance: High

Thanks, Jay. Please see below.

- To address the current infant formula crisis, FDA has been monitoring the status of the infant formula supply by using the Agency's 21 Forward food supply chain continuity system, which was developed during the pandemic to provide a comprehensive, data-backed understanding of how COVID-19 is currently impacting food supply chains.

- FDA requires immediate short-term funding for the 21 Forward system to speed the analysis of incoming data and help us track the impact of efforts to increase infant formula availability, including importation efforts.

- An estimated $1 million in additional funds would support the following through the end of FY 2022:
  - anticipated 40% increase in cores and 1.85 additional FTEs for 4.25 months to support daily reporting, increased data integration, and inter-agency analyses for the formula supply chain crisis.

- This increased capacity would allow the Infant Formula IMG to automate the processing and production of the following data on a weekly and daily basis:
  - Weekly infant formula production data (in coordination with National Economics Council)
    - Production of routine and specialty formulas, by week, unit, total pounds, including extra volume coming in via Operation Fly Formula and via FDA enforcement discretion
    - Likely to also include tracking of raw material shortages
  - Sales and availability data (in-stock %) for over 500 infant formula UPCs across 50 states and US territories on weekly and daily basis
    - Current data source is IRI; Nielsen may be an additional data source needed in near-term
  - Dashboards to automate comparison of production and sales/availability data to demand and distribution data:
    - US births by state and territory
    - WIC enrollment rates
    - WIC and Medicaid data on use of amino acid-based and extensively hydrolyzed formulas
    - CDC SVI Index
    - DOT data sources on trucking and distribution.

The White House has expressed the need for dashboards available to them directly, so we are working with the HHS supply chain control tower group for any lessons learned. They are trying to help as possible, but are limited by their contracts in providing additional data cores and engineering support directly to 21 Forward. Please see the list below of the analysis they are looking for from FDA on a weekly basis.

- Latest national insights:
  - Demand:
    - How have unit sales and volume sales moved since pre-recall?
    - Can we detect in data whether WIC waivers on container size have had a notable effect?
    - How has it changed for AA and EH in particular?
  - Availability:
    - How have in-stock rates changed since pre-recall for routine formula? Have they still leveled off since April? Where do we have uncertainty?
    - How has it changed for AA and EH in particular?
    - Are there any insights we can say through an equity lens? (either way, let's see if Allison Kolbe can do some SVI analysis this week?)
  - Production:
    - What qualitative / quantitative messages can we share about how production volumes nationally have changed?
- State insights:
  - Is there anything shareable w.r.t. states with particular supply concern?
- Operation Fly Formula:
  - AA and EH shipments: What can we say about amount of those shipments, and their impact on the market?

Thanks again for your help,
Suzanne

From: Tyler, James <James.Tyler@fda.hhs.gov>
Sent: Monday, May 23, 2022 12:35 PM
To: Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>
Subject: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

Janet wants to see it. Just some bullets with some sub-breaks if you can.

Jay Tyler
Chief Financial Officer
U.S Food and Drug Administration

OFBAP
Office of Finance, Budget, Aquisitons, and Planning

From: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Sent: 5/20/2022 1:01:40 PM
To: Heather E Hawley (b) (6) @mitre.org]
CC: Erin D Williams (b) (6) @mitre.org]; James T O'Neal (b) (6) @mitre.org]
Subject: Re: [EXTERNAL] Touching base: food support

Sounds good

From: Heather E Hawley <(b) (6) @mitre.org>
Sent: Friday, May 20, 2022 7:47:56 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Erin D Williams <(b) (6) @mitre.org>; James T O'Neal <(b) (6) @mitre.org>
Subject: RE: [EXTERNAL] Touching base: food support

Hi Janet,

Understood – I will circle back with you in a couple of weeks, if I don't hear from you before then.

Heather

Heather Hawley, MITRE
Cell: (b) (6)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, May 20, 2022 8:55 AM
To: Heather E Hawley <(b) (6) @mitre.org>
Cc: Erin D Williams <(b) (6) @mitre.org>; James T O'Neal <(b) (6) @mitre.org>
Subject: Re: [EXTERNAL] Touching base: food support

Hi Heather. Am in (b) (6) at moment. Can talk after I have a chance to assess the situation and the infant formula situation is in better shape. Jw

---

From: Heather E Hawley <(b) (6) @mitre.org>
Sent: Friday, May 20, 2022 5:27:40 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Erin D Williams <(b) (6) @mitre.org>; James T O'Neal <(b) (6) @mitre.org>
Subject: [EXTERNAL] Touching base: food support

Dear Janet,

I hope this email finds you well. I saw the recent news about your new role at FDA and am reaching out to offer the support of your Health FFRDC. Would you be able to carve out 25 minutes soon to discuss how our policy, program, and supply chain expertise might be of help in achieving your goals?

Sincerely yours,
Heather

Heather Hawley
Manager, Health Innovation
CMS Alliance to Modernize Healthcare (The Health FFRDC)
a federally funded research and development center, operated by The MITRE Corporation
(b) (6) @mitre.org | (b) (6)
MITRE is a not-for-profit organization that operates federally-funded research and development centers for the United States government.

From: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Sent: 5/23/2022 2:43:22 PM
To: Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]
Subject: Re: 21 Forward Funding

Thanks. Jw

From: Tootle, William <William.Tootle@fda.hhs.gov>
Sent: Monday, May 23, 2022 2:13:02 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Subject: RE: 21 Forward Funding

OK. We will adjust the OFPR amount accordingly.

Bill Tootle

Director, Office of Budget
Office of Finance, Budget, Acquisitions and Planning (OFBAP)
U.S. Food and Drug Administration
4041 Powder Mill Road
Beltsville, MD 20705

301-796-4579/4710 (O)
(b) (6) *(C)*

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, May 23, 2022 2:10 PM
To: Tootle, William <William.Tootle@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Subject: RE: 21 Forward Funding

$(b) (4)

Thanks

From: Tootle, William <William.Tootle@fda.hhs.gov>
Sent: Monday, May 23, 2022 2:09 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Subject: RE: 21 Forward Funding

Is the CDER requirement exactly $(b) (4) ?

Bill Tootle

Director, Office of Budget
Office of Finance, Budget, Acquisitions and Planning (OFBAP)
U.S. Food and Drug Administration
4041 Powder Mill Road
Beltsville, MD 20705

301-796-4579/4710 (O)
(b) (6) *(C)*

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, May 23, 2022 2:04 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>
Subject: RE: 21 Forward Funding

OK, so $(b) (4) for this.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 23, 2022 2:02 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>
Subject: Re: 21 Forward Funding

They can probably negotiate Palantir down. Jw

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:59:49 PM
To: Tyler, James <James.Tyler@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>
Subject: RE: 21 Forward Funding

There is a $(b) (4) though – where is that coming from?

From: Tyler, James <James.Tyler@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:58 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>
Subject: RE: 21 Forward Funding

Ok thanks. Bill, please have DBEC give Suzanne a CAN to charge.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:51 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>
Subject: Re: 21 Forward Funding

I think we should go ahead with funding this since the timeframe is so short. We will look at the big picture later. Jw

---

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, May 23, 2022 12:01:26 PM

To: Tyler, James <James.Tyler@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: 21 Forward Funding

+Janet

Also just want to double check we've accounted for the money going to CDER for opioids PM from reserve. Thanks.

From: Tyler, James <James.Tyler@fda.hhs.gov>
Sent: Monday, May 23, 2022 11:59:05 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Tootle, William <William.Tootle@fda.hhs.gov>
Subject: 21 Forward Funding

Hi Julie,

OFPR (Suzanne Roosen) contacted me about getting $1M to enhance 21 forward for infant formula/foods supply chain tracking and data analytics. They want to move quickly on putting more funding on a contract vehicle that is readily available. We can use $1M of the freed up Commissioner's reserve money that was going to go toward COVID testing validation, but is no longer needed. What are your thoughts?

Jay Tyler
Chief Financial Officer
U.S Food and Drug Administration

OFBAP
Office of Finance, Budget, Aquisitions, and Planning

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/19/2022 8:16:59 AM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: RE: Infant Formula - Media Round Up

Thx jw

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Friday, February 18, 2022 8:37 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: Infant Formula - Media Round Up

Privileged & Confidential

FYI – in case you haven't seen it, Media Round Up below provided by OMA. Most of the media coverage today covered FDA Key Messages. Two outlets, WSJ and Politico, asked questions related to timeline of FDA's response. See politico story below.

FDA learned of suspected infant formula illness four months before recall **(Politico)**

A timeline of events is being developed and Reactive Q&A for related-timeline questions is under development.

Lastly, while certainly not indicative of what's happening nationally, I did visit my local grocery store tonight and found infant formula availability, in general, in decent condition. See photo below. There were clear Abbott out-of-stocks, but some Abbott products remained on shelf and, when lots on shelf were checked, they were correctly of lots unaffected by the recall.

We'll be tracking supply chain impacts closely and advising of anything noteworthy. We'll also issue a more formal, internal OFPR Food Safety Update early tomorrow.

FY

Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good evening – Attached and pasted below is an initial media coverage report following yesterday's announcement regarding Abbott infant formula. Coverage largely included the FDA's key messages about the public warning, product recall information, the agency's ongoing investigation efforts, as well as mention of the four infant illnesses (including one death) and hospitalizations in three states – Minnesota, Texas and Ohio. While The Today Show and CNN articles note issues related to infant formula supply chain-related shortages that have been ongoing, there are currently no mentions of hoarding or shortages reported related to the Abbott infant formula recall and FDA's related advisory. The Office of Media Affairs will continue to provide updates on coverage through the weekend, particularly monitoring both for any mentions of shortages specifically spurred by the Abbott recall and related FDA advisory.

Infant Formula Recall

U.S. Media Coverage, 2/18/22

Newlinks and Articles removed to protect copyright

From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Friday, February 18, 2022 1:11 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress

<CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Thanks all,

Our updates are now live: https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022

From: Newhart, Corinne
Sent: Friday, February 18, 2022 12:12 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas

<Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

An update to our Advisory will be posted shortly to reflect the recall notice from the firm.

Final language is attached and I will provide the link once we are live.

Thanks all,
Corinne

From: Newhart, Corinne
Sent: Thursday, February 17, 2022 5:12 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James

<James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

We are now live:

Advisory: FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022) | FDA

CORE Investigation Table: https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks

The PR will be live shortly

Thanks all,
Corinne

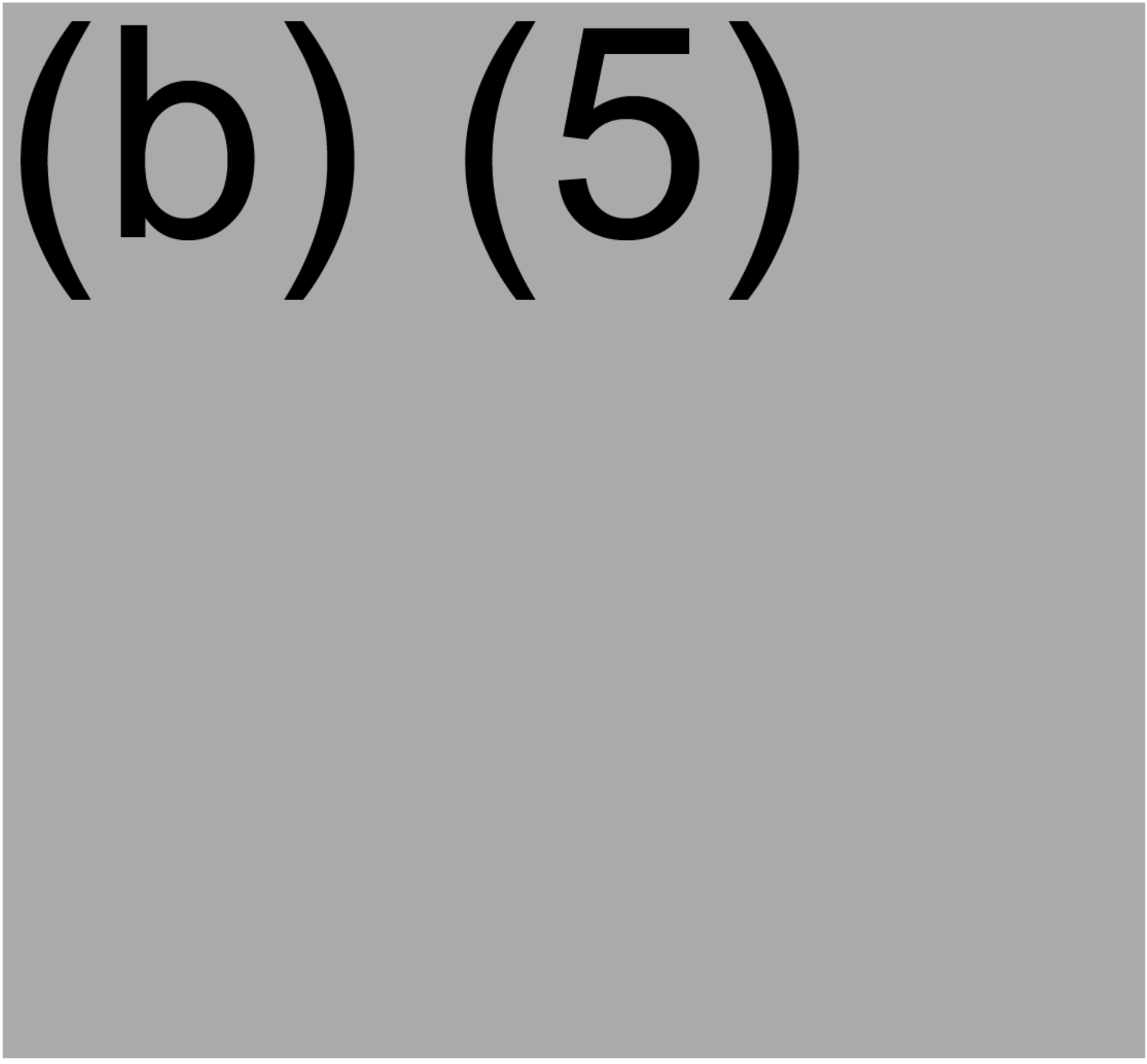
From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Thursday, February 17, 2022 4:15 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

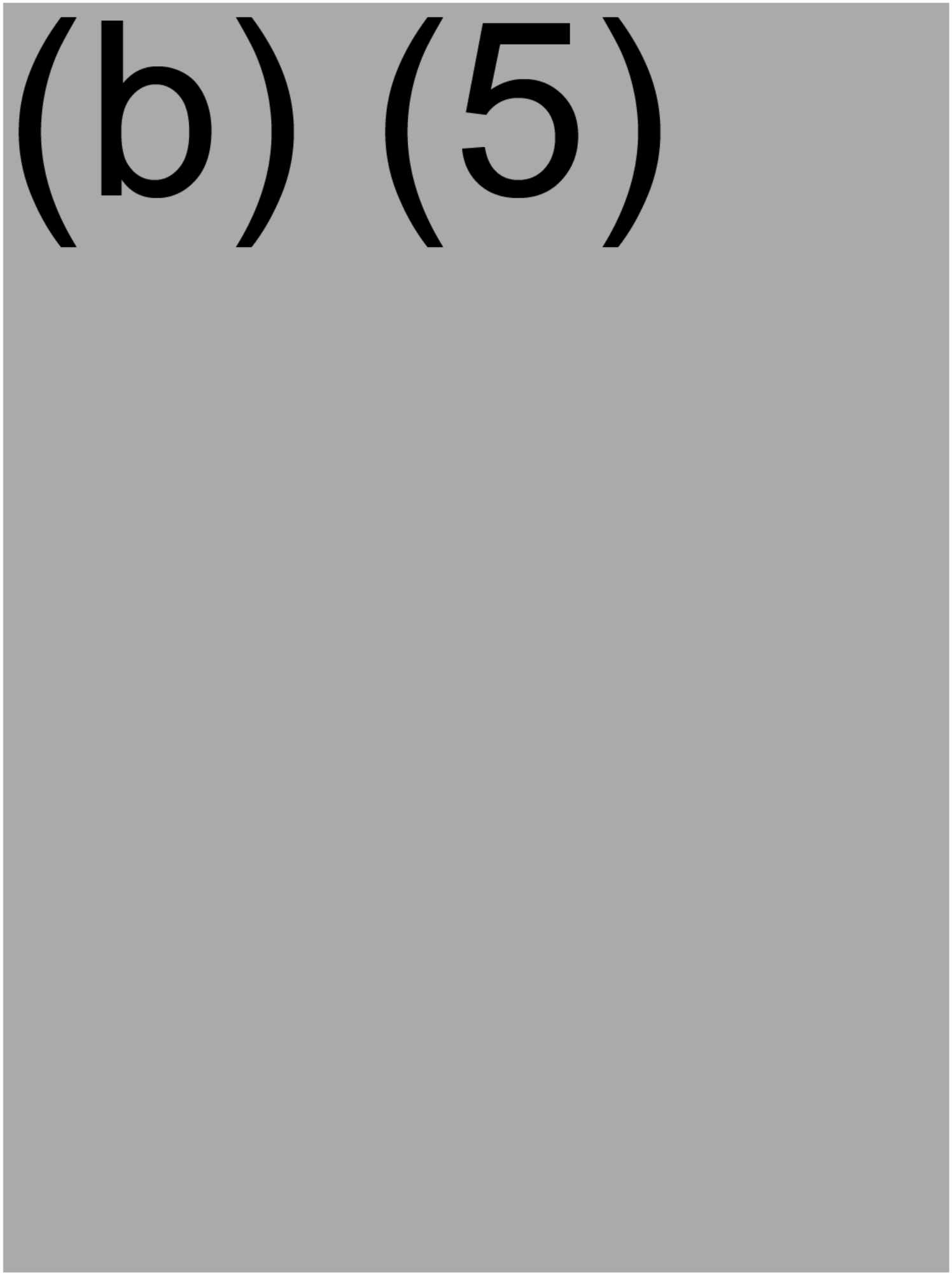
Good afternoon,

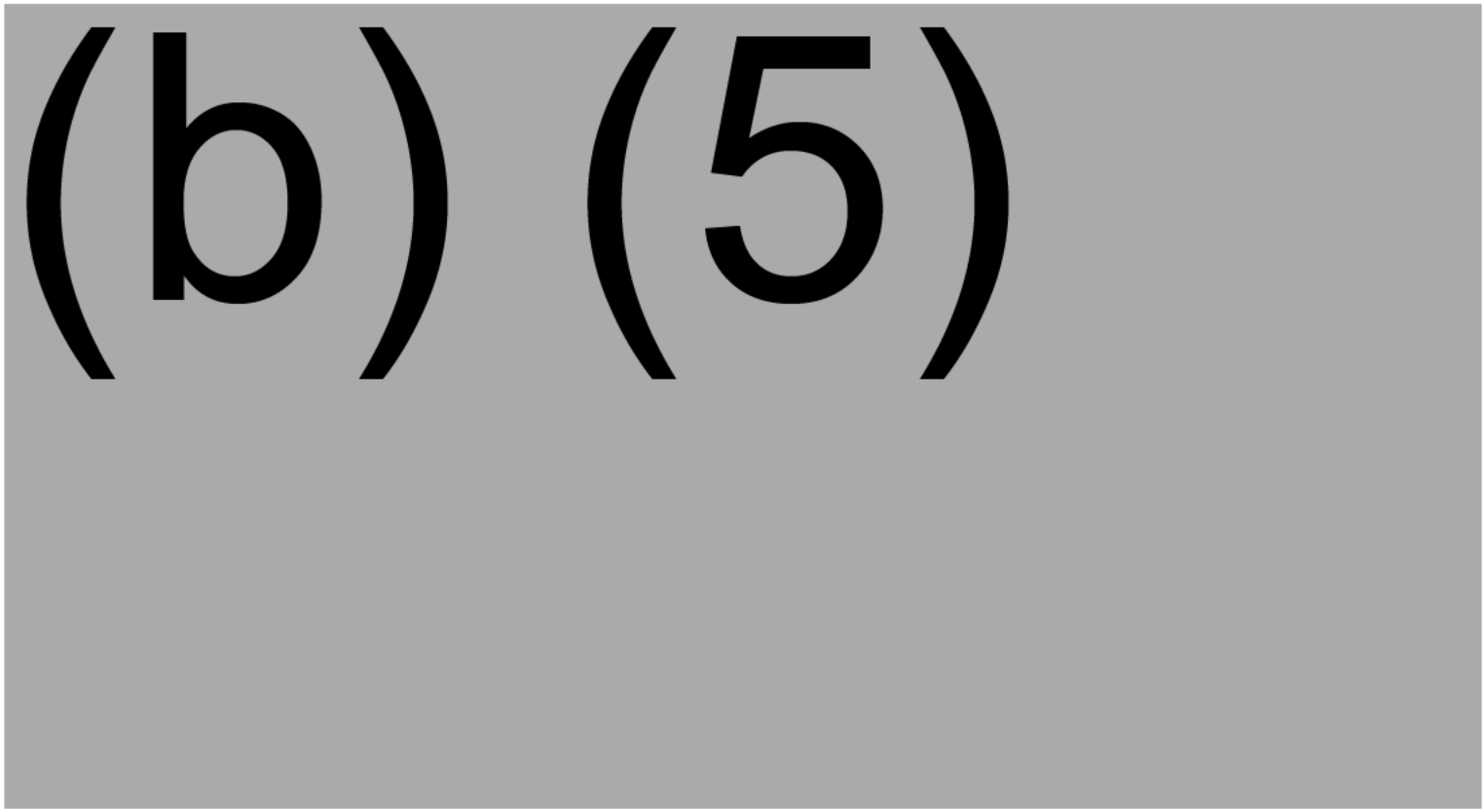
Below is our final language, we are still targeting 5pm posting. I will send the link once we are live.

FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022)

Do not use certain powdered infant formulas produced at Abbott Nutrition's Sturgis, MI facility




(b) (5)



From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Thursday, February 17, 2022 1:16 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora

<Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

Our Advisory and Press Release are now scheduled for 5pm today.

Final text will be provided in advance of posting.

Thank you all,
Corinne

From: Newhart, Corinne
Sent: Wednesday, February 16, 2022 9:03 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OO-OFBA-Congressional-Government <OO-OFBA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Cathy Abi-Khattar <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; OFVM-CFSAN-CVM-OEP <OFVM-CFSAN-CVM-OEP@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: MOVING Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

This email is to inform leadership that we will be issuing a new advisory today on the investigation of three consumer complaints of *Cronobacter sakazakaii* infections and one complaint of *Salmonella* Newport infection.

The advisory is in clearance now and we are targeting a release before COB today, to align with the addition of this investigation to the CORE Investigation Table.

Those who need to clear have or will be contacted separately.

If you have any questions or concerns, please let me know. I will share final language with this group in advance of posting and the link once we are live.

Thanks all,
Corinne

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/23/2022 5:59:03 PM
To: Desai, Vid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91b722d8adf748aaa8e91f77ad37a272-Vidyut.Desa]
Subject: RE: URGENT: FW: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

Totally agree. We need people to look to you folks rather than turning to the vendors. jw

---

From: Desai, Vid <Vid.Desai@fda.hhs.gov>
Sent: Monday, May 23, 2022 5:22 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: URGENT: FW: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

Not a problem… responding to such urgent needs is a muscle I want us to develop internally.

Vendors love being our "knights in shining new tech armor". I'd like our internal Knights to be the heroes. We're getting there and I did not like the optics of us saying no to such opportunities…This may not be the best time for us to lead, but this is the type of capability we should and need to have internally…

Thanks
-Vid

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 23, 2022 4:32 PM
To: Desai, Vid <Vid.Desai@fda.hhs.gov>
Subject: RE: URGENT: FW: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

(b) (5) [redacted] Sorry for the fire drill. We need to talk more about how to get the plan for supply chain together. Lee Cohen has agreed to be a subject matter lead along with Brooke Courtney and has read the BAH report in depth and is starting to talk to the players in the Centers. Clearly the longer-term plan needs to integrate the ingested data with our firm inventory and other data sources we are building. I will try to get you more money as soon as possible. jw

---

From: Desai, Vid <Vid.Desai@fda.hhs.gov>
Sent: Monday, May 23, 2022 4:06 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: URGENT: FW: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

We can do this internally… We're getting some team members who can engage and support this… Ram may need to get a few folks from BAH to support some activities but all of this can and should be possible very quickly and at a fraction of $1M…

Let me know what else you need from us..(b) (5) [redacted]

-Vid

From: Iyer, Ram <Ram.Iyer@fda.hhs.gov>
Sent: Monday, May 23, 2022 3:37 PM
To: Desai, Vid <Vid.Desai@fda.hhs.gov>; Chaudhry, Mohammed (Sohail) <Mohammed.Chaudhry@fda.hhs.gov>; Montgomery, Joseph <Joseph.Montgomery@fda.hhs.gov>
Subject: RE: URGENT: FW: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

Hi Vid,

Sohail and I spoke a couple of times on this and I also spoke with Nathan Beck from OEMS who has been working with OFPR and Palantir (b) (5)

In the meantime, we are already mobilizing ODT team to work on this.

Thanks

Ram

Please note that I process my email considering my current work/life needs and I don't expect others to synchronize with it. Please respond at a time convenient to you.

Ram C Iyer
Office of Data, Analytics, & Research
Phone: (b) (6)
Email: ram.iyer@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Desai, Vid <Vid.Desai@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:45 PM
To: Chaudhry, Mohammed (Sohail) <Mohammed.Chaudhry@fda.hhs.gov>; Montgomery, Joseph <Joseph.Montgomery@fda.hhs.gov>; Iyer, Ram <Ram.Iyer@fda.hhs.gov>
Subject: URGENT: FW: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

Ram, Sohail,

Can you two quickly discuss options and give me some concrete things we can use now…

Also, I suspect this was someone in DAS they communicated with…Can we see what we know and I am pretty sure we can do what is needed here with what we have and no need for new 21 Forward stuff…

I need a response asap given the urgency

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:39 PM
To: Desai, Vid <Vid.Desai@fda.hhs.gov>
Subject: Fwd: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

---

From: Tyler, James <James.Tyler@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:32 PM
To: Woodcock, Janet
Cc: Tootle, William; Tierney, Julia
Subject: FW: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

Here is more detail from OFPR. See below. OFPR indicates that there are other options and that they have discussed other options with ODT (last year?), but nothing that they can implement quickly and be responsive to the White House et al.

From: Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>
Sent: Monday, May 23, 2022 1:27 PM
To: Tyler, James <James.Tyler@fda.hhs.gov>
Subject: RE: Send Me A Detailed Breakout of the $1M for 21 Forward that you need
Importance: High

Thanks, Jay. Please see below.

- To address the current infant formula crisis, FDA has been monitoring the status of the infant formula supply by using the Agency's 21 Forward food supply chain continuity system, which was developed during the pandemic to provide a comprehensive, data-backed understanding of how COVID-19 is currently impacting food supply chains.

- FDA requires immediate short-term funding for the 21 Forward system to speed the analysis of incoming data and help us track the impact of efforts to increase infant formula availability, including importation efforts.

- An estimated $1 million in additional funds would support the following through the end of FY 2022:
  - anticipated 40% increase in cores and 1.85 additional FTEs for 4.25 months to support daily reporting, increased data integration, and inter-agency analyses for the formula supply chain crisis.

- This increased capacity would allow the Infant Formula IMG to automate the processing and production of the following data on a weekly and daily basis:
  - Weekly infant formula production data (in coordination with National Economics Council)
    - Production of routine and specialty formulas, by week, unit, total pounds, including extra volume coming in via Operation Fly Formula and via FDA enforcement discretion
    - Likely to also include tracking of raw material shortages
  - Sales and availability data (in-stock %) for over 500 infant formula UPCs across 50 states and US territories on weekly and daily basis
    - Current data source is IRI; Nielsen may be an additional data source needed in near-term
  - Dashboards to automate comparison of production and sales/availability data to demand and distribution data:
    - US births by state and territory
    - WIC enrollment rates
    - WIC and Medicaid data on use of amino acid-based and extensively hydrolyzed formulas
    - CDC SVI Index

- DOT data sources on trucking and distribution.

The White House has expressed the need for dashboards available to them directly, so we are working with the HHS supply chain control tower group for any lessons learned. They are trying to help as possible, but are limited by their contracts in providing additional data cores and engineering support directly to 21 Forward. Please see the list below of the analysis they are looking for from FDA on a weekly basis.

- Latest national insights:
  - Demand:
    - How have unit sales and volume sales moved since pre-recall?
    - Can we detect in data whether WIC waivers on container size have had a notable effect?
    - How has it changed for AA and EH in particular?
  - Availability:
    - How have in-stock rates changed since pre-recall for routine formula? Have they still leveled off since April? Where do we have uncertainty?
    - How has it changed for AA and EH in particular?
    - Are there any insights we can say through an equity lens? (either way, let's see if Allison Kolbe can do some SVI analysis this week?)
  - Production:
    - What qualitative / quantitative messages can we share about how production volumes nationally have changed?
- State insights:
  - Is there anything shareable w.r.t. states with particular supply concern?
- Operation Fly Formula:
  - AA and EH shipments: What can we say about amount of those shipments, and their impact on the market?

Thanks again for your help,
Suzanne

From: Tyler, James <James.Tyler@fda.hhs.gov>
Sent: Monday, May 23, 2022 12:35 PM
To: Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>
Subject: Send Me A Detailed Breakout of the $1M for 21 Forward that you need

Janet wants to see it. Just some bullets with some sub-breaks if you can.

Jay Tyler
Chief Financial Officer
U.S Food and Drug Administration

OFBAP
Office of Finance, Budget, Aquisitions, and Planning

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/24/2022 4:32:21 PM
To: 'Califf, Robert' [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: RE: FLAG: WaPo

Please. You are not naïve. jw

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, May 24, 2022 4:28 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: Re: FLAG: WaPo

Thank you. I agree that attacking Frank is not the right approach. Just the facts—I'm sure he was blowing off steam and not knowing who he was talking to.

rmc

From: Erica Jefferson <Erica.Jefferson@fda.hhs.gov>
Date: Tuesday, May 24, 2022 at 4:26 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, Kimberlee Trzeciak <Kimberlee.Trzeciak@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Mark Raza <Mark.Raza@fda.hhs.gov>
Subject: Re: FLAG: WaPo

We are addressing:

- How Frank characterized his role. what Frank's role is.
- Addressing his comment regarding being told to "stand down" by JW.
- Clarifying that JW is not "leading" efforts to reopen Abbott. Noting the CD defines the terms.

(b) (5)
We are working on a response now and Tara will circulate to this small group for review.

Erica

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, May 24, 2022 4:20 PM
To: Jefferson, Erica; Trzeciak, Kimberlee; Woodcock, Janet; Tierney, Julia; Colonius, Tristan; Raza, Mark
Subject: Re: FLAG: WaPo

Have you told them that this is incorrect information?

rmc

From: Erica Jefferson <Erica.Jefferson@fda.hhs.gov>
Date: Tuesday, May 24, 2022 at 4:01 PM
To: Kimberlee Trzeciak <Kimberlee.Trzeciak@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Robert Califf <(b) (6) @fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Mark Raza <Mark.Raza@fda.hhs.gov>
Subject: Re: FLAG: WaPo

Editorial expected tomorrow and we have a 6 pm deadline for the news article, which we also expect to post tomorrow as well.

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Tuesday, May 24, 2022 3:59 PM
To: Woodcock, Janet; Jefferson, Erica; Califf, Robert; Tierney, Julia; Colonius, Tristan; Raza, Mark
Subject: RE: FLAG: WaPo

Do we know when this will post? If it wasn't going to be an area of inquiry tomorrow, it certainly will be after this comes out.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, May 24, 2022 3:55 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Subject: RE: FLAG: WaPo

Well it is absolutely not the case that I am "leading efforts to outline what Abbott must do to re-open the facility" as everyone on this email is well aware. Nor did I ever say "stand down" on any corrective action plan-this is simply incorrect. What I did do is intervene to get expert advice from neonatologists and peds endo to decide that the specialty formulas should not be recalled. jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Tuesday, May 24, 2022 3:49 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Subject: FLAG: WaPo

We should discuss. I will need to flag for the WH and HHS immediately, (b) (5) [redacted].

We are not, in fact all playing on the same team.

I won't be able to join the 4 p.m. as my team and I are strategizing on how to manage the fallout from this and we still need to get the update PR out today.

Erica

From: Kindy, Kimberly <Kimberly.Kindy@washpost.com>
Sent: Tuesday, May 24, 2022 3:33 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: [EXTERNAL] Deadline request for comment

Hello Michael,

In a conversation with The Washington Post on Friday, Frank Yiannas disclosed a number of details about the FDA's handling of a whistleblower complaint about the Abbott infant formula factory, and the agency's response to reports of baby deaths and hospitalizations tied to formula from the plant. Would the FDA like to comment on any of these statements by Yiannas?

- Frank Yiannas didn't learn about the October whistleblower complaint until February. Until then, he was never told of its existence nor any details about the claims it conveyed.
- When Yiannas began work on a corrective action plan for the Abbott plant in February, he was told to "stand down" – or words to that effect -- by Principal Deputy Commissioner Janet Woodcock, who is now leading efforts to outline what Abbott must do to reopen the facility.
- Yiannas continues to play no direct role in oversight of the Abbott facility.
- Neither of FDA's food policy divisions report to Yiannas, and neither does the agency's food safety inspectors.

In addition, these are direct quotes from Yiannas's conversation. Would you like to comment on these?

- "It wasn't sent to me and it wasn't shared with me internally. How does this happen?" Yiannas said, referring to the October whistleblower complaint. "There were early signals and in any safety profession you want to take those seriously to stop the domino effect. That didn't happen."
- "Why didn't we act more quickly on the complaints and the whistleblower report? Who knew what when?" Yiannas said. "Those are going to be some of the tough questions that will have to be answered"

The Post would also welcome any additional details or comments that the agency would like to share regarding Yiannas' comments. The deadline for all responses to this request are today by 6 p.m.

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/24/2022 3:56:08 PM
To: Rob Califf [(b) (6) @fda.hhs.gov]
Subject: FW: FLAG: WaPo

The below inquiry from the Post makes it crystal clear where some of the misrepresentations we have been dealing with are coming from. jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Tuesday, May 24, 2022 3:49 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Subject: FLAG: WaPo

We should discuss. I will need to flag for the WH and HHS (b) (5) .

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Erica

From: Kindy, Kimberly <Kimberly.Kindy@washpost.com>
Sent: Tuesday, May 24, 2022 3:33 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: [EXTERNAL] Deadline request for comment

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- "Why didn't we act more quickly on the complaints and the whistleblower report? Who knew what when?" Yiannas said. "Those are going to be some of the tough questions that will have to be answered"

The Post would also welcome any additional details or comments that the agency would like to share regarding Yiannas' comments. The deadline for all responses to this request are today by 6 p.m.

From: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Sent: 5/26/2022 10:04:21 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
CC: Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]
Subject: Re: Infant Formula Competition

Yes are there is a large overhead associated with the billing, disputes, procedural matters etc. jw

---

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Thursday, May 26, 2022 9:50:45 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: RE: Infant Formula Competition

This was my concern about UF/priority review. It likely won't result in real benefits soon enough and without a lot of effort pulled from elsewhere.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, May 26, 2022 9:45 AM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: Re: Infant Formula Competition

Rather small program for UF. Doubt juice would be worth the squeeze. More cost effective to put in more BA unless this was part of a larger UF program.

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Thursday, May 26, 2022 9:31:54 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: Infant Formula Competition

Hi All – As I just mentioned, NEC just scheduled a last minute meeting this morning to discuss a number of proposals from NEC on infant formula competition. I just got the attached paper and am reviewing myself. Welcome input from others.

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/25/2022 7:08:51 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: RE: Follow up: WaPo

Thanks, not too bad. jw

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, May 25, 2022 6:02 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: RE: Follow up: WaPo

Flagging the WaPo editorial. It's unfortunately what we expected, but the headline is worse than the rest of the piece. I did get them to make one important update to have them make clear they advocate for Congress to give us the clear authority to require formula makers to let us know about potential supply problems.

The FDA must be held to account for the baby formula crisis

The baby formula debacle has taught the nation many lessons. Among the most important is how the Food and Drug Administration failed. The agency did an insufficient job inspecting and monitoring formula factories. It reacted sluggishly to a whistleblower and to reports of sick infants. And it neglected to take timely action to prevent the shortage after a major production plant closed in February.

The timeline tells the story: Last September, the FDA made its first visit to Abbott's Sturgis, Mich., baby formula plant during the pandemic and concluded the facility was not "in a clean and sanitary condition." Around then, the Minnesota Department of Health alerted the FDA to a sick infant who consumed formula from the Sturgis plant. In October, a whistleblower sent the FDA a 34-page document alleging falsifying of records and uncleanliness at the Sturgis plant. (The agency says a "failure in FDA's mailroom" prevented top officials from seeing it for months.) More reports of sick babies arrived on Dec. 1 and Jan. 11. But the FDA didn't investigate the plant again until Jan. 31, which is when it found evidence of a bacteria deadly to infants. Abbott shut down the plant and issued a voluntary recall in mid-February — five months after the initial red flags.

Four suppliers control almost all of the U.S. baby formula market. The massive drop in availability of Abbott formula quickly led to a nationwide shortage, a situation the FDA should have seen coming. But not until mid-May did the agency announce it would streamline the onerous process for importing supplies from abroad. (Formula is finally arriving from Europe with more expected from Britain in early June.)

The FDA needs an urgent overhaul of its food safety division. In an extensive Politico report last month, former acting FDA commissioner Stephen Ostroff put it bluntly: "The food program is on the back burner. To me, that's problem No. 1." FDA food investigations peaked in 2011 at 10,641 and have been falling ever since. Beefing up inspections, staffing and oversight must be a priority for FDA Commissioner Robert M. Califf, who received a blistering grilling Wednesday on Capitol Hill.

Congress must also do its part to boost funding and give the FDA clear oversight authority, including requiring companies to report potential supply problems. House Appropriations Committee Chairwoman Rosa L. DeLauro (D-

Conn.) deserves credit for flagging FDA problems, including the troubling lack of inspections, for years. The agency only has nine full-time staff who review baby formula reports. There are a handful of on-the-ground inspectors, but only one specializes in infant formula manufacturing. This is inadequate and highlights how wrong it was for 192 House Republicans to vote against giving the FDA a mere $28 million in additional funding.

Abbott is also at fault. While the company likes to point out that the bacteria found at the plant did not match the exact illness the infants had, it's clear there were major problems at the Sturgis facility. Abbott leadership needs to do more than say "we're sorry." More testing at the facility is the minimum needed.

Many failures led to this crisis, and the pandemic exacerbated them. But when the FDA is not looking carefully, there are serious and deadly consequences.

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Tuesday, May 24, 2022 9:32 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: Follow up: WaPo

All,

Sharing updates regarding the forthcoming Washington Post editorial and news article. Thanks to Michael and Tara for leading the charge on these efforts.

From Michael on the editorial planned. **Not currently scheduled to run tomorrow.**

Based on what we know, the editorial will conclude that FDA "utterly failed on multiple levels" -- to initially conduct inspections, swiftly follow up on the complaints and for not doing more sooner to mitigate shortages. It will also mentioned the challenges in the foods program that were outlined in the Politico story -- division, low morale, not seen as priority. *The writer did note that she previewed their news team's story and she called it "more scathing."*

The editorial writer sent questions that were mostly fact-check type questions, which we responded to with cleared language as well as links to a number of resources. Notably, Michael and Tara flagged:

- Traceback of illness is complex, lack of reporting requirements/testing due to push-back from industry– such as the points highlighted by the NYT story
- Ultimately our job is to ensure that companies can produce safe product – Abbott had numerous violations, contamination that needs to be addressed – we couldn't just let contaminated product continue to be sold
- FDA has been working throughout the pandemic and before the recall to mitigate shortages
- It is a consolidated market and that's a private industry decision on whether to make infant formula, as well as whether foreign companies want to import product here
- We lack the authorities (which we are currently seeking) to require manufacturers of infant formulas or essential medical foods to notify FDA when they become aware of a circumstance that could lead to a shortage of these products;

From Tara on the news coverage planned. **Timing unknown, but could occur as soon as tomorrow (pre or post hearing).**

In addition to the context I shared earlier and the planned response, the news reporter has indicated that they are finishing a piece that is fairly narrowly focused on the chronology that got us here, namely the roles of FDA and Abbott. We inquired as to whether other factors like market share and authorities we do/don't have from Congress with regard to supply and testing will be included in the story, but so far, the reporter has indicated that these are not areas of interested for the article.

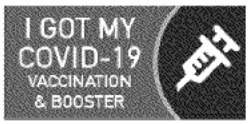
We do know that tomorrow, the news desk will be covering the two hearings and has expressed interest in doing a story about precisely where the formula from Zurich going to Indiana will ultimately end up.

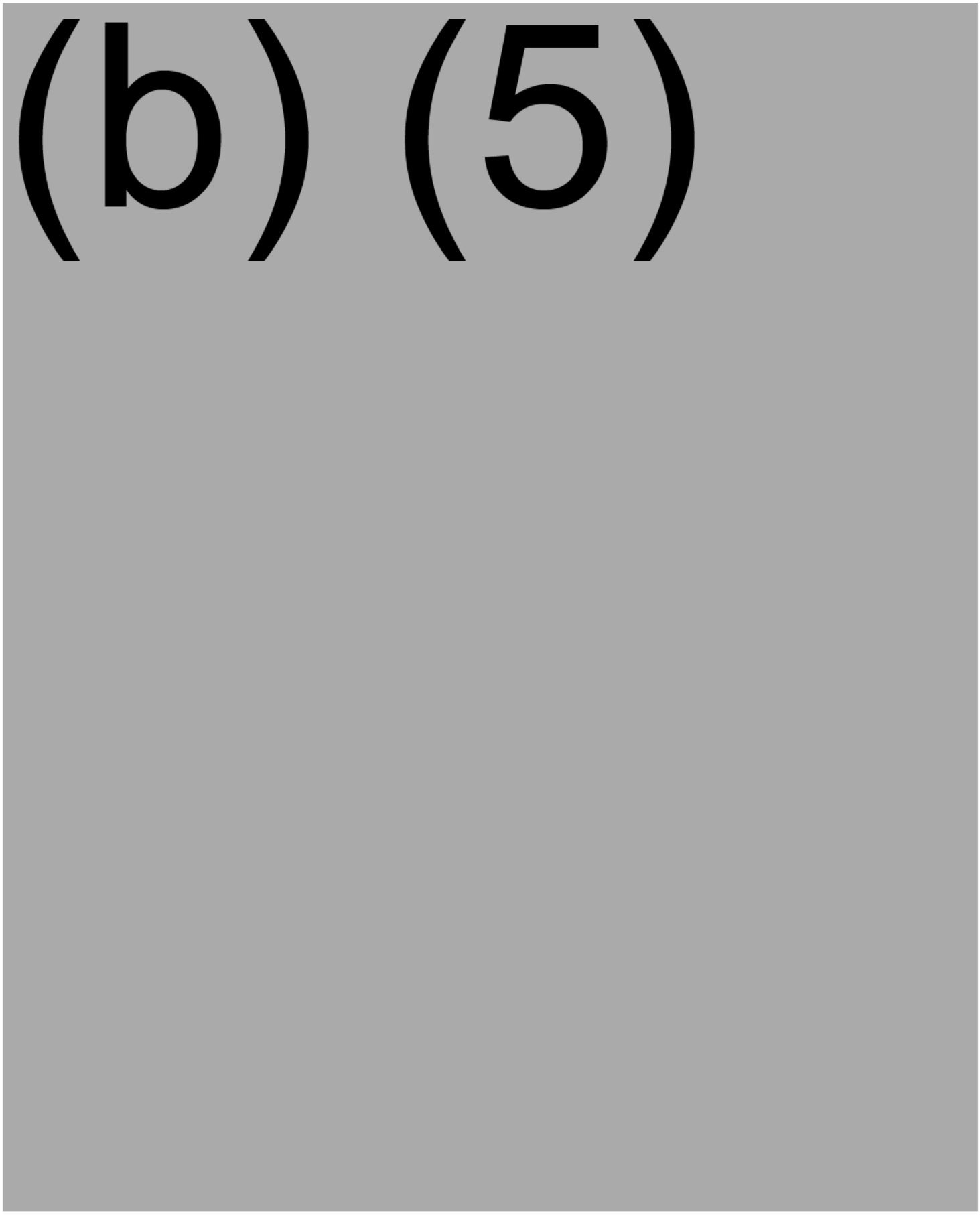
We will keep you updated as we learn more about timing and of course share the articles and editorial.

Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov

Executive Assistant: Kristen.Tugwell@fda.hhs.gov (temporary)




(b) (5)

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From: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Sent: 2/20/2022 12:25:19 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Dickinson, Elizabeth (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05cb143d66ed470ebe4dba5c54a88074-EDickins]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: Re: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Thanks. I'm in the loop. Jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, February 20, 2022 11:57:19 AM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Dickinson, Elizabeth (FDA) <Elizabeth.Dickinson@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: Fwd: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

FYI

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Sunday, February 20, 2022 9:22 AM
To: Newhart, Corinne; Yiannas, Frank; Goldman, David; Farrar, Jeff A.; Prater, Donald; Mayne, Susan; Stearn, Douglas; Boon, Caitlin; Musser, Steven M; Dooren, Jennifer; Ramos, Melissa *; Smith-Dulley, Jasmine *; Jefferson, Erica; Felberbaum, Michael; Pfaeffle, Veronika; Rhodes, Courtney
Cc: Morris, Larry; Summers, Tracy S; Moxley, Shera; CFSAN-OCD-CPES; CFSANTradepress; CFSANEXECSEC; OCA-OPLIA-Congressional-Government; Meister, Karen G; Das, Sharmi; Abi-Khattar, Cathy; CFSAN-Webmaster; Lehman, Kristen; Benton, Denise; Colonius, Tristan; Lockeed, Matthew; Goitom, Mahlet; Hattis, Daniel; Earley, Rosemary; Vera, Rita; Price, Deborah S; Iguina, Graciela; ORA Press; Norris, Gary; CFSAN OC SRT; CFSANEXECSEC; OC OCC Legal Requests-Foods Mailbox; Beckerman, Peter; Alexander, Nicholas; CORE Senior Leadership Team; CORE Communications; Tobias, Lindsay; McDermott, Catherine; Byerts, Kirsten; FDASocialMedia; OMA Foods Vet Med Team; OMA Leadership; FDASocialMedia; CORE Response Team 2; Lotze, Andrea; Assar, Carrie; Kulas, Megan; Davis, Marjorie; Klontz, Karl C; Pettengill, James; Oxenham, Ann; Hollis, Simone; Newby, Edette J; Darlington, Leonora; Smoot, Leslie; Sheehan, John; Kavanaugh, Claudine; Fox, Teresa; Jasperse, Carie; Singleton, Shannon
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Providing an update on additional media coverage since the Friday evening report. We continue to see key facts of the public advisory and recall highlighted, with occasional mentions of this warning coming amidst an ongoing infant formula supply-chain related shortage. **However, we are now started to see mentions of local recall-related supply issues.** To date, there have been four mentions of supply issues specifically related to the

Abbott recall and FDA's related advisory in local news outlets: CBS Kansas local news points out the WIC customers were affected by the recall and quotes parents who had to throw away their WIC-purchased product as a result of the recall and noted trouble exchanging the formula as advised by Abbott, NBC Connecticut local news quotes a doctor at Connecticut Children's saying the hospitals supply is affected by the recall as well as a local diaper bank, and Fox News Connecticut notes parents having a difficult time finding infant formula amid supply shortages are now also dealing with a product recall. The Office of Media Affairs is continuing to closely monitor both for mentions on traditional and social media. Notable new media coverage:

- NBC nightly news ran a segment, "Nationwide baby formula recall causes panic for some parents," which included aspects related to how the recall, unique formulations, and supply-chain issues are affecting consumers and their families.
- NBC Connecticut's article notes recall-related supply issues at a local hospital. "According to Dr. Sink, the supply of formula at Connecticut Children's is affected. They are looking for alternatives. 'We are actively working through either liquid products that are ready to feed, those are not affected, or other products that were not part of the recall,' said Dr. Sink." The article also notes that The Diaper Bank of Connecticut is affected by the FDA's warning. They have several hundred cans of powdered infant formula that will now go to waste.
- FOX 61 Connecticut says parents having a difficult time finding infant formula amid supply shortages are now also dealing with a product recall.
- ABC Wichita, Kansas (KAKE)'s points out that many parents get their formula under the WIC program and all their stock was impacted by the recall. The recall affects Similac, Alimentum and EleCare products with an expiration date of April 1, 2022 or later. Kenny Geiger gets Similac formula for his son through the Women, Infant and Children, or WIC, program. "'There's a lot of people that, you know, get all their cans on WIC, and all of their cans were recalled,' Geiger said. Geiger said it was a close call when he and his wife found out about the recall. 'We had to dump out...cause we make our pitchers the night before for the whole next day...so we had to dump that whole thing out,' he said. Only three of his cans were a part of the recall. He said he feels lucky that he has enough product to get by for now, but he knows that's not the case for others. 'There's a lot of people who get it on WIC and a lot of people that can't afford to just go around and buy one, two, three, five more cans of formula to get through the month'...' Geiger said he has also had a hard time exchanging the formula. However, according to Abbott, the manufacturer's, website, you can apply for a refund or replacement online by clicking here.'"
- Pittsburgh Action News 4 discussed a local infant who is hospitalized this week after using the recalled infant formula. "Edward Savka's 10-month-old daughter is being treated at UPMC Children's Hospital. Savka said he's concerned she got sick from a baby formula that is now on recall. Savka showed Pittsburgh's Action News 4 the bottle of Similac powdered baby formula that he and his wife opened Wednesday evening to give their daughter. A few hours after that, Savka said the family was at UPMC Children's Hospital. He said his daughter had a fever, a seizure and other symptoms."
- The New York Times highlighted that the recall, which comes during a drastic baby food shortage, affects certain lots of Similac, Alimentum and EleCare with expiration dates of April 1, 2022, or later. Products affected by the recall will also have a long sequence of numbers on the bottom of the container that starts with the first two digits 22 through 37, and contains K8, SH or Z2.

U.S. Media Coverage Update, 2/20/22

Nationwide baby formula recall causes panic for some parents

Date: Published, February 18, 2022

NBC nightly news included aspects related to how the recall, unique formulations, and supply-chain issues are affecting consumers and their families.

# # #

FDA Issues Warning Against Using Certain Powdered Baby Formulas

The Diaper Bank of Connecticut is affected by the FDA's warning. They have several hundred cans of powdered infant formula that will now go to waste.

By: Siobhan McGirl
Date: February 18, 2022
NBC Connecticut

Newslink and articles removed to protect copyright concerns

FDA warns against using certain powdered baby formulas, Pittsburgh family says their child is now sick

"She had all the symptoms of food poisoning. Severe diarrhea, obviously they're checking for COVID, can't rule that factor out but I don't think it's COVID," Edward Savka said.

By: Staff
Date: February 18, 2022
Pittsburgh Action News 4

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

Some Wichita parents worried and frustrated about baby formula after nationwide recall

By: Maeve Ashbrook

Date: February 19, 2022

ABC Wichita, Kansas (KAKE)

Some Wichita parents are worried after a nationwide recall of powdered baby formula.

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

Formula recall adds stress for Conn. parents already dealing with shortages

Three popular infant formulas have been recalled, which may further impact supply and demand issues that have made formulas hard to find.

By: Gaby Molina

Date: February 18, 2022

FOX 61 Connecticut

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

Recall affects Similac, Alimentum and EleCare formulas made at Abbott's Sturgis, Mich., plant; FDA is investigating complaints of four infant illnesses3 Types of Baby Formula Recalled After Reported Bacterial Infections

Abbott Nutrition issued voluntary recalls of their popular Similac, Alimentum and EleCare formulas after four infants were hospitalized with bacterial infections.

By: Isabella Grullón Paz

Date: February 18, 2022

The New York Times

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Newslink and articles removed to protect copyright concerns

Baby Formula Recalled by Abbott After Reports of Bacterial Contamination

By: Omar Abdel-Baqui

Date: February 18, 2022

The Wall Street Journal

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

FDA urgently warns against using these baby formulas made in the same Michigan plant after infant dies and three fall ill

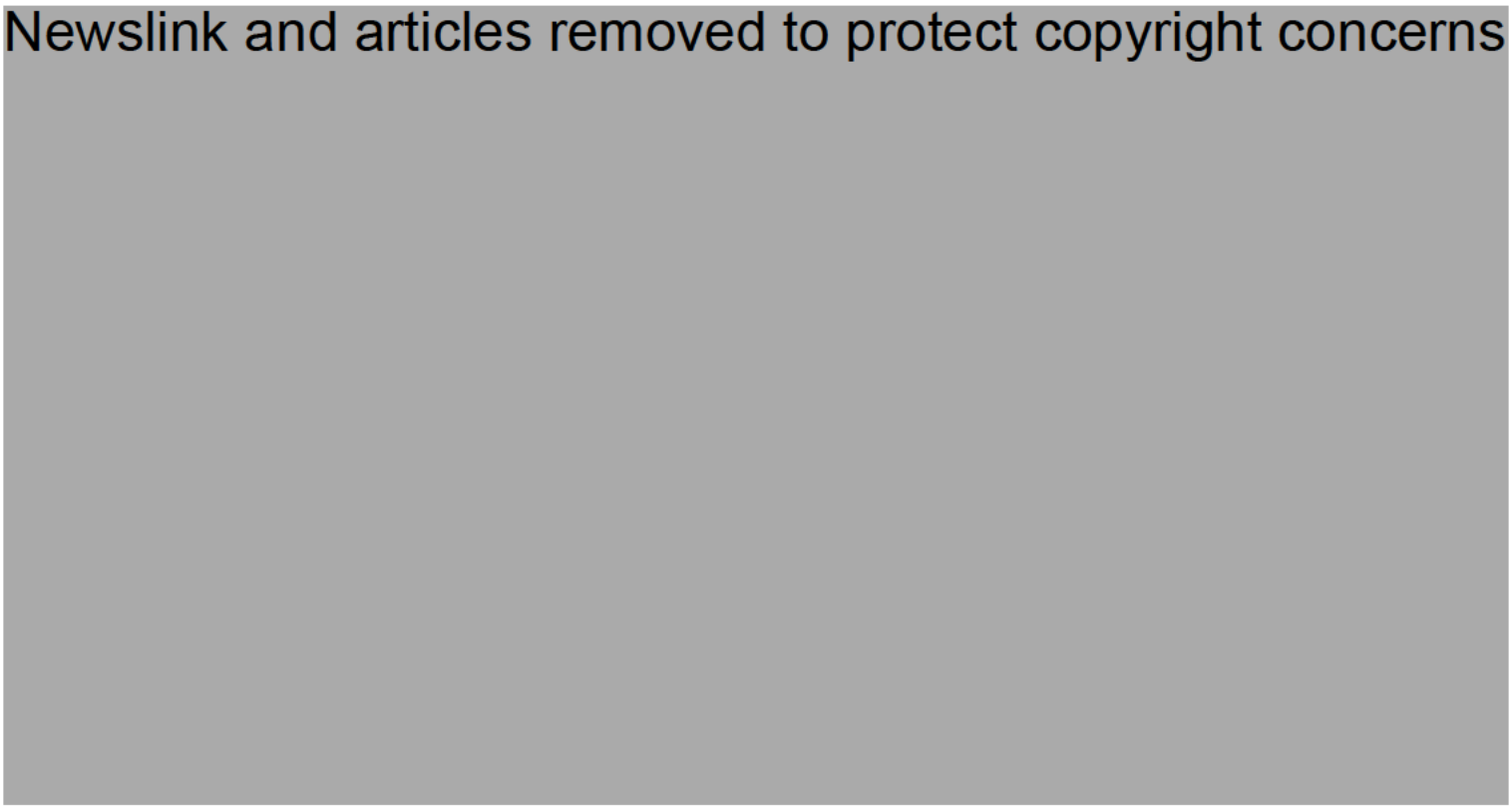
By: Andrea Cavallier for Dailymail.com and Associated Press

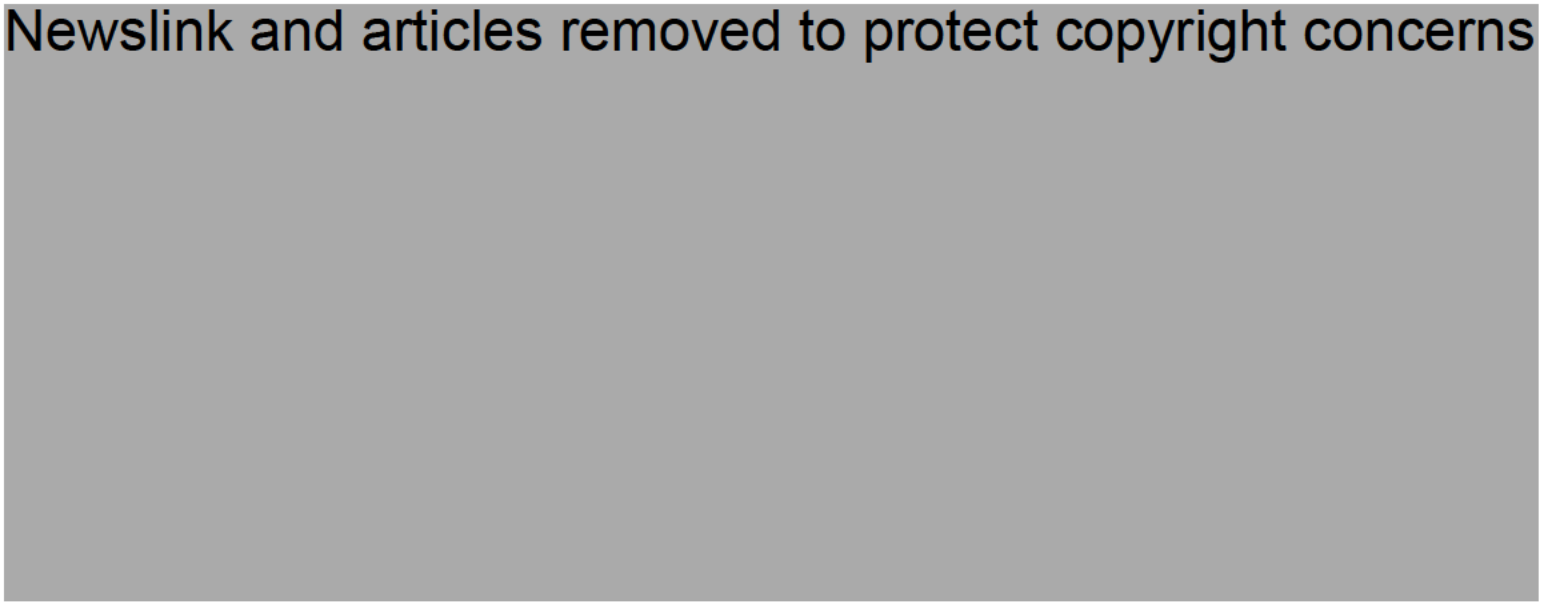
Date: Published, February 18, 2022; Updated, February 19, 2022

The Daily Mail

Newslink and articles removed to protect copyright concerns


Newslink and articles removed to protect copyright concerns


Newslink and articles removed to protect copyright concerns

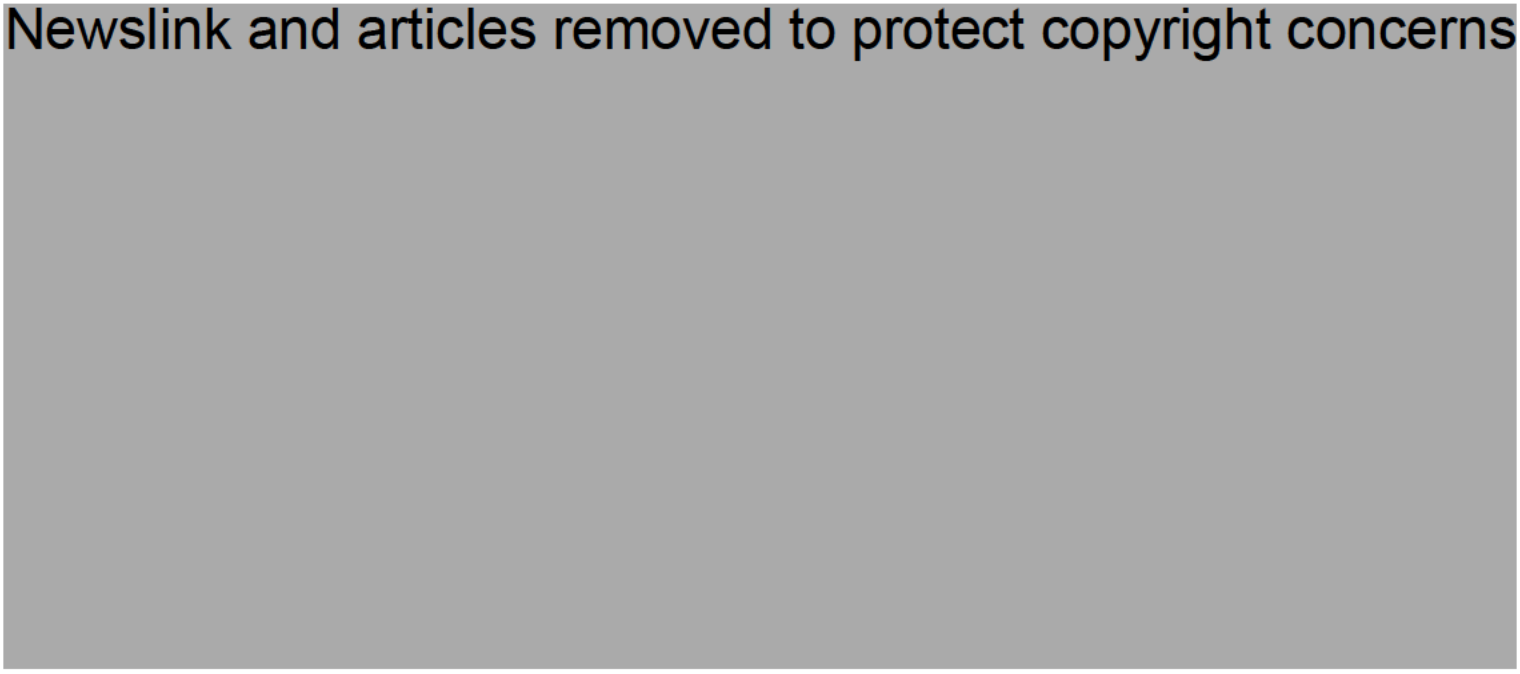


FDA investigates possible Salmonella infections from powdered infant formula

By: Douglas Jones

Date: Posted February 17, 2022; Updated February 18, 2022

WFTS Tampa Bay ABC Action News



# # #

FDA warns against using 3 powdered baby formulas linked to infections

By: Bob D'Angelo

Date: February 18, 2022

WSB-TV Atlanta 2 (Cox Media Group)

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Indiana Department of Health: FDA warns consumers not to use certain powdered infant formula
By: Staff
Date: February 19, 2022
WIMS Radio

Newslink and articles removed to protect copyright concerns

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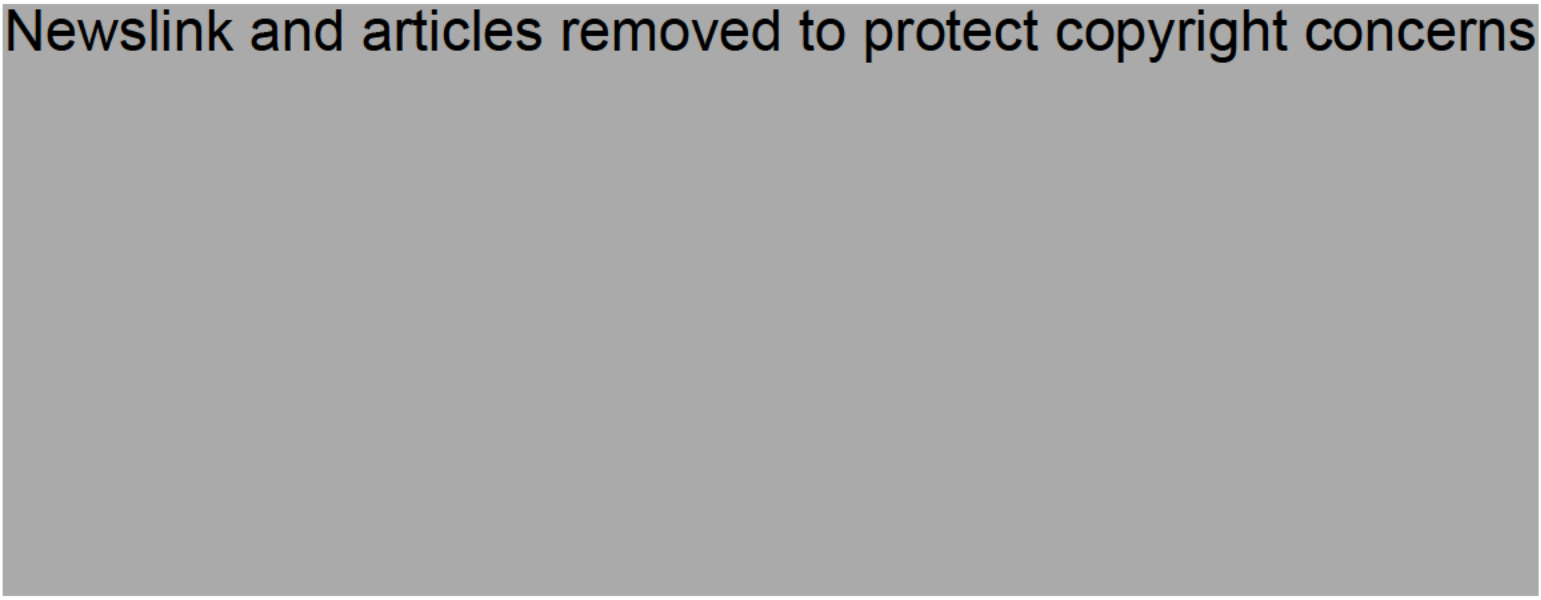
FDA warns against using certain infant formulas over Salmonella risks
By: Staff
Date: February 18, 2022
Spectrum News

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns



FDA Warns of Infant Formula Powders Tied to Infections

By: Robert Preidt

Date: February 18, 2022

InsideNova.com (Healthday News)

Newslink and articles removed to protect copyright concerns

# # #

Tara G. Rabin
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-3157 / Cell: (b) (6)
Tara.Rabin@fda.hhs.gov

From: Rabin, Tara G.
Sent: Friday, February 18, 2022 7:40 PM
To: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin

<Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pfaeffle, Veronika <Veronika.Pfaeffle@fda.hhs.gov>; Courtney Rhodes (Courtney.Rhodes@fda.hhs.gov) <Courtney.Rhodes@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good evening – Attached and pasted below is an initial media coverage report following yesterday's announcement regarding Abbott infant formula. Coverage largely included the FDA's key messages about the public warning, product recall information, the agency's ongoing investigation efforts, as well as mention of the four infant illnesses (including one death) and hospitalizations in three states – Minnesota, Texas and Ohio. While The Today Show and CNN articles note issues related to infant formula supply chain-related shortages that have been ongoing, <u>there are currently no mentions of hoarding or shortages reported related to the Abbott infant formula recall and FDA's related advisory</u>. The Office of Media Affairs will continue to provide updates on coverage through the weekend, particularly monitoring both for any mentions of shortages specifically spurred by the Abbott recall and related FDA advisory.

Infant Formula Recall

U.S. Media Coverage, 2/18/22

Contents

Media Summary

On Thursday, February 17, 2022, the FDA released a press release with a quote from Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas while the agency investigates consumer complaints of Cronobacter sakazakii and Salmonella Newport infections.

Coverage largely included the FDA's key messages about the public warning, product recall information, the agency's ongoing investigation efforts, as well as mention of the four infant illnesses (including one death) and hospitalizations in three states – Minnesota, Texas and Ohio.

While The Today Show and CNN articles note issues related to infant formula supply chain-related shortages that have been ongoing, there are currently no mentions of hoarding or shortages reported related to the Abbott infant formula recall and FDA's related advisory. Stating:

- *"The FDA warning comes amidst a baby formula shortage. Major chains like CVS, Walmart and Target are currently battling supply issues."* (The Today Show)

- *"The US is facing a shortage of baby formula.*

According to market research firm IRI, stores' infant formula inventories in mid-January were down 17% from where they were in mid-February 2020, just before the pandemic hit US shores.

The Infant Nutrition Council of America, whose members include the largest formula makers Abbott Nutrition, Reckitt Benckiser and Gerber Products Co., said earlier this month that manufacturers were working to quickly ensure availability and access to infant formulas.

In a statement, the group acknowledged reports of challenges across the supply chains, including impacts on transportation, labor and logistics.

'Members of INCA are committed to meeting the needs of families who rely on infant formula — it is their top priority,' the group said." (CNN)

Media Coverage

FDA warns about some powdered infant formula amid investigation of 4 illnesses (ABC News)
Date: February 17, 2022
Good Morning America

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

# # #

FDA warns against some baby formulas after customer complaints of contamination (NBC News)

The U.S. Food and Drug Administration is cautioning parents and caregivers after recent reports of infections and one death.

By: Ariana Brockington and Samantha Kubota

The Today Show

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Newslink and articles removed to protect copyright concerns

# # #

Abbott recalls baby formulas after four infants reportedly fall ill

By: Sophie Reardon
Date: February 18, 2022
CBS News

Newslink and articles removed to protect copyright concerns

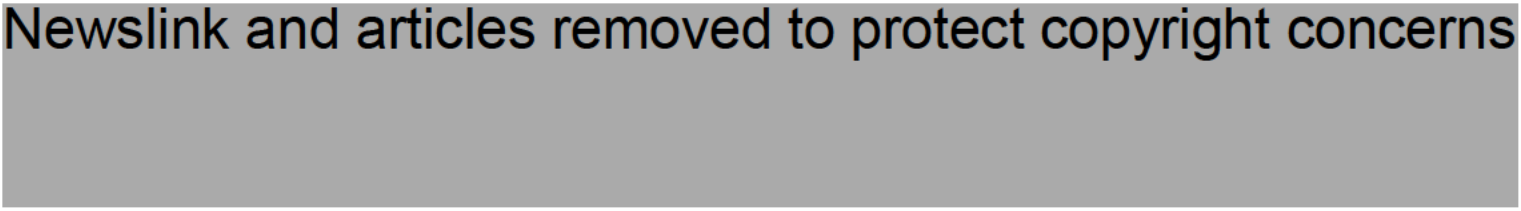
FDA says parents should avoid certain powdered baby formula after reports of 4 bacterial infections

By: Aya Elamroussi
Date: February 18, 2022
CNN

# # #

Baby formula recall 2022: FDA warns consumers not to use select Similac, Alimentum and EleCare

By: Kelly Tyko
Date: February 17, 2022
USA Today



Newslink and articles removed to protect copyright concerns

FDA urgently warns against using these baby formulas after infant dies (Associated Press)
Correspondent: By Associated Press
Date: February 18, 2022
The New York Post

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

Stop using these baby formulas, the FDA says, after 4 infants are hospitalized

By: Rina Torchinksy
Date: February 17, 2022
NPR

Newslink and articles removed to protect copyright concerns

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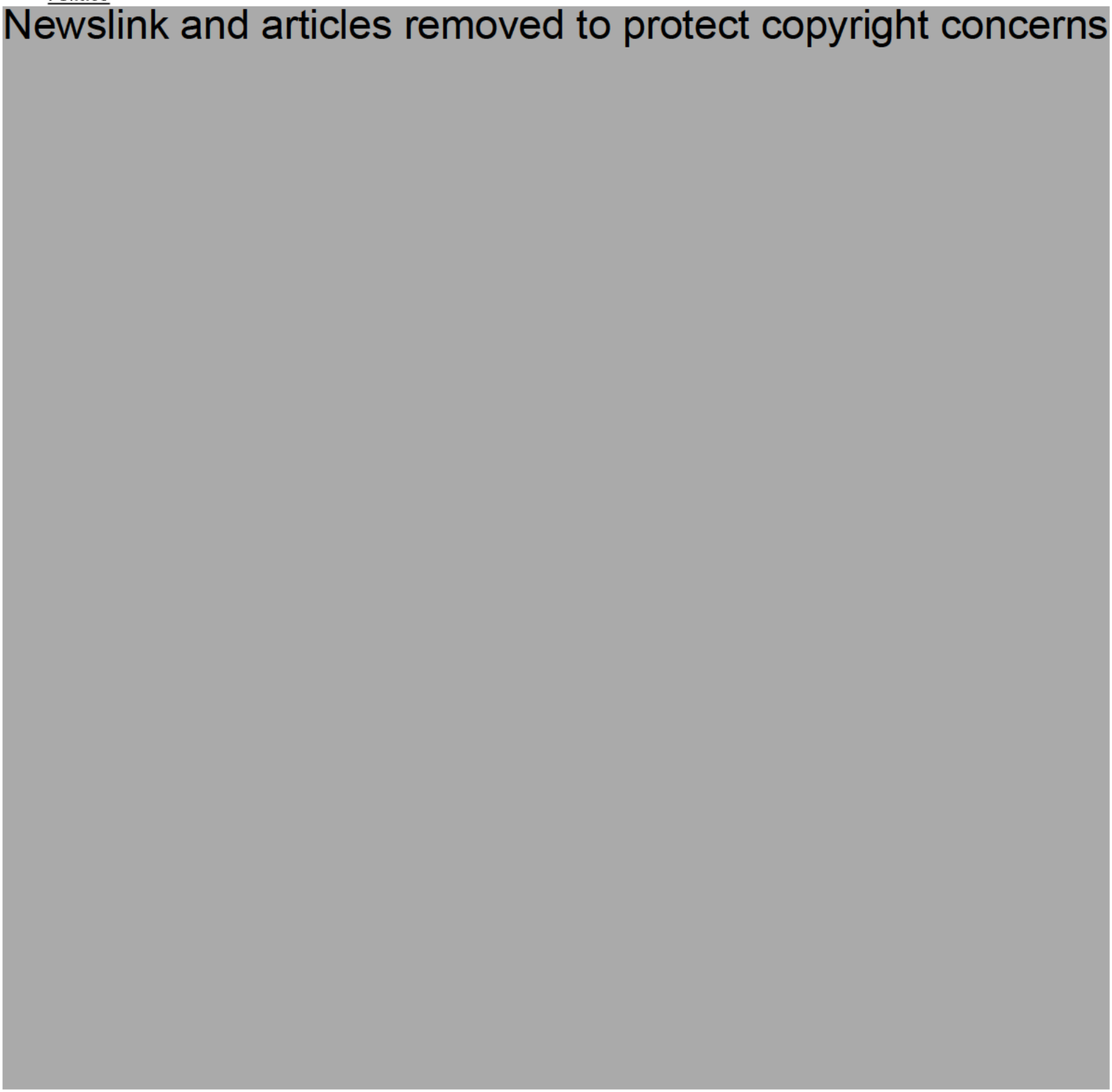
FDA learned of suspected infant formula illness four months before recall

The Minnesota Department of Health investigated a case of an infant who was sickened by Cronobacter sakazakii in September 2021, the state agency told POLITICO.

Correspondent: Helena Bottemiller Evich

Date: February 18, 2022

Politico



Newslink and articles removed to protect copyright concerns

FDA: Do not use recalled infant formulas tied to infections (Associated Press)

By: Matthew Perrone
Date: February 18, 2022
AP

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

FDA warns against using some infant formulas after hospitalizations, death (Nextar Media Wire)

By: Addy Bink
Date: February 17, 2022
News Nation

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

Three baby formulas recalled by Abbott Nutrition amid warnings from FDA

By: Olafimihan Oshin
Date: February 17, 2022
The Hill

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

FDA Warns Against Using Recalled Baby Formulas Tied To Infections

By: Associated Press and Ash-har Quraishi
Date: February 18, 2022
Newsy

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

Formula Recall: How to Check if Your Abbott Baby Formula Is Safe

If you use certain types of Similac, Alimentum or EleCare, you may need to throw them away. Here's how to see if your baby's formula is affected by the recall.

By: Alison DeNisco Rayome

Date: February 18, 2022

CNET

Newslink and articles removed to protect copyright concerns

Newslink and articles removed to protect copyright concerns

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Baby formula recall: Stop feeding infants with these products, FDA warns

By: Katherine Rodriguez

Date: February 18, 2022

NJ.com

Newslink and articles removed to protect copyright concerns

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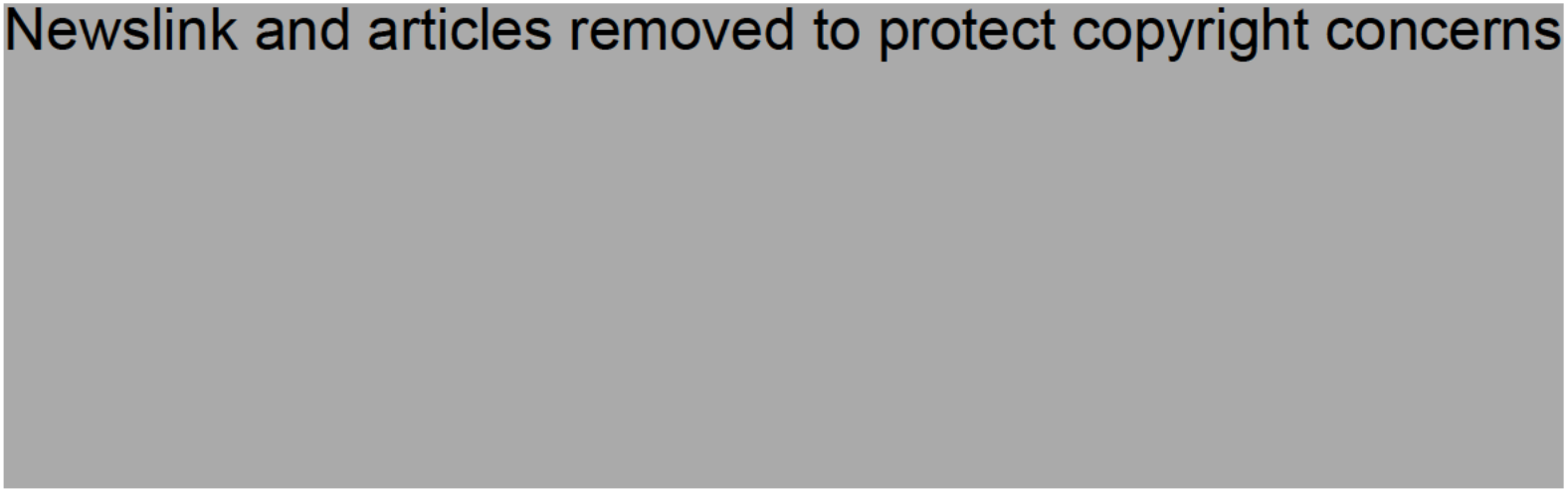
FDA Warns Parents Not To Use Some Similac, Alimentum And EleCare Powdered Infant Formula

By: CBS Boston Staff

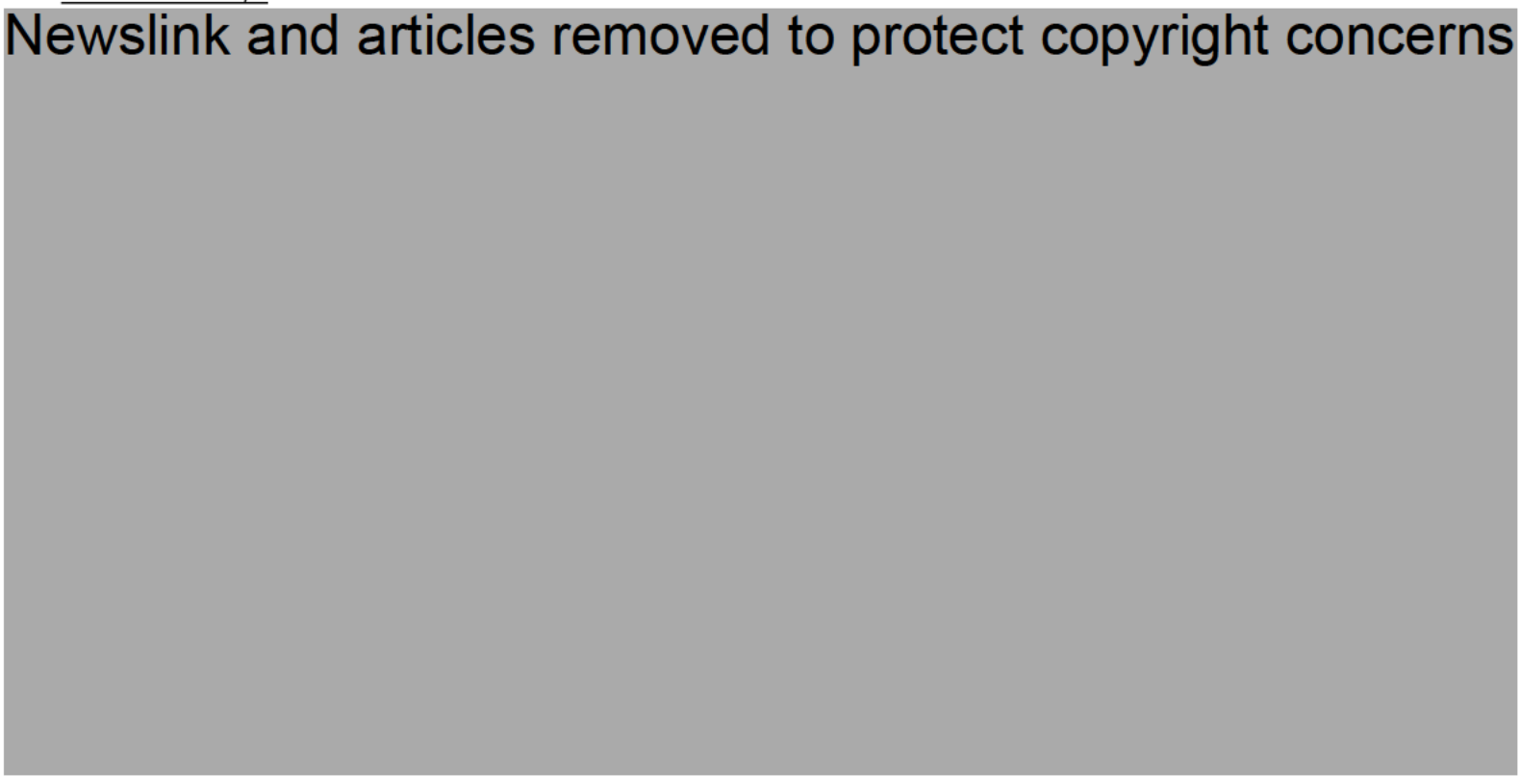
Date: February 18, 2022
CBS Boston



# # #

Recall: FDA warns parents to check labels of powder baby formula

By: News 12 Staff
Date: February 18, 2022
News 12 Brooklyn



# # #

FDA Warns Against Using Certain Powder Infant Formulas

Abbott voluntarily recalled several of its baby formula products after four infants reportedly got sick. The powder formulas were distributed across the country, and possibly exported to other countries, the Food and Drug Administration said.

By: Broadcast
Date: February 18, 2022

CBS Sacramento

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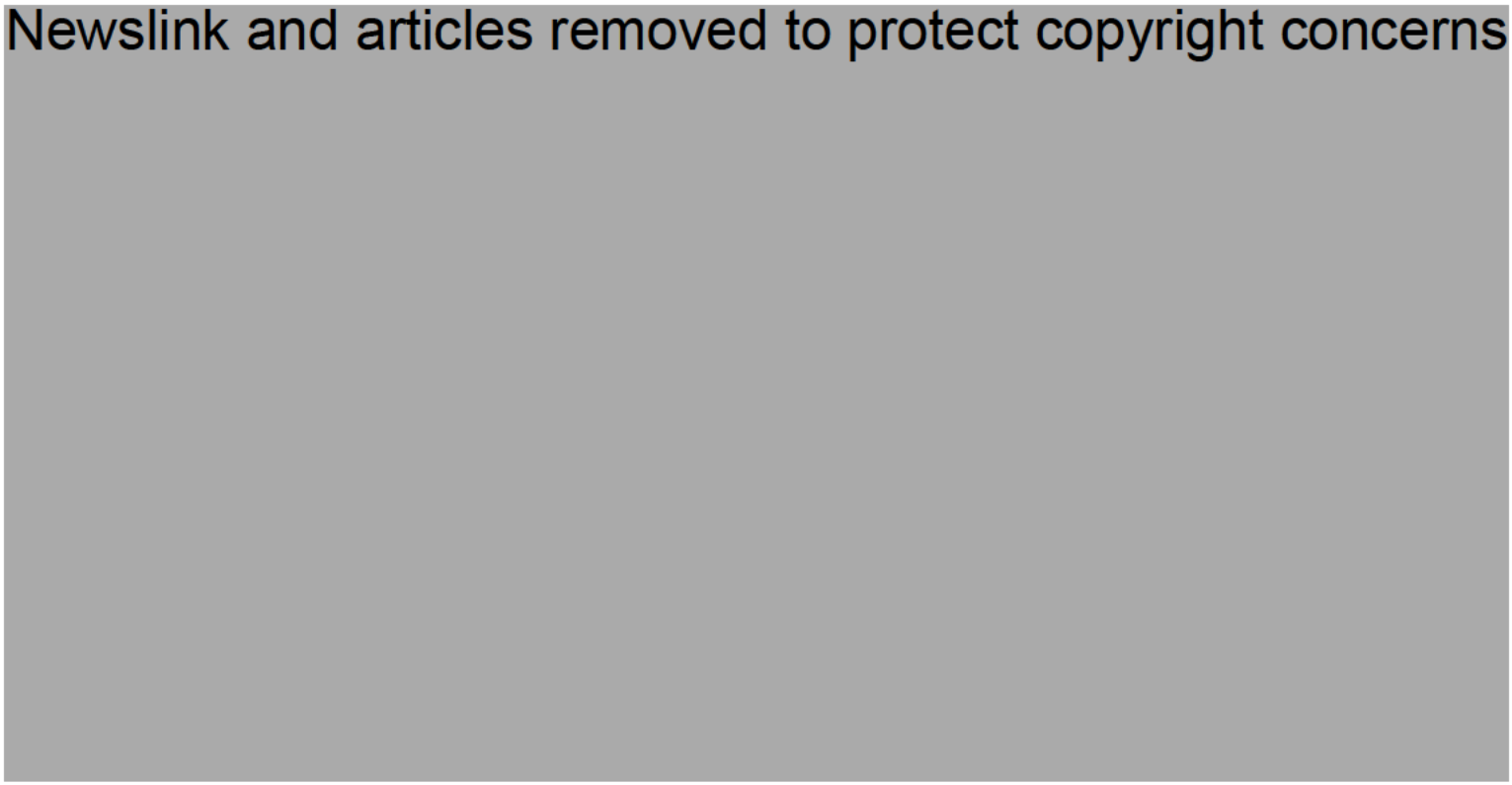
Urgent warning issued about infant formula and Cronobacter, Salmonella infections

By: News Desk
Date: February 17, 2022
Food Safety News (FSN)



From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Friday, February 18, 2022 1:11 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora

<Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Thanks all,

Our updates are now live: https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022

From: Newhart, Corinne
Sent: Friday, February 18, 2022 12:12 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

An update to our Advisory will be posted shortly to reflect the recall notice from the firm.

Final language is attached and I will provide the link once we are live.

Thanks all,
Corinne

From: Newhart, Corinne
Sent: Thursday, February 17, 2022 5:12 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

We are now live:

Advisory: FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022) | FDA

CORE Investigation Table: https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks

The PR will be live shortly

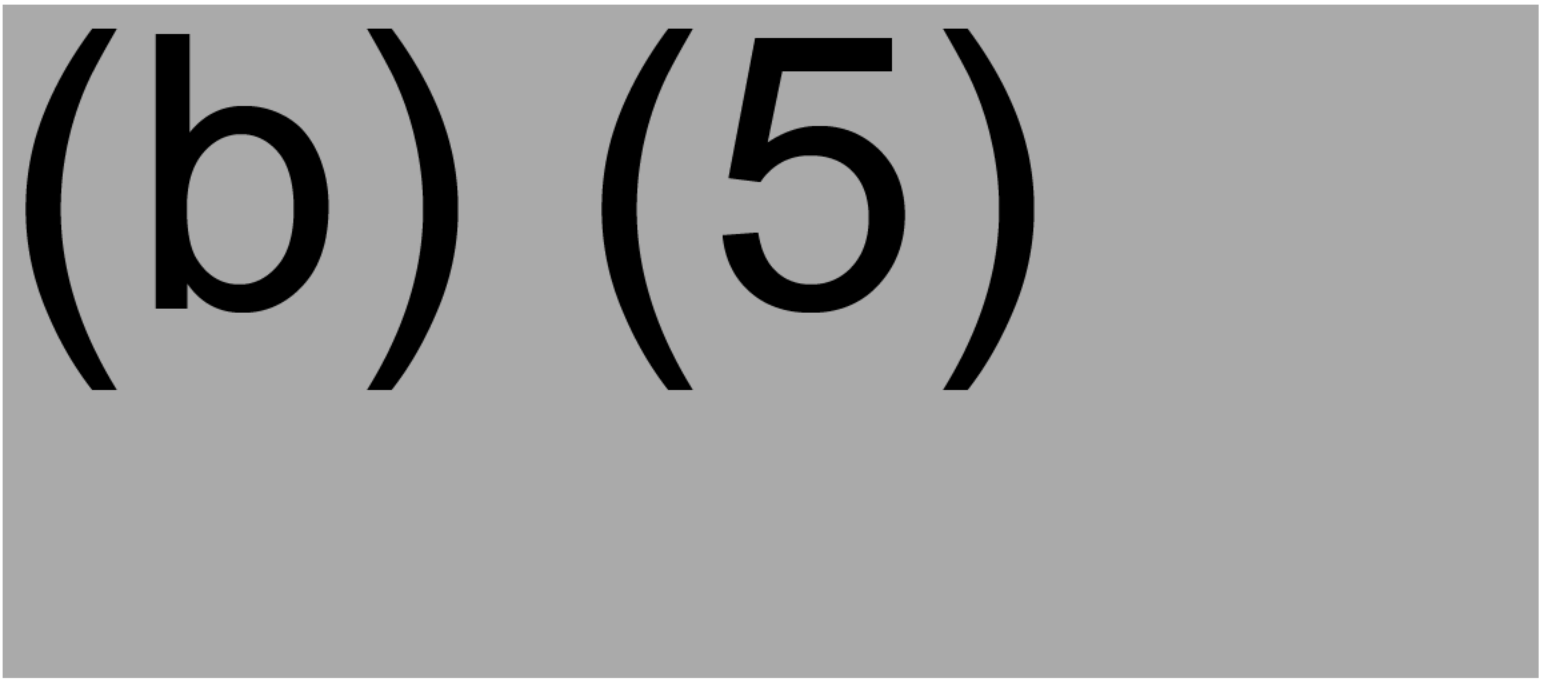
Thanks all,
Corinne

From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Thursday, February 17, 2022 4:15 PM

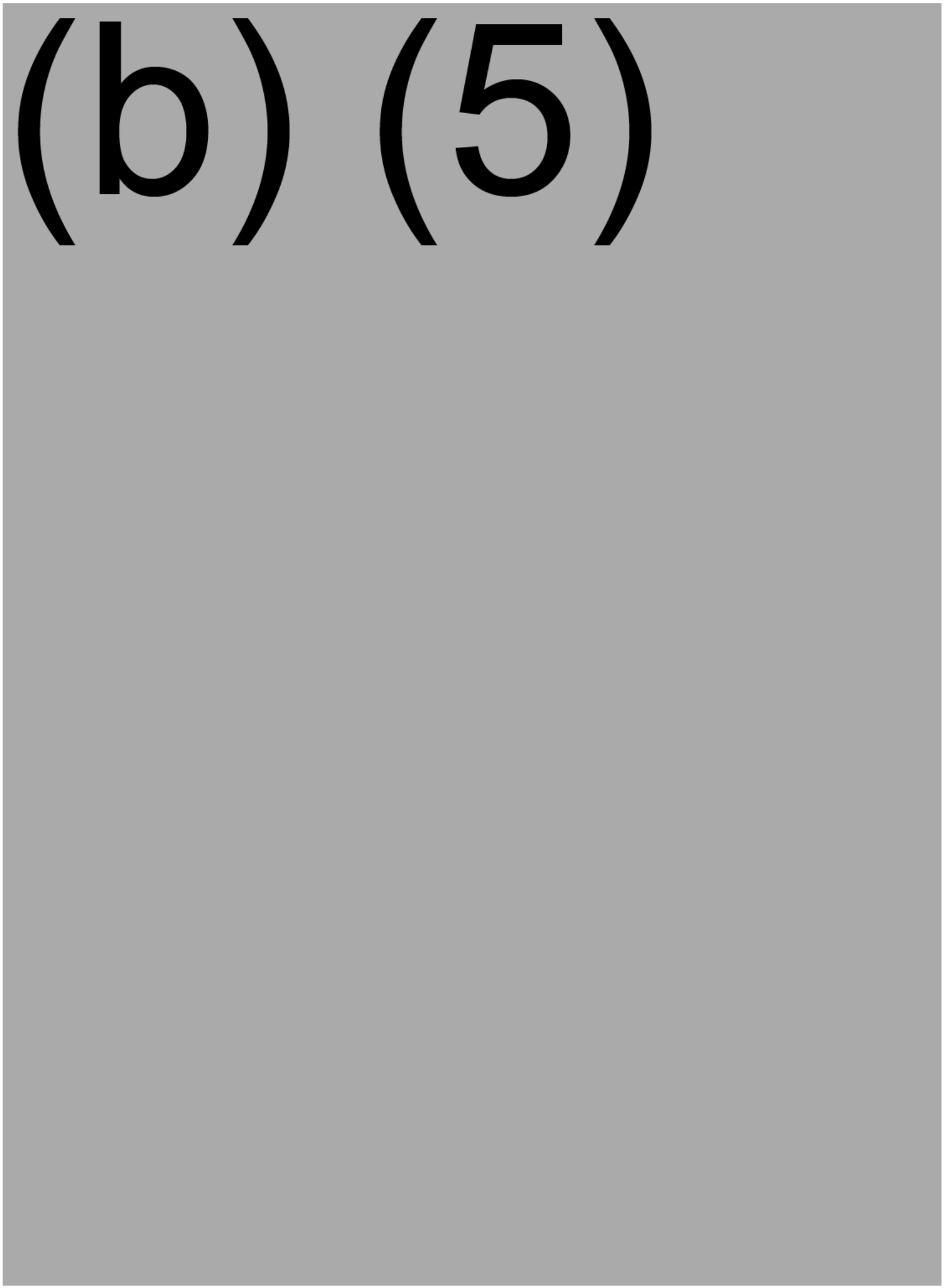
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: RE: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

Below is our final language, we are still targeting 5pm posting. I will send the link once we are live.



(b) (5)


(b) (5)

(b) (5)

From: Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Sent: Thursday, February 17, 2022 1:16 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OCA-OPLIA-Congressional-Government <OCA-OPLIA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Abi-Khattar, Cathy <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: MOVING 5pm Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

Good afternoon,

Our Advisory and Press Release are now scheduled for 5pm today.

Final text will be provided in advance of posting.

Thank you all,
Corinne

From: Newhart, Corinne
Sent: Wednesday, February 16, 2022 9:03 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Farrar, Jeff A.

<Jeff.Farrar@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Ramos, Melissa * <Melissa.Ramos@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Morris, Larry <Larry.Morris@fda.hhs.gov>; Summers, Tracy S <Tracy.Summers@fda.hhs.gov>; Moxley, Shera <Shera.Moxley@fda.hhs.gov>; CFSAN-OCD-CPES <CFSAN-OCD-CPES@fda.hhs.gov>; CFSANTradepress <CFSANTradepress@fda.hhs.gov>; CFSANEXECSEC <CFSANEXECSEC@fda.hhs.gov>; OO-OFBA-Congressional-Government <OO-OFBA-Congressional-Government@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Cathy Abi-Khattar <Cathy.Abi-Khattar@fda.hhs.gov>; CFSAN-Webmaster <CFSAN-Webmaster@fda.hhs.gov>; Lehman, Kristen <Kristen.Lehman@fda.hhs.gov>; Benton, Denise <Denise.Benton@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Lockeed, Matthew <Matthew.Lockeed@fda.hhs.gov>; Goitom, Mahlet <Mahlet.Goitom@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Vera, Rita <Rita.Vera@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>; Iguina, Graciela <Graciela.Iguina@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>; CFSAN OC SRT <CFSANOCSRT@fda.hhs.gov>; OFVM-CFSAN-CVM-OEP <OFVM-CFSAN-CVM-OEP@fda.hhs.gov>; OC OCC Legal Requests-Foods Mailbox <OCOCCLegalRequestsFoods@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; CORE Senior Leadership Team <CORESeniorLeadershipTeam@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McDermott, Catherine <Catherine.McDermott@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; OMA Foods Vet Med Team <OMAFoodsVetMedTeam@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; CORE Response Team 2 <COREResponseTeam2@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Davis, Marjorie <Marjorie.Davis@fda.hhs.gov>; Klontz, Karl C <Karl.Klontz@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Hollis, Simone <Simone.Hollis@fda.hhs.gov>; Newby, Edette J <Edette.Newby@fda.hhs.gov>; Darlington, Leonora <Leonora.Darlington@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Sheehan, John <John.Sheehan@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Fox, Teresa <Teresa.Fox@fda.hhs.gov>; Jasperse, Carie <Carie.Jasperse@fda.hhs.gov>
Subject: MOVING Today: New Advisory: Cronobacter/Salmonella - Powdered Infant Formula

This email is to inform leadership that we will be issuing a new advisory today on the investigation of three consumer complaints of *Cronobacter sakazakaii* infections and one complaint of *Salmonella* Newport infection.

The advisory is in clearance now and we are targeting a release before COB today, to align with the addition of this investigation to the CORE Investigation Table.

Those who need to clear have or will be contacted separately.

If you have any questions or concerns, please let me know. I will share final language with this group in advance of posting and the link once we are live.

Thanks all,
Corinne

From: Robert Rutkowski (b) (6)
Sent: 3/10/2022 2:24:29 PM
To: Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Keith Abouchar [keith.abouchar@mail.house.gov]
Subject: [EXTERNAL] Call on Abbott and FDA to clarify the scope of the infant formula recall

Janet Woodcock
Acting Commissioner
via Caitlin Pennington, Executive Assistant
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
caitlin.pennington@fda.hhs.gov, janet.woodcock@fda.hhs.gov,
FDAOMA@fda.hhs.gov

Re: Call on Abbott and FDA to clarify the scope of the infant formula recall

Dear Commissioner:

Abbott and the Food and Drug Administration should clarify which infant formula products are part of a recall from Abbott's Sturgis, Michigan facility, which is being investigated after five infant illnesses and two deaths that may have been caused by Cronobacter infection from contaminated formula.

Abbot first announced a recall covering products manufactured in the facility on February 17, 2022. That recall covered Similac, Alimentum and EleCare powdered formulas with lot codes beginning with the first two digits 22 through 37 that contained a K8, SH, or Z2, with an expiration date in April of this year or later.

On February 28, Abbott expanded the recall to include Similac PM 60/40 powdered infant formula with Lot # 27032K80 (can) and Lot #27032K800 (case), a product that confusingly appears to fall within the original recall as described on the Abbott and FDA websites. This recall was announced after an infant who had consumed formula from this lot contracted Cronobacter infection and died.

In addition, consumers have taken to social media with complaints that products that have lot codes and expiration dates within the recalled range do not appear as part of the recall when they enter information into the company's recall website, similacrecall.com.

FDA initiated an inspection of the facility in Sturgis in late January, and found Cronobacter present in environmental samples. An agency review of the firm's internal records also indicated environmental contamination with Cronobacter sakazakii and that Abbott had previously destroyed product due to the presence of Cronobacter.

Abbott and the FDA have failed to clearly communicate to consumers which products are covered by the recall and which are not.

Lastly, the latest "expansion" announcement suggests that Abbott may not have correctly identified all affected products from the facility in its original recall. Given the events of this outbreak and ongoing investigation to identify the source of the contamination, consumers deserve to know if there are any remaining products made in that facility that have not been recalled, and provided an explanation for why they are not affected by the contamination.

Abbott and the FDA to clarify the scope of the infant formula recall, including being straight with consumers about which products made in Abbott's Sturgis facility are part of the recall.

Yours sincerely,
Robert E. Rutkowski

cc:
Legislative Correspondence Team
1705 Longworth House Office Building
Washington DC 20515
Office: (202) 225-4131
Fax: (202) 225-4300
keith.abouchar@mail.house.gov

(b) (6)

From: Colonius, Tristan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2B3590C046734A2E928858BD579ED852-TRISTAN.COL]
Sent: 5/17/2022 9:59:45 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
Subject: RE: One pager

I've done a little reformatting and we can all work in this link:

(b) (5)

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, May 17, 2022 9:44 AM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>
Subject: Re: One pager

From: Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Date: Tuesday, May 17, 2022 at 9:43 AM
To: Andi Fristedt <Andi.Fristedt@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, Robert Califf <(b) (6) @fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Frank Yiannas <Frank.Yiannas@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Erica Jefferson <Erica.Jefferson@fda.hhs.gov>, Kimberlee Trzeciak <Kimberlee.Trzeciak@fda.hhs.gov>, Maren McBride <Maren.McBride@fda.hhs.gov>
Subject: RE: One pager

Thanks – give me a few minutes and I will send out a SP link in so we can edit in one place.

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 9:41 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>
Subject: RE: One pager

Added some flags on additional authorities at the highest level. More detail to come and happy to talk through any of these options.

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 8:41 AM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>
Subject: RE: One pager

A few very quick reactions from me in advance of calls we have today.

On the issue of importing from other countries – we already do some. Product is coming in from Ireland, Netherlands, etc. The supply chain has a spreadsheet showing imported product from different countries over the last two years (made to US standards). Frank – can you ask them to summarize that as text bullets for us? I don't know if the (b) (4) domestic manufacturing includes US companies that manufacture abroad (Abbott manufactures in Ireland; is that counted as domestic based on the company or outside the country based on the plant?)

Susan

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, May 17, 2022 7:43 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>
Subject: One pager

Friends,

Quite a day yesterday. I saw a team in high gear putting it all out for many days to get these key elements in place. I've tried to distill our key strategy down to one page based on what you've told me.. I realize that each element has many tactical components that will take a huge amount of work by people who are already at the max. If this is off course or there are major additional steps, please let me know, and feel free to edit.

I have seen what you are capable of doing, and its impressive.

rmc

To: mailto:(b) (6)
Subject: Urgent Need for Staff to Assist with Infant Formula Importation

Dear Senior Leaders:

I'm sure you are well aware of the infant formula shortage issue that the nation is facing. Many of us on this email chain and throughout the Agency are working urgently on this matter, including by facilitating the importation of infant formula that meets safety and nutrition standards. We currently have a critical need for assistance with CFSAN's work related to this importation guidance. They are seeking project managers or any staff with similar skills who can help organize and track requests to import under the guidance, and who can begin ASAP. This is expected to be a 60-90 day project but not necessarily full time. If there are team members who could assist with this critical matter, either on a part- or full-time basis, please contact Rebecca Buckner, Senior Science Advisor in CFSAN's Office of the Center Director, at rebecca.buckner@fda.hhs.gov.

I greatly appreciate our staff's ability to pull together in times of crisis, and to he each other.

Janet Woodcock

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/27/2022 7:37:54 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dcce89b861b673-JOS]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: Re: Availability Request - Infant Formula (IF) Weekend/Holiday Update

I

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Friday, May 27, 2022 5:50:11 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Thanks, Frank. I can made these work.

Erica

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, May 27, 2022 5:49 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Going straight to principals given the late in the day holiday Friday…

Saturday is confirmed for 1:30-2:00 PM – this time worked for all that I received responses for.

Based on the responses I've received…
Can we make 8:30-9:00 AM work on Sunday?
Can we make 2:30-3:00 PM work on Monday?

Placing holds now. If these times don't work let me know, otherwise accepting the calendar invite works!

Thank you,
frank

From: Olivarria, Frank
Sent: Friday, May 27, 2022 1:45 PM
Subject: Availability Request - Infant Formula (IF) Weekend/Holiday Update
Importance: High

Good afternoon, Happy holiday Friday (with early dismissal I hear, for those who can… 😊) -

OC/OCOS is requesting weekend and holiday syncs on IF, 30 mins Sat-Monday. Please let me which of the below offerings work for your principal, including any preferences.

Infant Formula (IF) Weekend/Holiday Update	OPTION 1	OPTION 2	OPTION 3	OPTION 4	OPTION 5	OPTION 6	OPTION 7	OPTION 8	OPTION 9
	Saturday, 5/28"				Sunday, 5/29:			Monday, 5/3	
	11:00-11:30 AM	12:00-12:30 PM	1:00-1:30 PM	1:30-2:00 PM	11:00-11:30 AM	1:30-2:00 PM	3:30-4:00 PM	10:30-11:00 AM	12:30-1:00 PM
Dr. Califf	*Preference Pending*	*Preference Pending*	*Preference Pending*	*Preference Pending*	*Preference Pending*	*Preference Pending*	*Preference Pending*	*Preference Pending*	*Preference Pending*
Julie Tierney (Frank for Susan)									
Dr. Woodcock (Jacque)									
Frank Yiannas (Larry)									
Andi Fristedt (Stephanie Fish)									
Erica Jefferson (Kristen/Lilliana?)									
Dr. Mayne (Landy for Natalie)									
Mark Raza (Deedee)									
Caitlin Boon (Melissa)									
Joshua Simms									
Judy McMeekin (Syrena)									

Thank you!
Frank

Frank A. Olivarria
Management and Program Analyst
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Tel: 240-402-9882
Frank.Olivarria@fda.hhs.gov

From: Croce, Teresa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3ABF9312C3984913BDE628D5E6FA48D1-TERESA.CROC]
Sent: 4/26/2022 5:00:55 PM
To: Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]
CC: Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]; Flowers, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9418b62ec07642d7bc53c564e008f5ce-Susan.Flowe]; Morris, Larry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591baaec2f0841a9b712b0c864bfc8f5-Larry.Morri]; Ramos, Melissa * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30d58cc38d04aa3894a8de1d0113efb-Melissa.Ram]; Delva, Landy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12acc8ed46874541a2823b6dc96c3372-Landy.Delva]

Subject: HOLD 1 of 2 - DPC Infant Formula Briefing (Joint FDA/USDA)

Start: 5/3/2022 5:00:00 PM
End: 5/3/2022 5:45:00 PM
Show Time As: Tentative

Required Attendees: Woodcock, Janet; Tierney, Julia; Colonius, Tristan; Yiannas, Frank; Boon, Caitlin; Stearn, Douglas
Optional Attendees: Thomas, Jacqueline; Flowers, Susan; Morris, Larry; Ramos, Melissa *; Delva, Landy

This is to hold the time on your calendar. If this time works for DPC, this hold will be replaced by a meeting from DPC; otherwise, I will cancel.

From: Croce, Teresa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3ABF9312C3984913BDE628D5E6FA48D1-TERESA.CROC]
Sent: 4/26/2022 5:01:01 PM
To: Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]
CC: Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]; Flowers, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9418b62ec07642d7bc53c564e008f5ce-Susan.Flowe]; Morris, Larry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591baaec2f0841a9b712b0c864bfc8f5-Larry.Morri]; Ramos, Melissa * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30d58cc38d04aa3894a8de1d0113efb-Melissa.Ram]; Delva, Landy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12acc8ed46874541a2823b6dc96c3372-Landy.Delva]

Subject: Canceled: HOLD 2 of 2 - DPC Infant Formula Briefing (Joint FDA/USDA)

Start: 5/4/2022 1:00:00 PM
End: 5/4/2022 1:45:00 PM
Show Time As: Free

Importance: High

Required Attendees: Woodcock, Janet; Tierney, Julia; Colonius, Tristan; Yiannas, Frank; Boon, Caitlin; Stearn, Douglas
Optional Attendees: Thomas, Jacqueline; Flowers, Susan; Morris, Larry; Ramos, Melissa *; Delva, Landy

This is to hold the time on your calendar. If this time works for DPC, this hold will be replaced by a meeting from DPC; otherwise, I will cancel.

From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 5/5/2022 11:01:23 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]
CC: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Hetlage, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1356d75869e43ffad945d0deb85598c-Daniel.Hetl]
Subject: Flagging, Politico on Abbott specialty/metabolic IF products

Good morning all,

Just a flag that Politico reached out to the media team yesterday for a story expected today. Helena is working on a story expected to post today regarding the FDA's recent announcement that the agency doesn't object to Abbott's release of certain specialty/metabolic products on a case-by-case basis. Helena has indicated she will be covering our announcement last week, but has also been told by Abbott that the delay is because "FDA was holding them up."

Tara worked with the program, OCC and me to provide the following response to the request.

-When did FDA first communicate to Abbott that it was OK with releasing some specialized formula w/informed consent - or in any other way? You may be aware Abbott's reps have been blaming FDA for the hold up here. I have heard mixed things - I've also heard that FDA may have put this option on the table earlier. Any clarity you can give would be much appreciated.

(b) (5)

-Is FDA considering adding other formulas to the list? I know Elecare Jr is a particularly high need right now.

(b) (5)

-Does the agency have any updates on timeline for the plant being fully operational? Is there any explanation you can provide on why the plant is still closed?

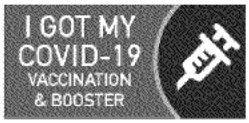
(b) (5)

Please let us know if you have any questions. We'll get the article around once it publishes.

Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov

Executive Assistant: Kristen.Tugwell@fda.hhs.gov (temporary)



From: Malais, Tanya [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F13699D67E9C491EAB11150A04F7FC6C-TANYA.MALAI]
Sent: 5/11/2022 12:24:41 PM
To: Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Yiannas, Frank; Woodcock, Janet; Tierney, Julia; Beckerman, Peter; Rabin, Tara G.; Jefferson, Erica; Boon, Caitlin; Croce, Teresa; Mark Russo; Simms, Joshua; Kavanaugh, Claudine

Subject: Infant Formula Meeting
Location: https://fda.zoomgov.com(b) (6)

Start: 5/11/2022 12:30:00 PM
End: 5/11/2022 1:30:00 PM
Show Time As: Tentative

Required Attendees: Yiannas, Frank; Woodcock, Janet; Tierney, Julia; Beckerman, Peter; Rabin, Tara G.; Jefferson, Erica; Boon, Caitlin; Croce, Teresa; Mark Russo; Simms, Joshua; Kavanaugh, Claudine

Please join a meeting at 12:30 pm on 5/11/2022 to discuss the status of the Abbott consent decree.

Hi there,

Tanya.Malais@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: +16692545252,,(b) (6) or +16692161590,,(b) (6)

Meeting URL: https://fda.zoomgov.com(b) (6)
Meeting ID: (b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.
Dial:

US: +1 669 254 5252 or +1 669 216 1590 or +1 646 828 7666 or +1 551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

International numbers

Join from an H.323/SIP room system

H.323: (b) (6) (US West)
(b) (6) (US East)

Meeting ID: (b) (6)

SIP: (b) (6)

From: Hattis, Daniel [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EEA12BDAA04F42F0AFB9DD6ABF39793A-DANIEL.HATT]
Sent: 5/12/2022 4:50:36 PM
To: Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bdaa04f42f0afb9dd6abf39793a-Daniel.Hatt]; Yiannas, Frank; Mayne, Susan; Woodcock, Janet
CC: Christin, Charlotte - OC; Pillsbury, Laura; Rogers, Michael; Colonius, Tristan; Boon, Caitlin; Klimczak, Katherine; Maren McBride

Subject: House/Senate Ag Approps Staff Briefing on Infant Formula
Location: https://fda.zoomgov.com/(b) (6)

Start: 5/16/2022 11:00:00 AM
End: 5/16/2022 12:00:00 PM
Show Time As: Tentative

Required Attendees: Yiannas, Frank; Mayne, Susan; Woodcock, Janet
Optional Attendees: Christin, Charlotte - OC; Pillsbury, Laura; Rogers, Michael; Colonius, Tristan; Boon, Caitlin; Klimczak, Katherine; Maren McBride

Hi all. This is the infant formula briefing for the House and Senate Ag Appropriations Staff. Please let us know if you have any questions. Thanks!

Hi there,

Daniel.Hattis@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: +16692545252,,(b) (6) or +16468287666,,(b) (6)

Meeting URL: https://fda.zoomgov.com/(b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 or +1 669 216 1590 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode: (b) (6)

International numbers

Join from an H.323/SIP room system

H.323: (b) (6) (US West)
(b) (6) (US East)

Meeting ID: (b) (6)

Passcode: (b) (6)

SIP: (b) (6)

Passcode: (b) (6)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 2/15/2022 9:21:29 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Romano, Lisa M. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9653957f210f4febb1c12c64207346d4-LROMANO]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Prater, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=291b4eab842148baba96df3bd8c31058-DPRATER]; Farrar, Jeff A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c862ce01b6714d4c9c5057306240469e-Jeff.Farrar]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]
Subject: Re: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

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From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, February 15, 2022 9:04:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter

<Peter.Beckerman@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Romano, Lisa M. <Lisa.Romano@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>; Farrar, Jeff A. <Jeff.Farrar@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>
Subject: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

FOOD SAFETY UPDATE

U.S. FOOD & DRUG ADMINISTRATION

From the Office of Food Policy and Response

Internal, Privileged, & Confidential

We want to provide you with a brief update on the *Cronobacter* sakazakii illnesses associated with powdered infant formula as a suspect vehicle, as this remains an evolving situation.

Epi Status

- The epi status remains unchanged from the first update.

- There remain 4 cases of infant illnesses reported to various FDA district offices between Sept 2021 to January 2022. All of the cases are reported to have consumed powdered infant formula (IF) produced in Abbott's facility in Sturgis, MI.

- Three (3) of the cases were ill due to *Cronobacter sakazakii* and one (1) due to Salmonellosis. All 4 cases were hospitalized and 1 resulted in a death attributed to *Cronobacter*.

- For more details, see attached Food Safety Update #1.

Investigation Status

- On January 31, FDA initiated an inspection at the Abbott Nutrition facility in MI in response to five consumer complaints received from September 2021 to January 2022;
  * 4 complaints relaying illnesses in infants consuming Abbott powdered infant formula and
  * one informant relaying questionable practices with the firm's manufacturing processes (OCI notified).

- On February 1, FDA initiated environmental sampling in the firms powdered infant formula manufacturing areas collecting 160 swabs; all in Zone 2. No Zone 1 samples were collected during the initial environmental investigation as the firm had not disassembled equipment such as dryers.

- To date, **4 environmental subs have been confirmed positive for C. sakazakii**. From those 4 subs, **11 isolates of C. sakazakii have been whole genome sequenced with multiple genotypes being detected**.

- As of today, there has not been a match to the limited clinical isolates available from CDC.

- An additional **14 isolates of C. sakazakii are pending WGS** and they too will be analyzed to determine if they match clinical isolates.

- Abbott independently found two positives for C. sakazakii on sister swabs taken at the same time as FDA sampling. FDA received isolates from these samples on 2/15/22 and is initiating WGS.

- The inspection is ongoing at the firm. Current initial inspection observations identified significant Good Manufacturing Practice concerns, such as cracks in dryers used for other dried infant products.

- On February 14, FDA contacted the manufacturer to relay the confirmed C. sakazakii isolates from environmental sampling at their Sturgis facility. The firm relayed they were not amenable to a recall or market withdrawal.

- Today, February 15, FDA spoke further with the firm to repeat the request for a recall of all products produced since November 2020, and to inform the firm that FDA plans to issue a consumer advisory as early as tomorrow (2/16/22). We have asked for a response on the request for recall by tomorrow (2/16) at noon EST.

- The firm continues to hold all powdered products produced between January 4 to present (the last clean in place cycle) that are still stored at the production facility.

Next Step

- FDA will issue our routine Outbreak Investigation Table on Thursday, 2/16/22. In the table, consistent with our routine practice, we will list that FDA is conducting an investigation into multiple C. sakazakii cases.

- Also, if Abbott declines to initiate a voluntary recall, FDA plans to issue a public Consumer Advisory tomorrow that warns consumers who have the Abbott brand Similac formula to avoid using products with specific lot codes and dates produced in Abbott's facility in Sturgis, Mi.

- CFSAN is also keeping the WIC Program up to date on our actions since 60% of infants in the WIC Program are using Abbott formulas and this may have implications for state WIC programs.

- FDA is also preparing a briefing paper to provide situational awareness to the White House Supply Chain Taskforce.

- FDA will return to the Sturgis facility, taking more samples including Zone 1 samples.

As usual, we will keep you updated on any noteworthy developments as the investigation continues.

Frank Yiannas

Deputy Commissioner, Food Policy & Response

U.S. Food and Drug Administration

10903 New Hampshire Ave.

Silver Spring, Maryland 20993
Tel: 301-796-4665

frank.yiannas@fda.hhs.gov

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
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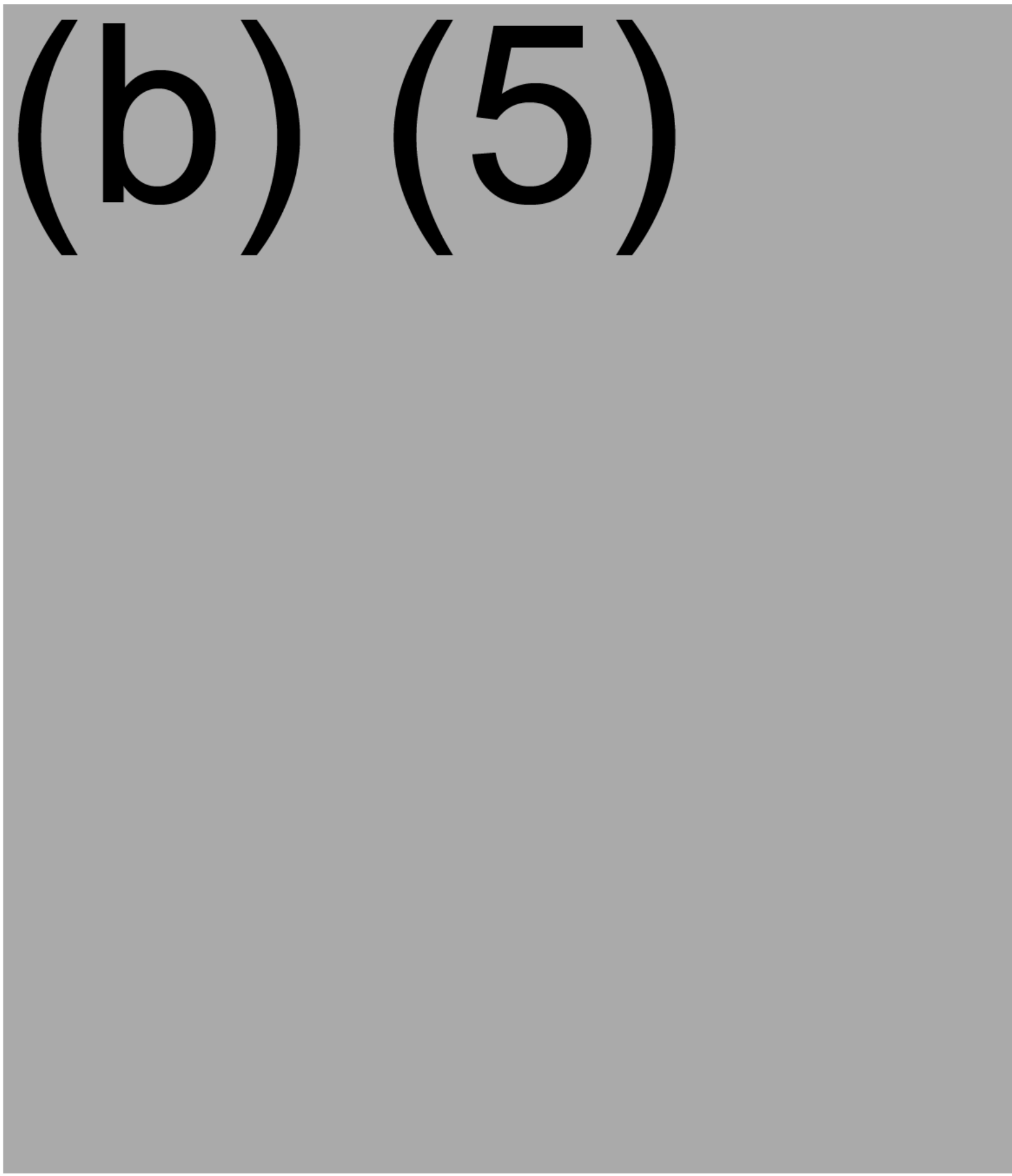
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Howard, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=905c2a2efa4c45f1b9f67cbd6fa26326-Megan.Howar]; Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Nguyen, Michael A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]
Subject: Edits
Attachments: 20220519 RMC Draft FY23 House Oral Testimony (for Commissioner Review)5.17.22[1].docx

Had to part with some of my favorite prose. See what you think about this.

rmc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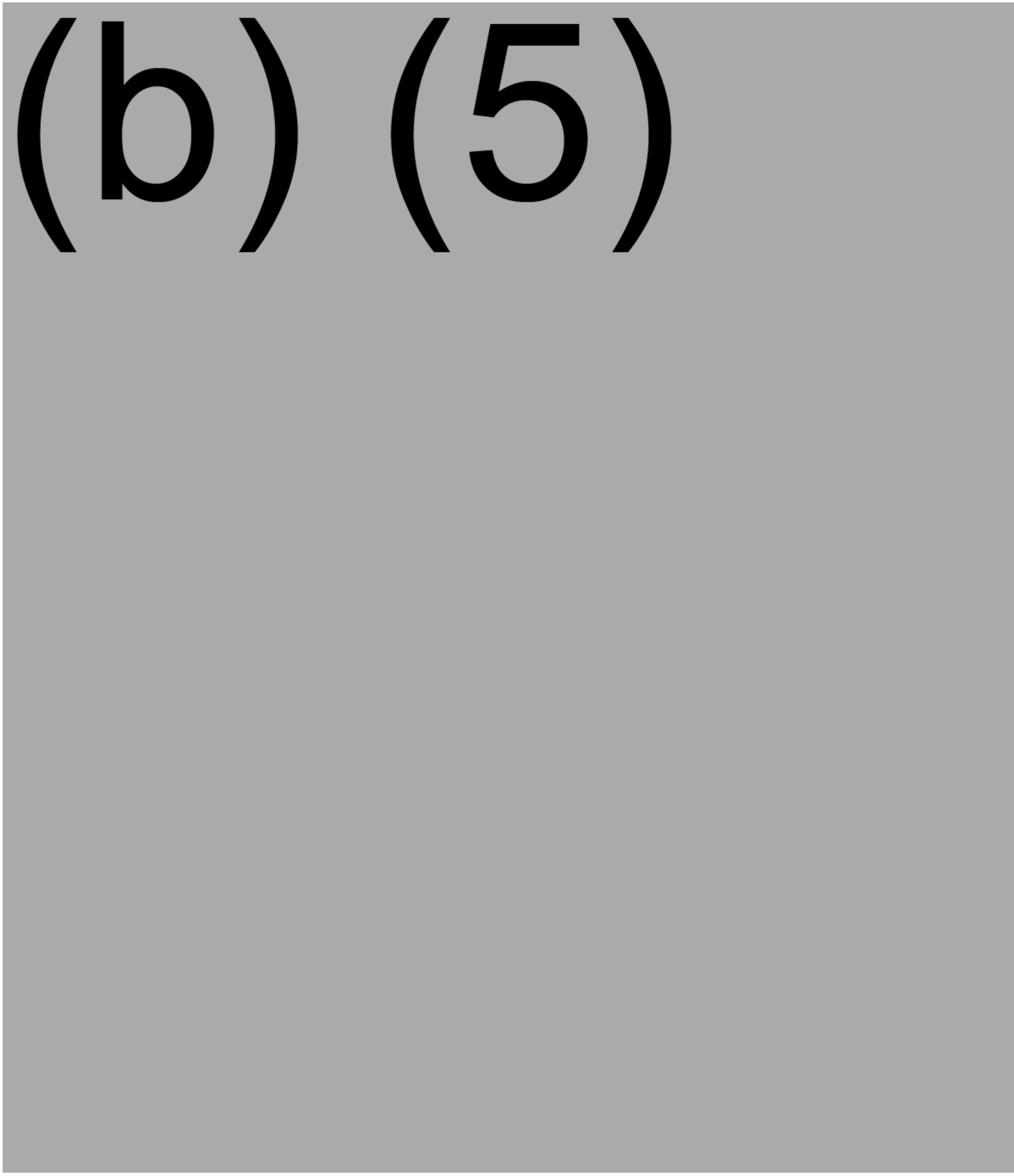
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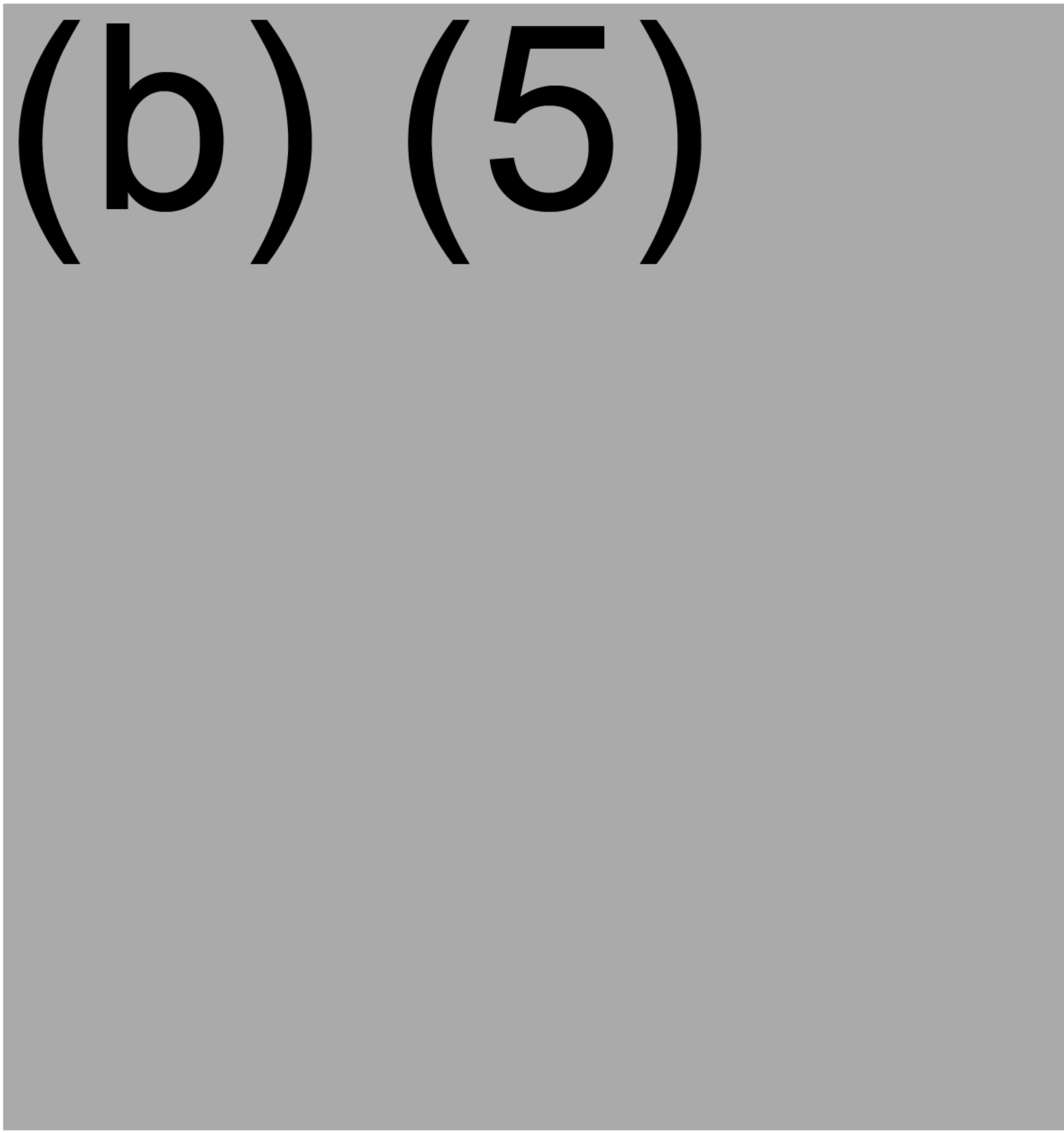
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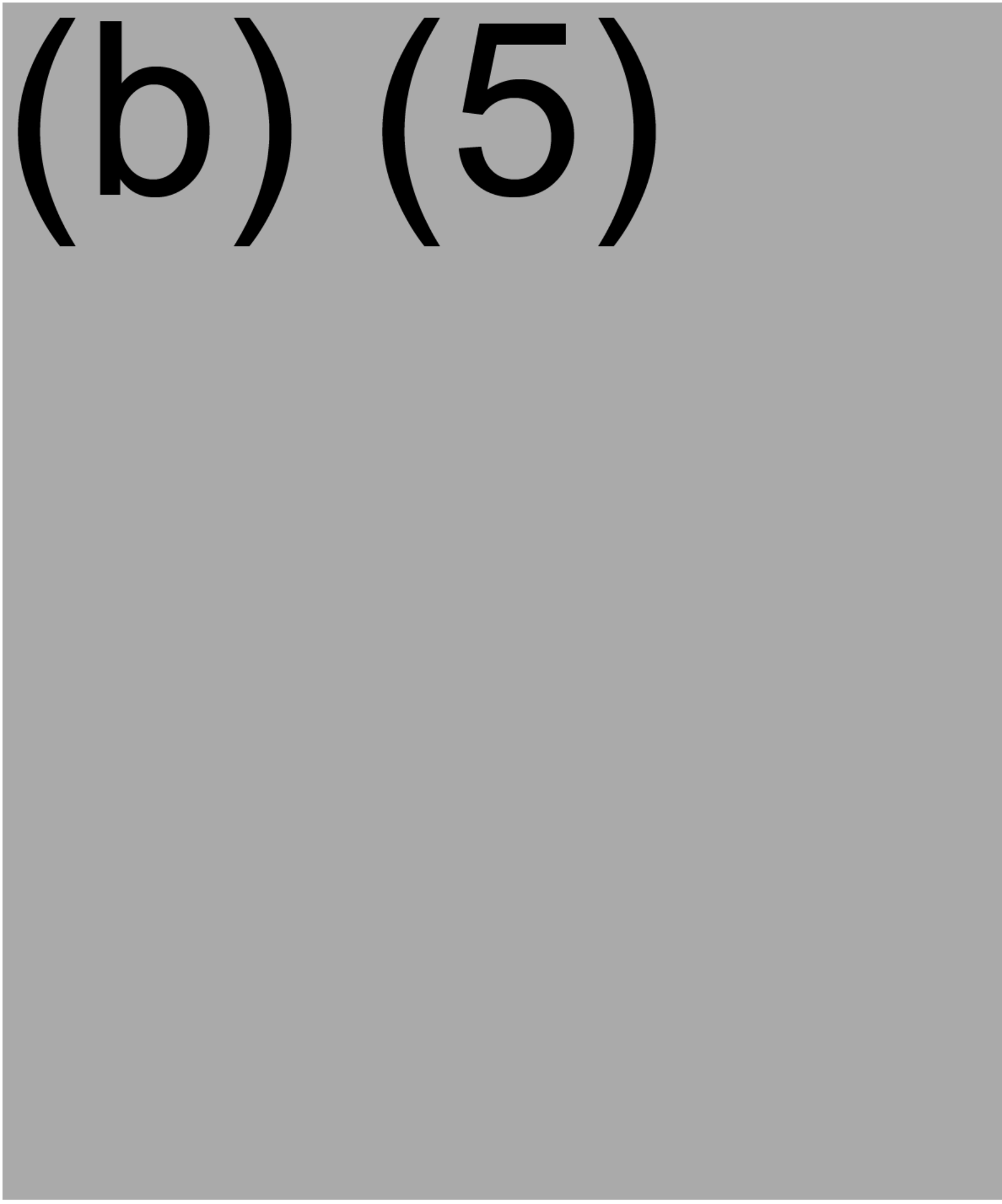
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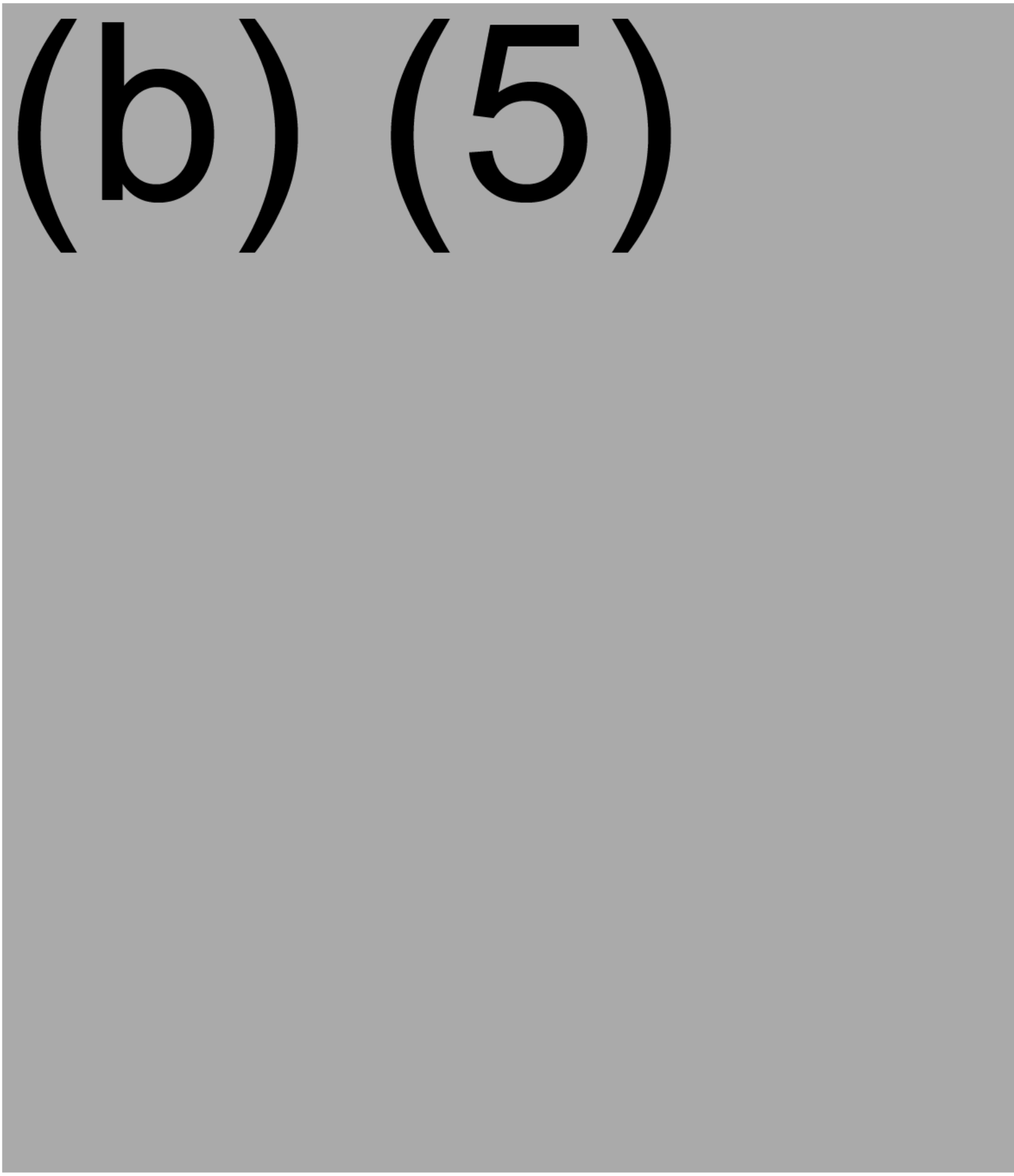
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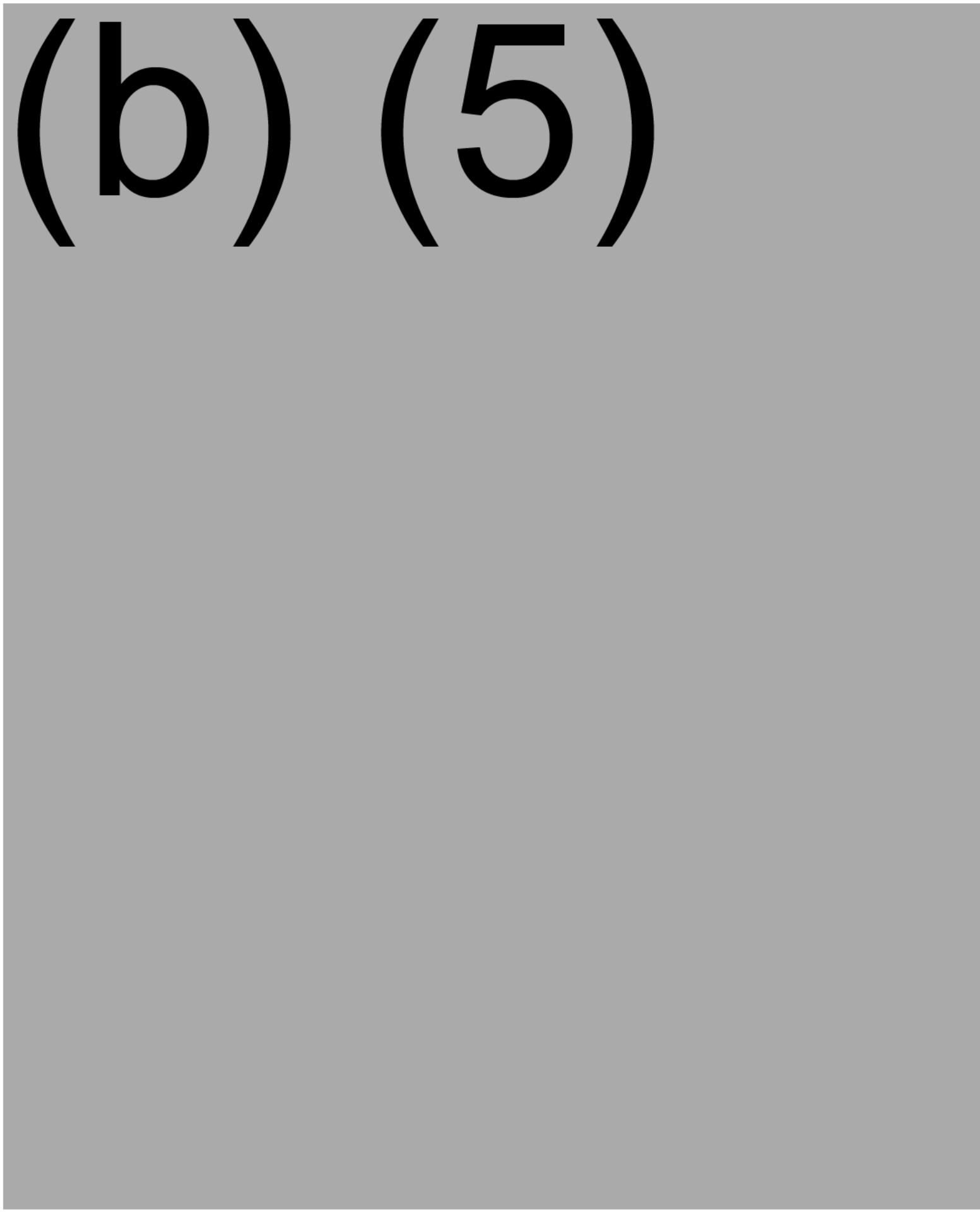
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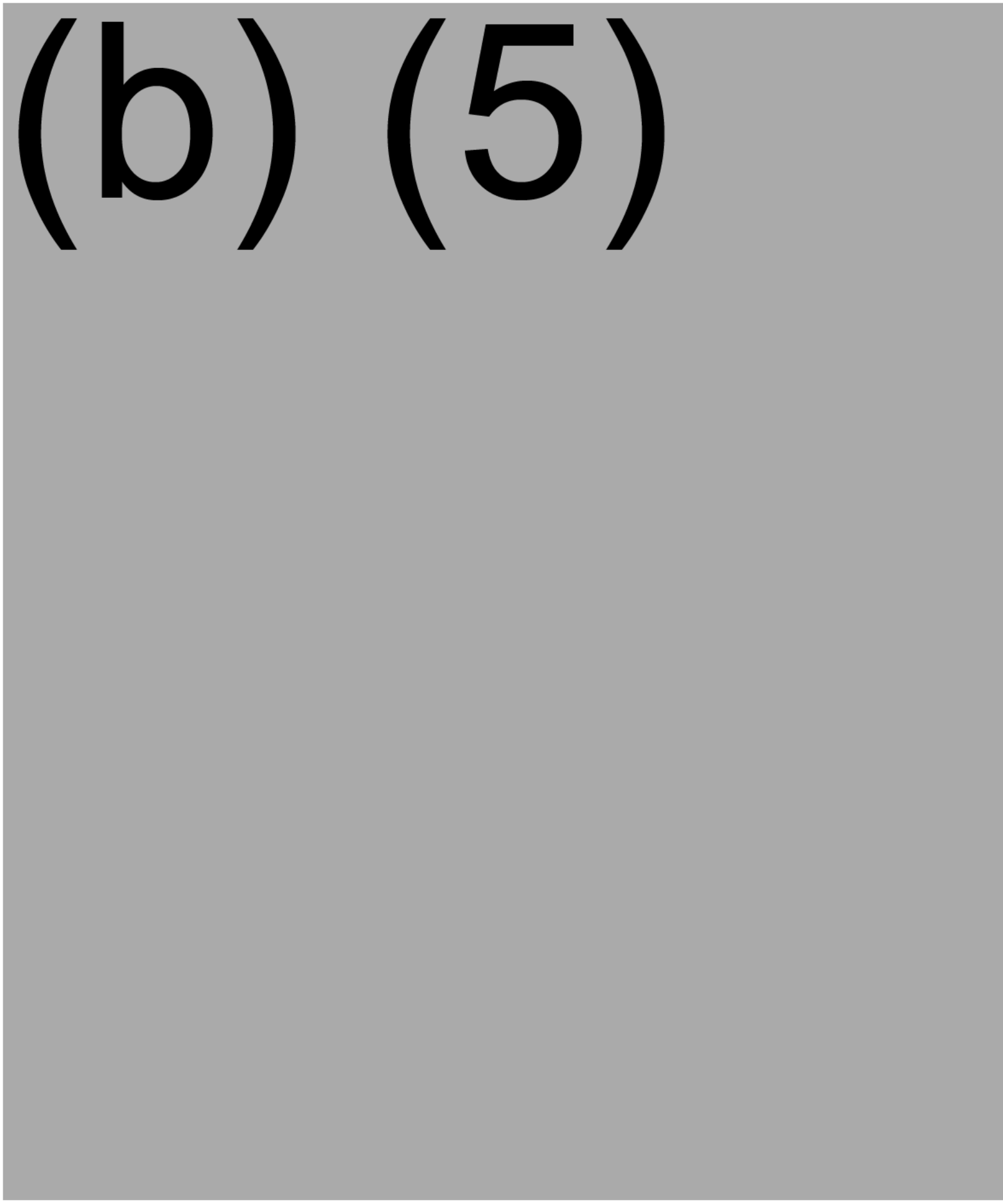
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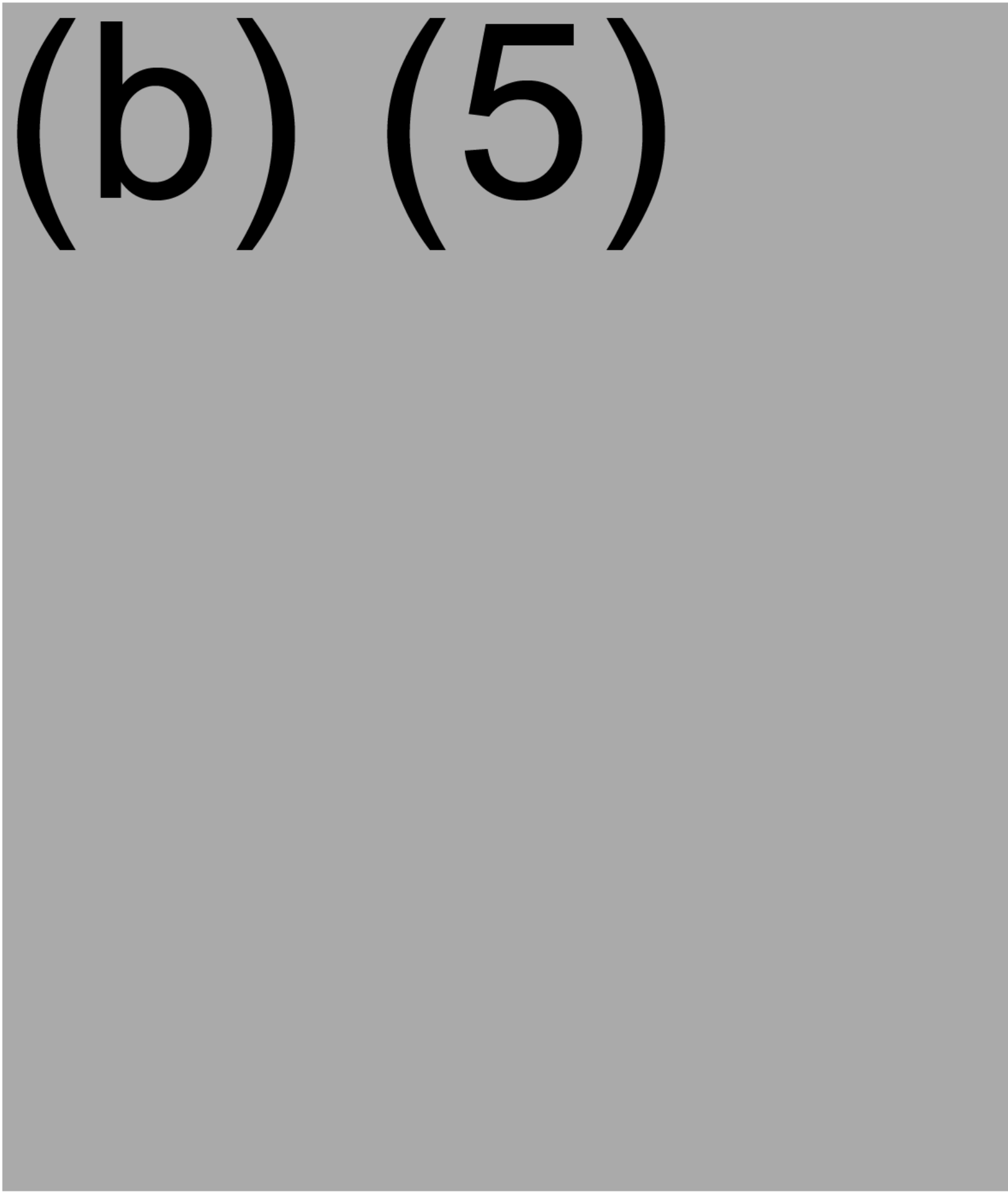
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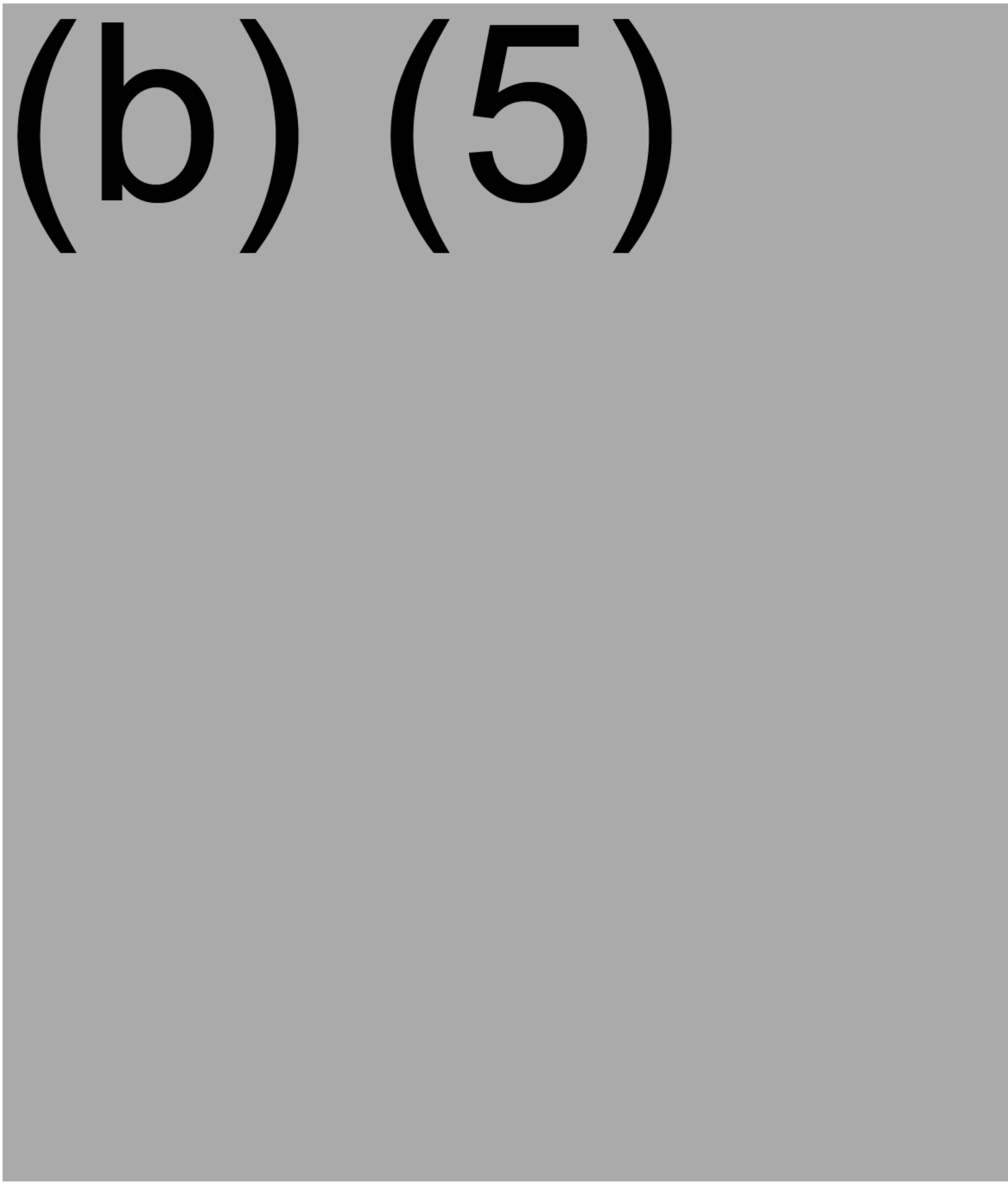
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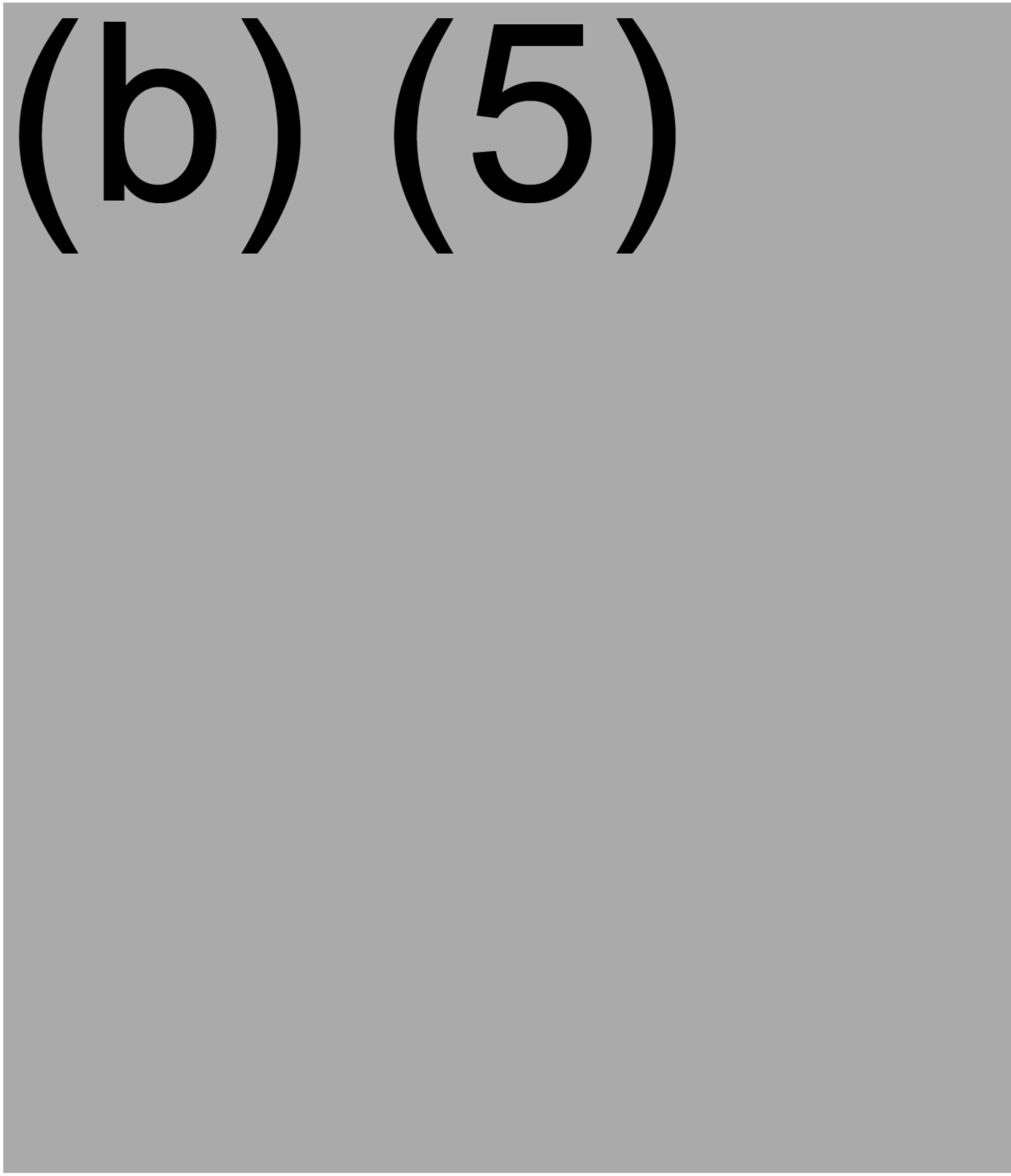
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Sent: 5/18/2022 11:41:27 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Toerner, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=042f3cdd9e89494ea8977f6be4b2b9a7-TOERNERJ]; Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dcce89b861b673-JOS]
Subject: Two Different Lists of Comparable Products from Different Outside Sources
Attachments: Appendix A. Maryland WIC Formula Substitutes.pdf

All:

To close the loop from this morning, below is a link to a list of comparable products. As we discussed, FDA has not traditionally provided lists of comparable products even in the medical products areas as it approaches practice of medicine. Thus, from a comms perspective perhaps we can point parents and caregivers to this :

https://naspghan.org/recent-news/naspghan-tools-for-hcps-affected-by-formula-recall/

Also, **attached** is a list of comparables that received from Maryland Board of Physicians.

Susan – the link above had NOT been shared with IF IMG. They have it now.

That's why I keep advocating the we keep **Infant Formula FDA IMG Planning** (InfantFormulaFDAIMGPlanning@fda.hhs.gov) in the loop, as they're so good with coordination.

Thanks

Frank

Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

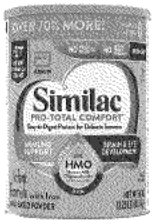
Appendix A. MARYLAND WIC FORMULA SUBSTITUTES

Maryland WIC staff are offering participants with affected products an alternate form (e.g., concentrate or ready to feed) of the current product they have on hand. If the caregiver prefers a product from another manufacturer, USDA has granted a waiver to allow for the provision of an alternate product

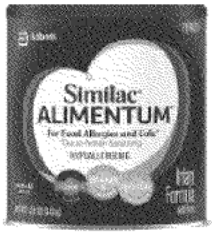
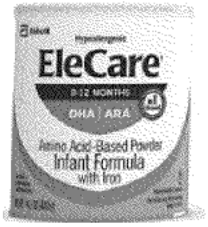
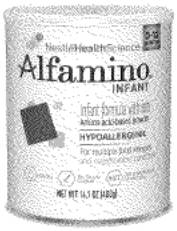
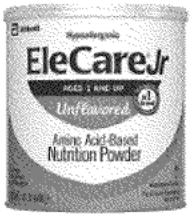
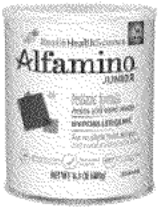
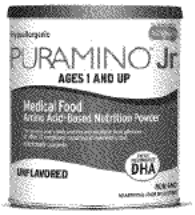
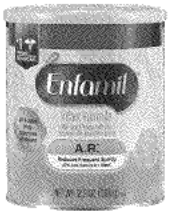
If Maryland WIC participants cannot find their usual formula, local WIC staff can change food benefits to offer options[1]:
1) Participants can purchase different container sizes of the same formula
2) Participants can switch to a different form of the formula (e.g. concentrate or ready-to-feed)
3) Participants can switch to a different manufacturer (available switches are listed below)

Formulas that family can change by calling WIC			
Your Baby's Formula	**Alternate Abbott Formulas**	**Alternate Gerber Formulas**	**Alternate Mead Johnson Formulas**
 Similac Advance	 1. Similac Pro-Advance  2. Similac 360 Total Care	 1. Gerber Good Start Gentle  2. Gerber Good Start GentlePro	 1. Enfamil Infant  2. Enfamil NeuroPro Infant

[1] This flexibility is due to a USDA waiver as a result of the nation-wide infant formula shortage.

 Similac Sensitive	 1. Similac Pro-Sensitive  2. Similac 360 Total Care Sensitive	 1. Gerber Good Start SoothePro	 1. Enfamil Gentlease  2. Enfamil NeuroPro Gentlease  3. Enfamil NeuroPro Sensitive
 Similac Total Comfort	 1. Similac Pro-Total Comfort	 1. Gerber Good Start SoothePro	 1. Enfamil Gentlease  2. Enfamil NeuroPro Gentlease

Formulas that require a healthcare provider's verbal order or medical documentation form to change			
Your Baby's Formula	**Alternate Gerber Formulas**	**Alternate Mead Johnson Formulas**	**Alternate Nutricia Formulas**
			

 Similac Alimentum	 1. Gerber Extensive HA	1. Nutramigen  2. Enfamil Pregestimil	
 Similac EleCare	 1. Alfamino Infant	 1. PurAmino	 1. Neocate Infant  2. Neocate Syneo
 Similac Elecare Jr.	 1. Alfamino Junior	 1. PurAmino Jr.	 1. Neocate Jr.
 Similac for Spit Up		 1. Enfamil AR (12.9oz or 27.4oz size only)	

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 5/20/2022 2:53:47 PM
To: Barrett, Kari [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef6f6c83b17f4fa2910c2f6b8d79b230-Kari.Barret]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Infant Formula FDA IMG Planning [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3b53331482d492c96150661e29efb04-Infant Form]
Subject: FW: [EXTERNAL] AAP Letters to President Biden and Congressional Leadership on Infant Formula Shortages
Attachments: 05-19-22 AAP Letter to President Biden on IF Shortages.pdf; 05-19-22 AAP Letter to Congressional Leadership on IF Shortages.pdf

Incoming from AAP and request for additional information and coordination – can folks please follow up. Happy to discuss.

Thanks,
Julie

From: Haro, Tamar Magarik <tharo@aap.org>
Sent: Thursday, May 19, 2022 6:32 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: [EXTERNAL] AAP Letters to President Biden and Congressional Leadership on Infant Formula Shortages

Hi Julia,

I wanted to make you aware of the letters AAP sent this evening to President Biden and Congressional leadership. Our press release can be found here. I wonder if there is a way for our teams to stay in regular contact about the supply chain issues and new supply coming online. Pediatricians quite literally do not know what to say to parents of children younger than 6 months when supply is not available. AAP was part of a meeting yesterday with USDA, FDA, and CDC and very little was said about the actual timeline and reality for when we can expect to see more supply. The team here at AAP would greatly appreciate any mechanism by which we can learn from FDA more about increased supply. Thanks for considering.

Thanks,
Tamar

TAMAR MAGARIK HARO (she/her)
Senior Director, Federal and State Advocacy
American Academy of Pediatrics
601 13th Street, NW | Suite 400 North | Washington, D.C. 20005
(202) 724-3307 (phone)
tharo@aap.org

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

AAP Headquarters
345 Park Blvd
Itasca, IL 60143
Phone: 630/626-6000
Fax: 847/434-8000
www.aap.org

Reply to
AAP Washington Office
601 13th St NW, Suite 400N
Washington, DC 20005
Phone: 202/347-8600
E-mail: kids1st@aap.org

May 19, 2022

President Joseph R. Biden
The White House
1600 Pennsylvania Ave, NW
Washington, DC 20500

Dear President Biden:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, we write to urge your Administration to do everything in its power to quickly increase the supply of safe infant formula in the United States. Families across the country are struggling to access formula—an essential source of nutrition for many infants—and are worried about how they will feed their children.

At some point during their first year, most US infants receive infant formula, and for many infants, most of their nutrition in the first year of life comes from infant formula. For the youngest children, infant formula is often the only source of nutrition. While AAP recommends exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, not all infants are partially or exclusively breastfed for the first 6 months. For those infants, the AAP recommends use of an iron-fortified infant formula as the best and safest alternative for the first year of life.

Since Abbott Nutrition announced a voluntary recall in February, families across the country have encountered reduced availability of infant formula products. The shortages have been especially acute for children with allergies, digestive issues, or metabolic disorders who require specialty formulas that were produced in Abbott's Sturgis, MI facility. While we appreciate the recent steps announced by your administration to increase formula supply, more must be done to reassure families and provide solutions for feeding their babies especially those younger than 6 months of age. This is particularly important for low-income families who rely on the Special Supplemental Nutrition Program for Women, Infants, and Children, or WIC, program to obtain infant formula. The variability in approaches taken by states with respect to the WIC program requires urgent federal attention.

Pediatricians across the country are providing guidance to families, caring for children who are now hospitalized due to lack of needed formula products, and doing our best to connect our patients with needed formula, but we need help. Without more formula supply, our options for where to direct families are severely limited. Families need clear, consistent, and calming guidance about what they should do if they are unable to find the infant formula products that they need as well as when to expect formula supply to increase.

As experts in infant nutrition, we are willing to work with you to develop these messages or other guidance that may be of help. Families deserve a clear timeline of when to expect formula supply to return to baseline levels as well as information about how scarce supplies can be prioritized to those in dire need. We are calling on your Administration to use every tool at its disposal to remedy this situation as quickly as possible and to provide clear communications to families.

Thank you for your attention to this urgent issue and know that we stand ready to work with you to ensure that families have access to the infant formula that they desperately need. If we can be of further assistance, please contact Tamar Magarik Haro at tharo@aap.org.

Sincerely,

Moira A. Szilagyi, MD, PhD, FAAP
President

MAS/mrc

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

AAP Headquarters
345 Park Blvd
Itasca, IL 60143
Phone: 630/626-6000
Fax: 847/434-8000
www.aap.org

Reply to
AAP Washington Office
601 13th St NW, Suite 400N
Washington, DC 20005
Phone: 202/347-8600
E-mail: kids1st@aap.org

May 19, 2022

The Honorable Nancy Pelosi
Speaker of the House
United States House of Representatives
1236 Longworth house Office Building
Washington, DC 20515

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
2468 Rayburn House Office Building
Washington, DC 20515

The Honorable Chuck Schumer
Majority Leader
United States Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
317 Russell Senate Office Building
Washington, DC 20510

Dear Speaker Pelosi, Minority Leader McCarthy, Majority Leader Schumer, and Minority Leader McConnell:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults, we write to urge you to act quickly to increase the supply of safe infant formula in the United States, provide additional funding to bolster the federal response, and enhance the authority of federal agencies in order to bring this crisis to an end and prevent a future one from occurring. Families across the country are struggling to access formula—an essential source of nutrition for many infants—and are worried about how they will feed their children.

At some point during their first year, most U.S. infants receive infant formula, and for many infants, most of their nutrition in the first year of life comes from infant formula. For the youngest children, infant formula is often the only source of nutrition. While AAP recommends exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, not all infants are partially or exclusively breastfed for the first 6 months. For those infants, the AAP recommends use of an iron-fortified infant formula as the best and safest alternative for the first year of life.

Since Abbott Nutrition announced a voluntary recall in February, families across the country have encountered reduced availability of infant formula products. The shortages have been especially acute for children with allergies, digestive issues, or metabolic disorders who require specialty formulas that were produced in Abbott's Sturgis, MI facility. Congress must take immediate action to remedy the current shortage and to prevent a similar supply issue from occurring in the future. At a minimum, we urge you to take immediate action on the following policies and are eager to work with you on other ways to ensure families across the country are able to provide their infants and children with the nutrition they require.

Additional Resources for FDA

The Food and Drug Administration (FDA) desperately needs additional resources in order to address the current shortage of FDA-regulated infant formula and certain medical foods, ensure the safety of these products, and prevent future shortages. Currently FDA has only 13 staff members who regulate and monitor production of infant formula products and no staff to respond to supply chain issues. Increased funding is necessary to enable the agency to strengthen and increase the number of FDA inspection staff and to provide resources for personnel working on formula issues including: reviewing applications for new products to come to the U.S. market, helping the agency stop fraudulent baby formula from entering the marketplace, and improving data collection on the infant formula marketplace. FDA's current limited capacity to monitor safe manufacturing practices at infant formula production facilities must be remedied. This is especially important as new products will be entering the U.S. market in order to increase the supply of infant formulas available to families throughout the country.

Advanced Notification

Given that infant formulas and specialty medical formulas are often the only source of nutrition for children across the country, FDA needs the authority to adequately prepare for, and if necessary, respond to potential supply disruptions. Manufacturers of infant formulas and other specialized medical foods should be required to proactively manage risk and develop risk management plans for supply of their product. Further, these manufacturers should be required to notify FDA and communicate with the agency if they expect a meaningful disruption in their domestic supply. This information also should be available to the U.S. Department of Agriculture (USDA) given their role in administering food assistance programs such as the Special Supplemental Program for Women, Infants, and Children, or WIC. Currently, no law requires manufacturers of infant formulas or essential medical foods to notify FDA when they become aware of a circumstance that could lead to a shortage of these products. FDA does, however, have the authority to require manufacturers of drug products to notify the agency of potential shortages, which has enabled it to prevent or mitigate drug shortages including those labeled for use in children. Requiring similar advanced notification for infant formulas and other medical foods would allow FDA to take earlier steps to promote the continued availability of these foods.

Role of WIC

WIC provides nutritious food (including infant formula), nutrition education, breastfeeding support, and referrals to health care and social services for millions of low-income women, their infants, and young children who are determined to be nutritionally at-risk. In the United States, 53% of all infants younger than 1 year are served by WIC, and about half of infant formula nationwide is purchased by participants using WIC benefits. Waivers from the USDA and contract flexibilities exercised by State WIC Agencies have allowed for flexibility in the program during the current shortage, including alternate container sizes and different forms and brands of formula. This has given WIC families more options to obtain infant formula amid limited supply on the shelves. While several waivers are currently available, not all states who could benefit from them have chosen to request them. The variability in approaches taken by states with respect to the WIC program requires urgent federal attention. Further, USDA relied on its pandemic authority in issuing these waivers; if we were not currently in a public health emergency, USDA would not have had the authority to immediately issue these waivers. Congress must act to ensure that in future disasters, emergencies, or times of product recalls or supply chain disruptions, USDA can immediately act to increase the number of infant formula products available to WIC participants nationwide. Congress should consider a more nationwide approach to waivers and ensure that USDA is aggressively and proactively providing technical assistance to states. Infant formula companies who contract with WIC should also be required to have a plan in place for how to provide needed formula to families in the event of a future shortage.

Donor Human Milk

The use of pasteurized donor human milk is safe when appropriate measures are used to screen donors and collect, store, and pasteurize the milk and then distribute it through established milk banks. Donor milk banks, such as those accredited by the Human Milk Banking Association of North America, represent a safe and effective approach to obtaining, pasteurizing, and dispensing human milk for use in Neonatal Intensive Care Units and other settings. However, accessibility to donor milk in the U.S. continues to be substantially limited in terms of supply, cost, and distribution. Congress should ensure greater federal regulatory oversight of donor human milk by the FDA. There is no current federal requirement for insurance coverage of donor milk, which often leaves families, especially families with preterm infants, responsible for the costs. Congress should ensure that families can access donor human milk on the basis of medical necessity, not financial status. Further, Congress can dedicate resources and raise awareness for donating and receiving safe donor human milk.

Insurance Coverage for Medical Nutrition

Many of the families who are searching for specialized formulas to meet their children's medical needs are the same families who frequently face denials for coverage of such products by their insurance. While medically necessary nutrition is sometimes the best or only treatment for a digestive or metabolic condition, insurance companies often deny coverage. Insurance companies will typically cover pharmaceuticals or biologics for treatment of these diseases; however, they are often used off label or may not be recommended by the treating physician as first line therapy. Further, pharmaceuticals and biologics are often costly and can have undesirable risks such as suppression of the immune system, which can increase a patient's risk of infection or cancer. Even when an insurance company does cover medically necessary nutrition, it often comes with the stipulation that the formula be administered through a feeding tube (for example, a nasogastric tube, placed through the nose into the stomach or a gastrostomy tube, surgically placed directly into the stomach). Surgery to place a feeding tube is expensive and these tubes carry additional risks. Congress should require both public and private insurance to cover medically necessary foods, such as highly specialized formulas, as a treatment option. Congress has previously recognized the importance of providing coverage for medically necessary nutrition and required TRICARE coverage for such therapies in the 2016 National Defense Authorization Act. We urge Congress to expand this requirement for other insured populations with rare digestive and metabolic conditions.

Thank you for your attention to this urgent issue and know that we stand ready to work with you to ensure that families have access to the infant formula that they desperately need. If we can be of further assistance, please contact Tamar Magarik Haro at tharo@aap.org.

Sincerely,

Moira A. Szilagyi, MD, PhD, FAAP
President

MAS/mrc

From: Rabin, Tara G. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D6E14C0D07AD46CA812A39A72C751BFE-TARA.GOODIN]
Sent: 5/22/2022 6:23:45 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
CC: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Hetlage, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1356d75869e43ffad945d0deb85598c-Daniel.Hetl]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]
Subject: Re: REVIEW REQUEST, 6PM TODAY: PR, FDA Flexibilities to Yield Millions of Cans of Additional Infant Formula to Increase Supply Available to U.S. Consumers
Attachments: DRAFT_PR_First Formula Imports 05222022.docx

Thank you.

Dr. Califf, look forward to your review at your earliest convenience.

Best,
Tara

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, May 22, 2022 6:05:37 PM
To: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: Re: REVIEW REQUEST, 6PM TODAY: PR, FDA Flexibilities to Yield Millions of Cans of Additional Infant Formula to Increase Supply Available to U.S. Consumers

Looks good. Jw

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Sunday, May 22, 2022 2:35:15 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: REVIEW REQUEST, 6PM TODAY: PR, FDA Flexibilities to Yield Millions of Cans of Additional Infant Formula to Increase Supply Available to U.S. Consumers

Dr. Califf and Dr. Woodcock,

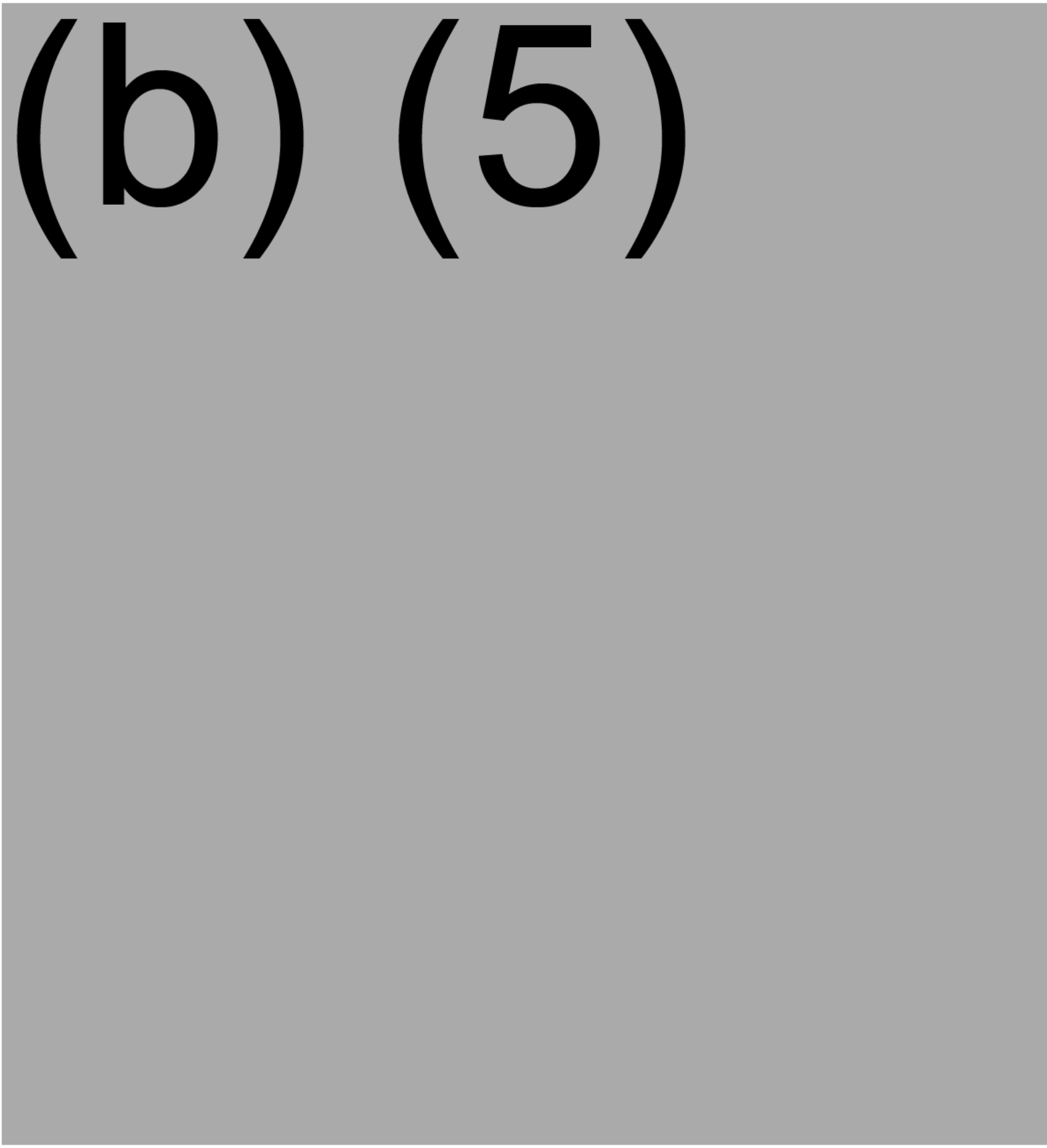
On Monday, we're aiming to issue a press release regarding our first enforcement discretion action under the infant formula importation guidance, flexibilities we are offering to allow importation of another infant formula from abroad and case-by-case release of Elecare pending Abbott testing. The press release includes a proposed quote attributed to Dr. Califf and is attached here for your urgent review, if possible by 6pm today.

Agency/Office: Infant Formula IMG/OFPR/CFSAN
Subject: FDA Flexibilities to Yield Millions of Cans of Additional Infant Formula to Increase Supply Available to U.S. Consumers
Deadline for comments: 6pm, Sunday, May 22
Planned release date: Monday, May 22
Driving event: Infant formula supply chain FDA progress updates

Best,
Tara

Tara G. Rabin
Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-3157 / Cell: (b) (6)
Tara.Rabin@fda.hhs.gov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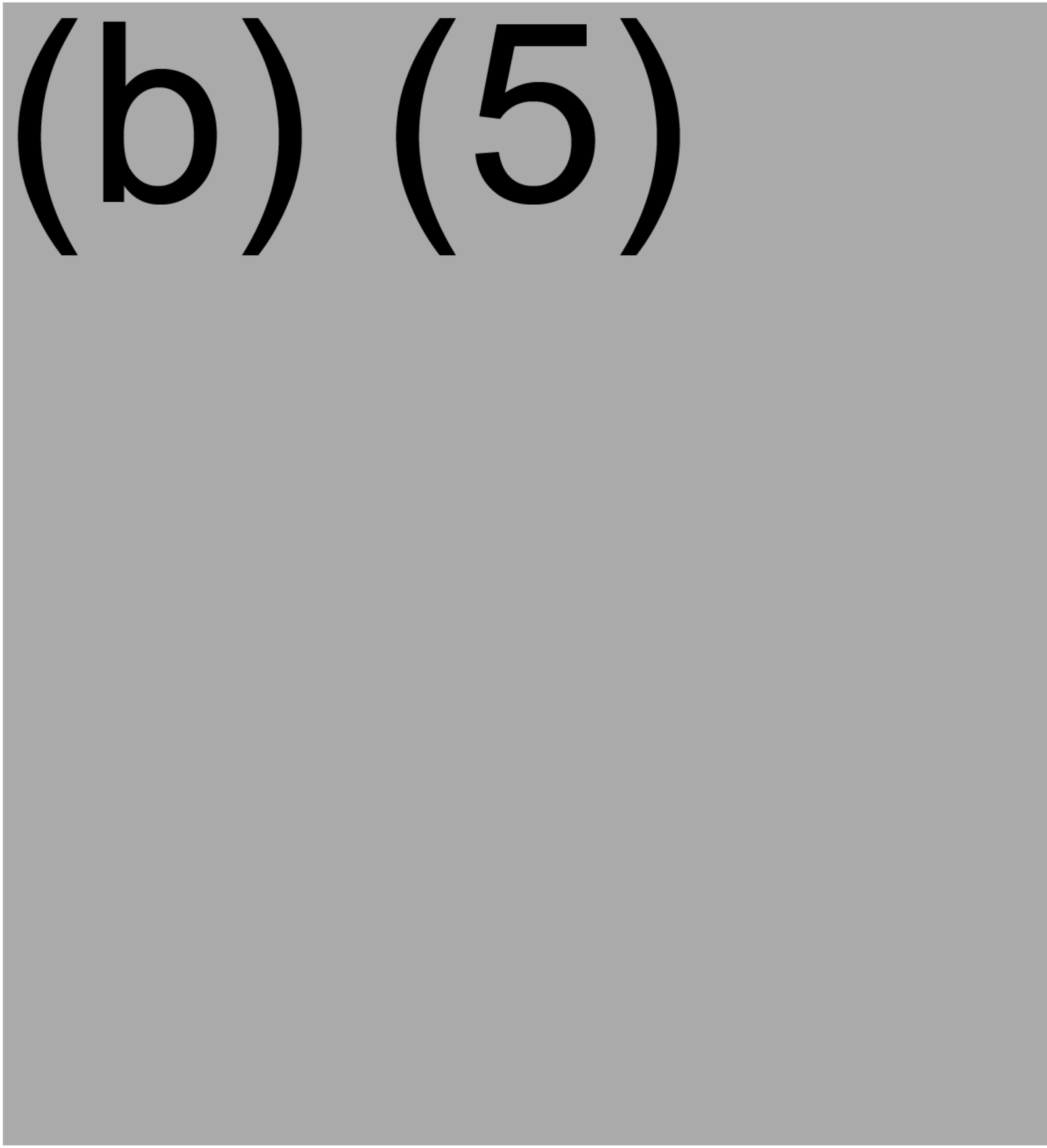
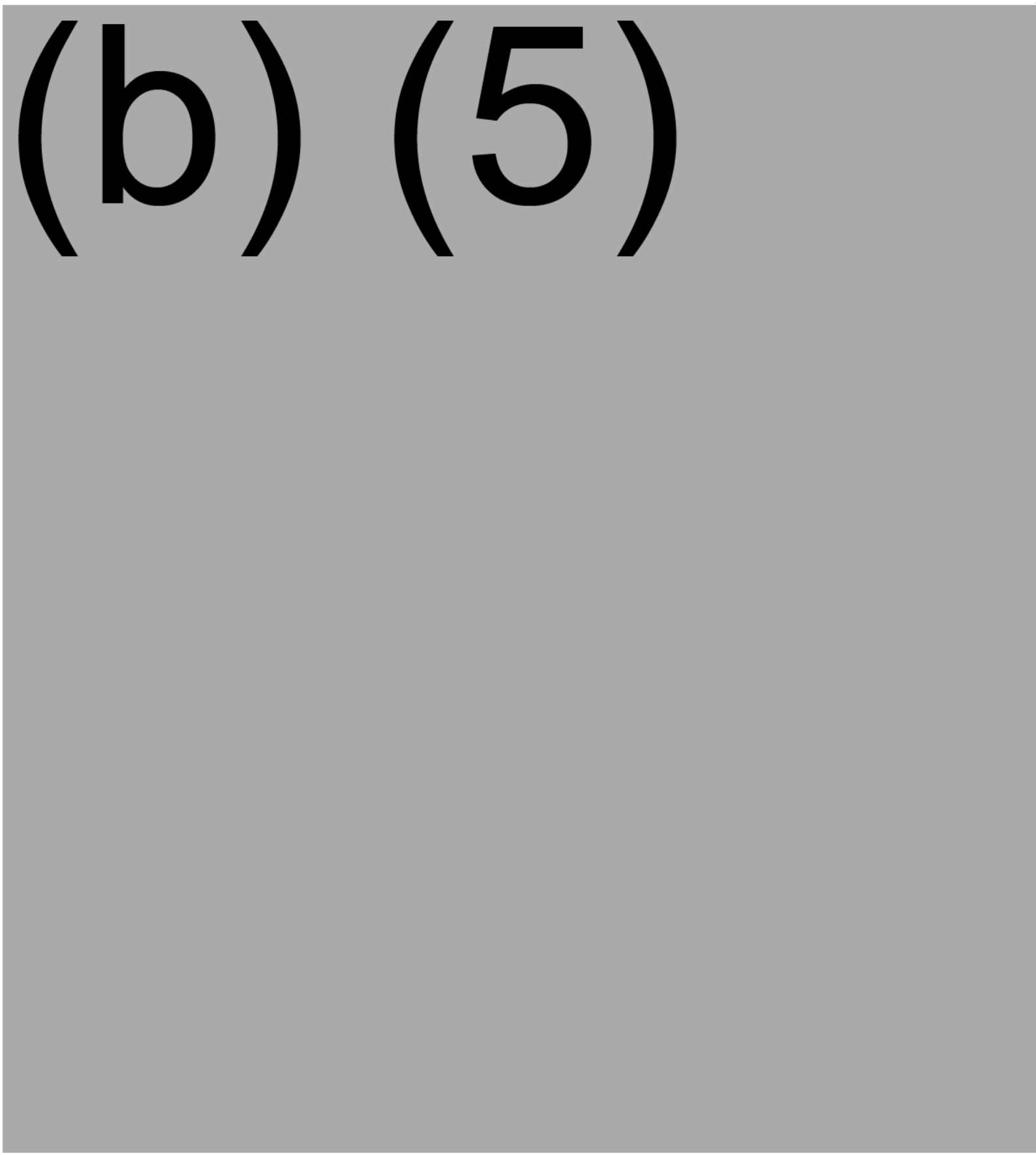

(b) (5)


(b) (5)

From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 5/23/2022 7:56:51 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; judy.mcmeekin@fda.hhs.gov; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dcce89b861b673-JOS]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]
CC: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: Fwd: Daily Updates: Status of Abbott's Resumption of Operations
Attachments: 5-23-22 FSRU Daily Update Status of Abbott Resumption of Operations.docx

I've asked the IF IMG to provide daily updates on the status of Sturgis reopening

Since I won't be on this morning's call, here's a summary.

I'll be prepared to provide verbal recaps every morning.

Frank

Get Outlook for iOS

Status of Abbott's Resumption of Operations at Sturgis, MI Facility
FSRU Daily Update

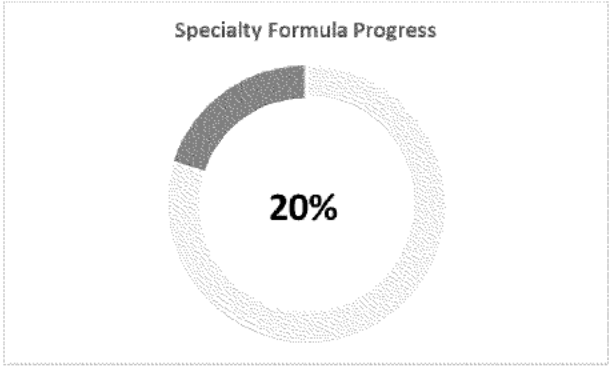
I. Objectives

- Provide a daily account of the progress that Abbott is making toward production of infant formula at their Sturgis, MI facility.
- Flag any potential progress delays or deviations from the Consent Decree (CD).
- Identify decision points for leadership.

II. Current Phase and Applicable CD Provisions

- Abbott is currently working on meeting CD provisions necessary to begin Specialty Operations (Paragraph 8 of CD).
    - These provisions are designed to prioritize the production of such formulas while maintaining appropriate oversight.
    - FDA's concurrence on submissions or reinspection is not required for resumption of Specialty Operations. However, the CD does not preclude responses or reinspection.
    - On 5/19, in response to FDA concerns regarding availability, Abbott confirmed they intend to begin Specialty Operations with Elecare.
- The CD contains additional requirements that Abbott must meet before expanding production to other formulas (Paragraph 9 of CD). This Update will be expanded to include Abbott's progress on these activities; however, given shortage concerns, FDA and Abbott's current focus is Specialty Operations.

III. Abbott's Status to Meeting CD Provisions for Resumption of Specialty Operations



Reported Date of Resumption of Specialty Operations: June 4, 2022[1]

[1] It is our understanding that on 5/20, Abbott's CEO informed FDA leadership of this start date.

CD Provision	Abbott's Status
Paragraph 8(A): Retain an independent Expert	Complete. Abbott provided FDA notice on 5/18 that Expert (IEH) retained.
Paragraph 8(B)(1): Verify the dry-out procedures for production equipment and processing environments and validate the test method for moisture verification used to assess dryness after the dry-out procedures for production equipment and processing environments	Abbott sent documentation regarding dry-out procedures and test method, 5/19 and 5/20, respectively. Although FDA concurrence is not required, FDA SMEs have reviewed and will provide feedback to Abbott on 5/23 and believe Abbott can incorporate feedback in short order.
Paragraph 8(B)(2): Conduct pre-production cleaning, sanitizing, and dry-out of production equipment and processing environments (using the verified dry-out procedures and the validated test method), followed by environmental testing for pathogens in the processing environment	Abbott has declined at this time to provide a date or estimated date by which their pre-production activities will be completed (other than their overall June 4 estimate for resumption).
Paragraph 8(B)(3): Provide FDA with the Expert's report documenting completion of the verification and validation activities and pre-production review set out in paragraph 8(B)	Abbott has declined at this time to provide a date or estimated date by which their Expert report will be submitted (other than their overall June 4, estimate for resumption). Abbott stated that their Expert will be onsite beginning 5/23.
Paragraph 8(E): After resumption of production, but before distribution, review batch records, in-process and finished product test results, and environmental monitoring test results and certify in writing to FDA all lots meet specifications	Abbott has not begun production and has not provided a date or estimated date by which their review and certification will be complete. Although FDA concurrence is not required before distribution occurs, FDA will review the certification to confirm lots meet specifications; this should not add time to distribution.

IV. Abbott's Status to Meeting CD Provisions for Resumption of Other Operations

As noted, the CD contains additional requirements that Abbott must meet before expanding production to other formulas (Paragraph 9 of CD). This Update will be expanded to include Abbott's progress on these activities; however, given shortage concerns, FDA and Abbott's current focus is Specialty Operations.

V. Upcoming Meetings and Decision Points

- Next Abbott meeting scheduled for Monday, 5/23 at 4pm EST.
    - SME feedback on Abbott's dry-out procedures and test method will be provided.
    - We will also request more detail from Abbott regarding their June 4 timeline and whether it can be sped without sacrificing safety. It is our understanding that FDA leadership is engaged in similar conversations with Abbott personnel at their level.
    - We will also ask for an estimate on distribution timing after resumption of production.
- An FDA determination on reinspection timing and approach will need to be made soon. The FSRU is developing an options paper for IMG and/or AEG consideration; targeting 5/24 for circulation.

From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 5/23/2022 9:26:58 AM
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CC: Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Roosen, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67e5a1139af248699616f7f8c44f46bd-Suzanne.Roo]
Subject: FW: Infant Formula Data from Nestle - Follow Up from Nestle Meeting
Attachments: Gerber PRC IF Summary_PCasey 052022.pptx; In-Stock% Total Formula by Brand 5.15.2022.pptx

Thanks Tristan. This is great.

Rob:

These data sets are completely in-line with what we've been sharing.

There WIC view is interesting and I'm told that the IF/WH data team have a WIC view that they're almost ready to share.

What the WIC chart that Nestle provides shows is just how much the WIC states that depended on Abbott have been challenged as there is not enough ABBOTT product to meet their needs. While WIC has issued waivers (to allow purchases in those states of other brands), the reality is those retailers in Abbott awarded WIC-contract states had inventory (and shelving displays) that was heavily weighted/skewed towards ABBOTT.

In Abbott awarded states, the rapid Waiver alone would not fix the states' dependency on Abbott formula, estab;ished logistical systems, etc (dependent on Abbott)....as other brands tried to spread their products a little more evenly to states where they did not have contracts.

Remember, we've heard that the WIC minimum stocking requirements by state that had awarded contacts to other brands (Reckit and Nestle) made retailers feel they were under legal obligation to keep a minimum inventory of those brands (Reckit or Nestle) in each store (so they didn't have surplus) and this hindered their ability to spread their existing inventories a little more evenly beyond their contract-awarded states.

When this is all said and done, and analyzed, I have no doubt that the WIC contract process will be the single biggest influencer on why there is so much consolidation in this industry and why it's been so hard to distribute existing inventory more quickly and easily.

They've been some powerful decade forces that can't be easily untangled in a couple of months.

Frank

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Sunday, May 22, 2022 11:07 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Tierney, Julia

<Julia.Tierney@fda.hhs.gov>
Subject: Infant Formula Data from Nestle - Follow Up from Nestle Meeting

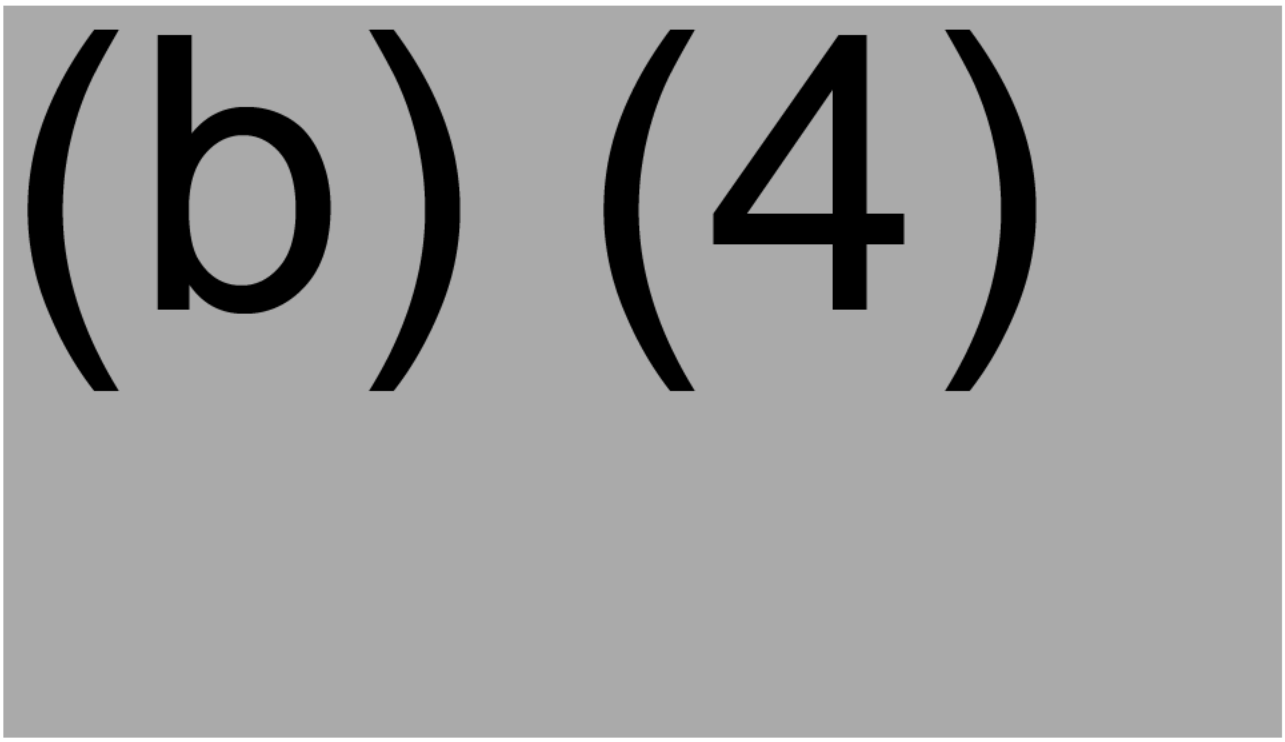
Hi all,

Nestle followed up this afternoon on data discussed at the meeting we had with them earlier this week. Note, this may contain commercial confidential information.

The first attachment is data about their call line. The second attachment is data that looks based on IRi data, it may be repetitive of data we've got, but still wanted to pass along.

Tristan Colonius, DVM, MPA, DACVPM
Acting Deputy Chief of Staff
Office of the Commissioner
O: 301.796.2624 | M: (b) (6)

FDA U.S. FOOD & DRUG ADMINISTRATION



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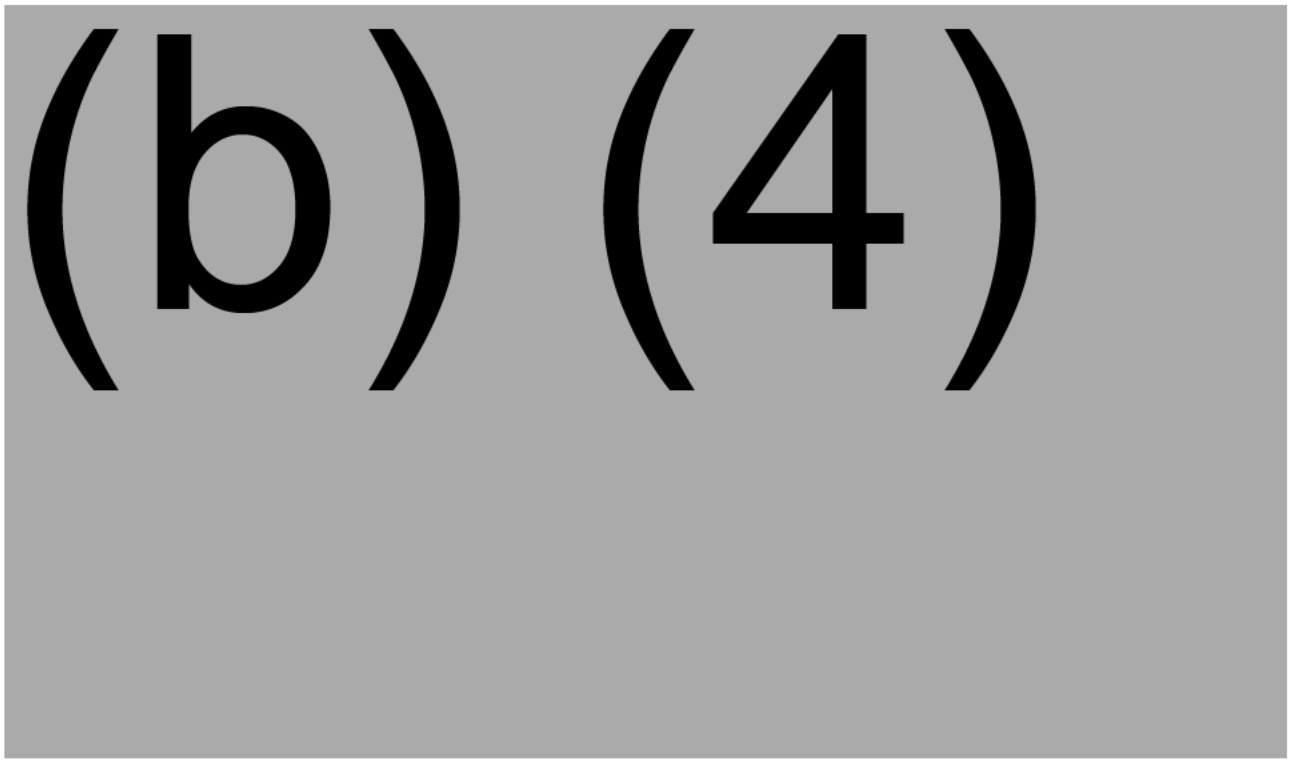
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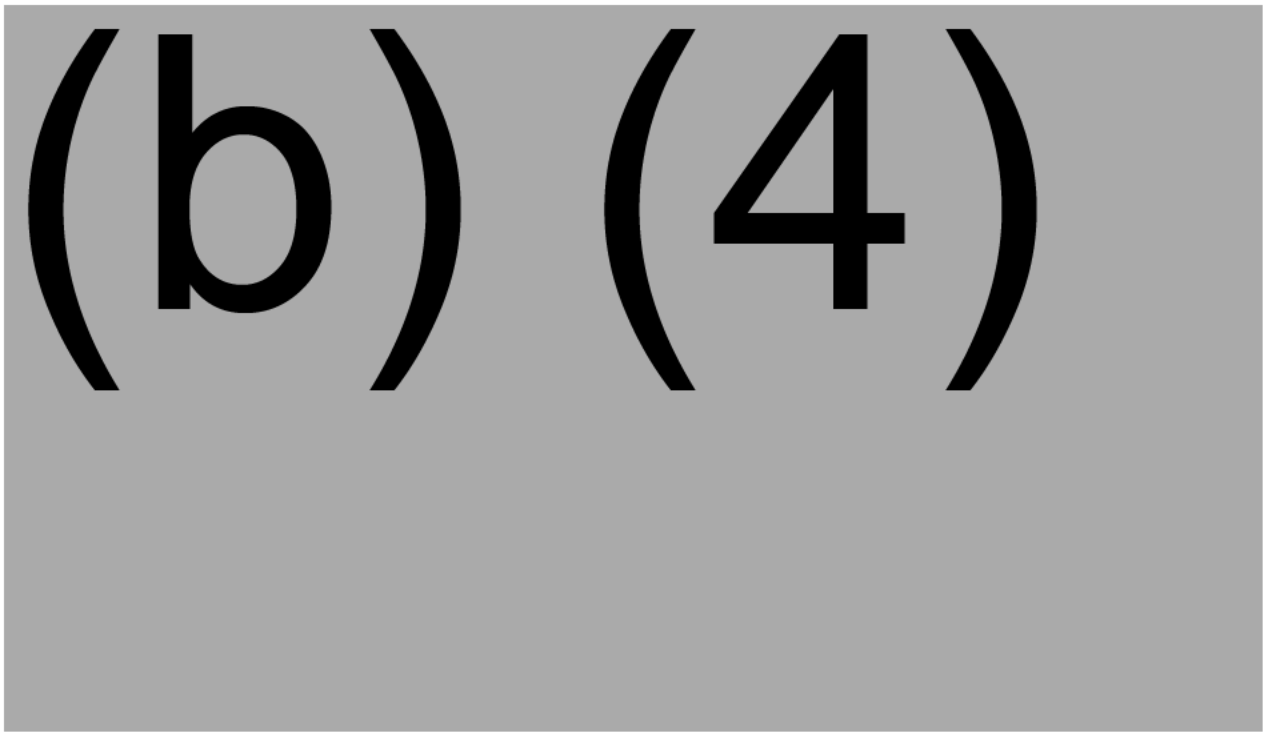
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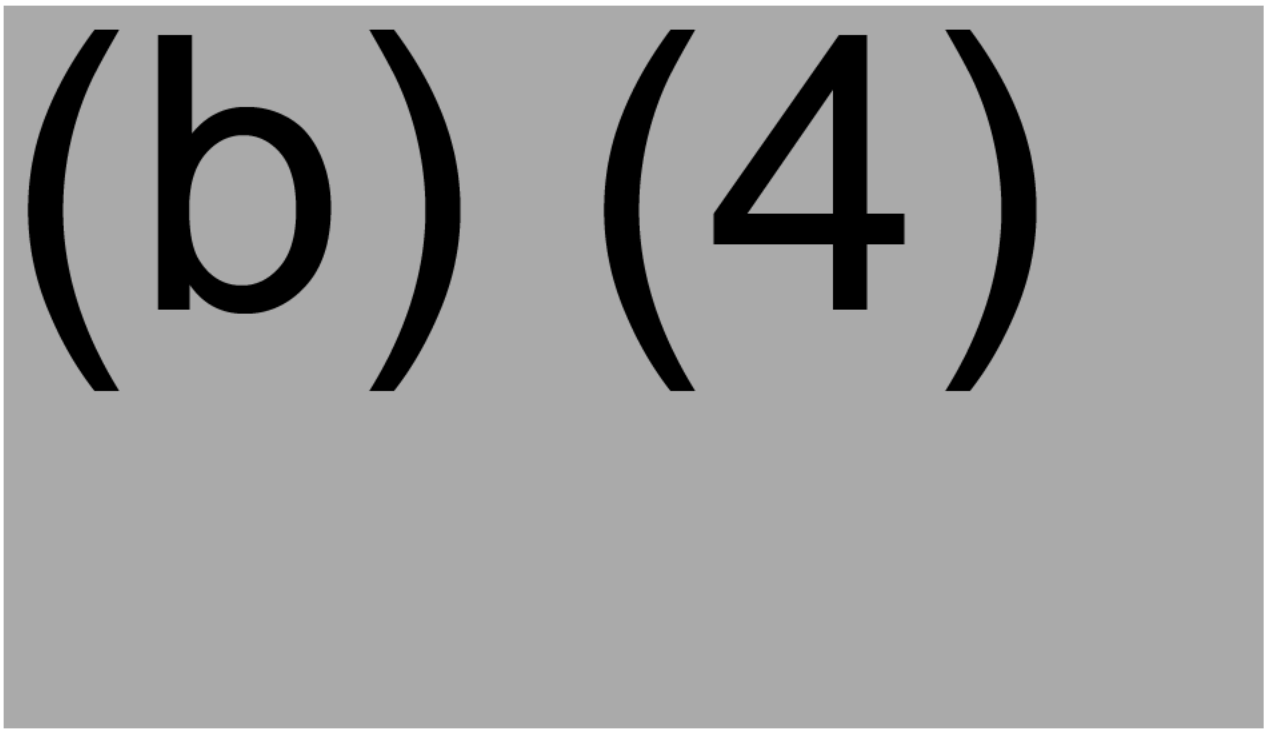
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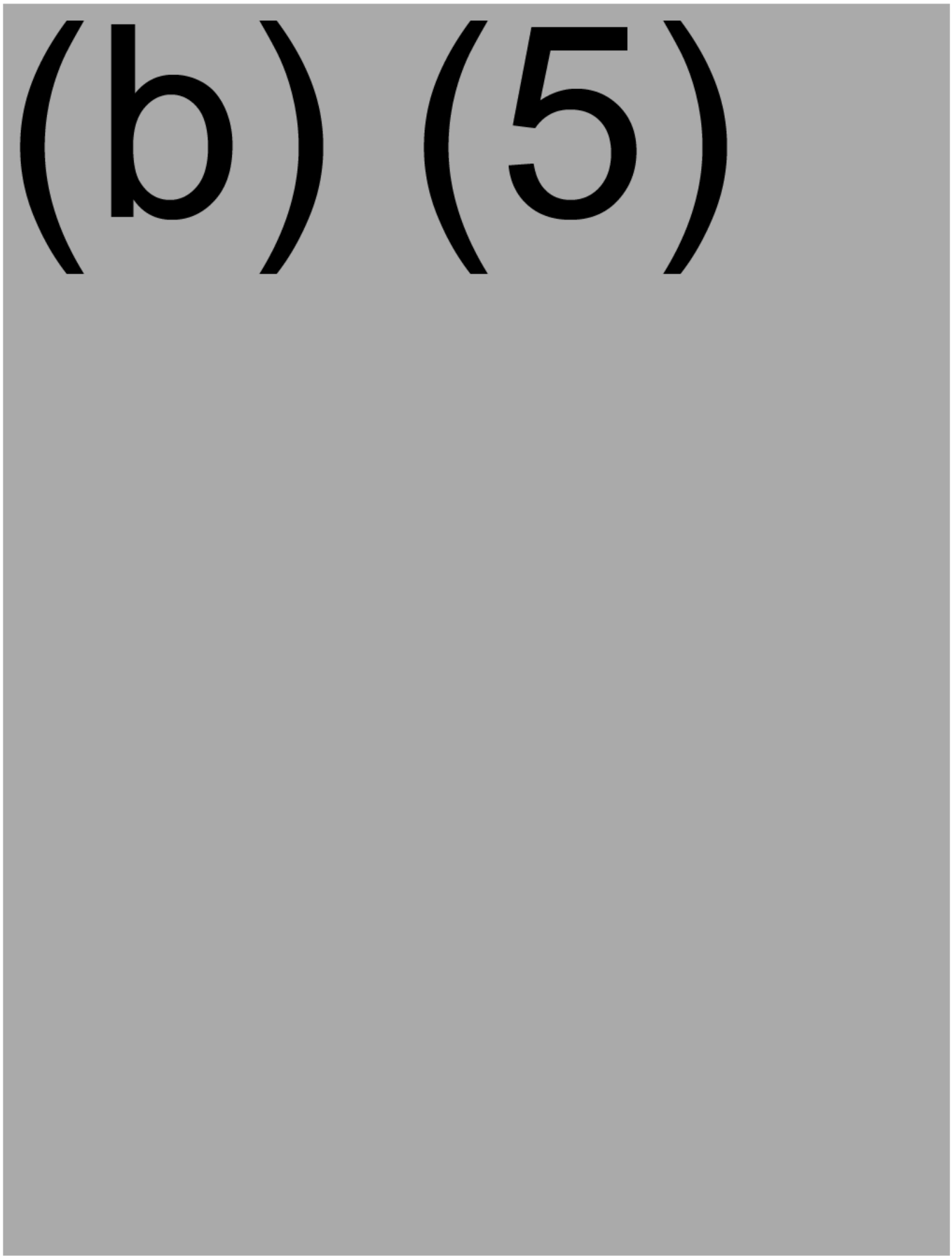
Sent: 5/23/2022 10:04:18 PM
To: Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Oral testimony
Attachments: 20220523 RMC Testimony Draft v2.docx

This is not good, but at least has my thoughts. Sorry for the delay, but I'll probably have more clarity in the early am.

rmc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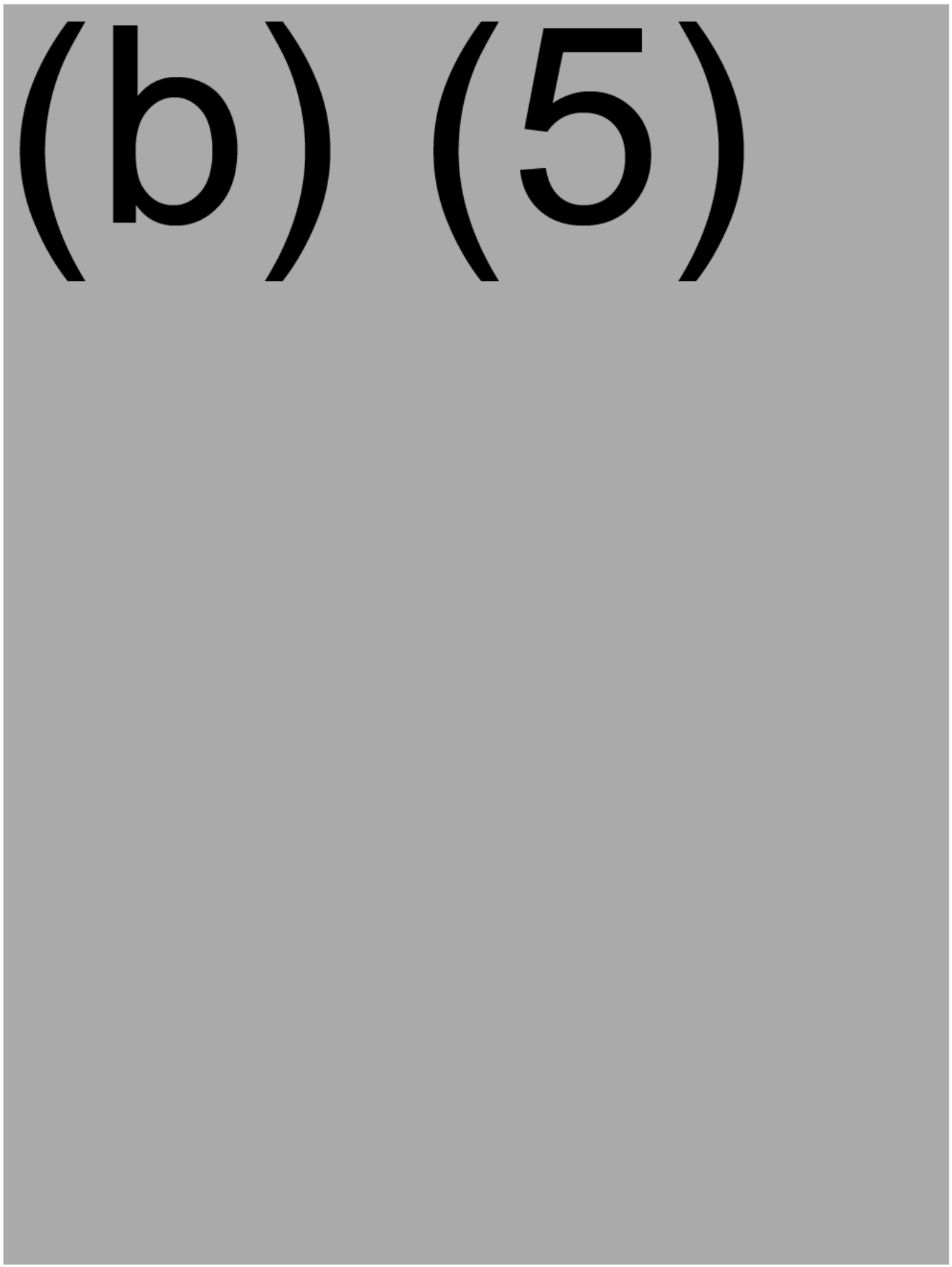
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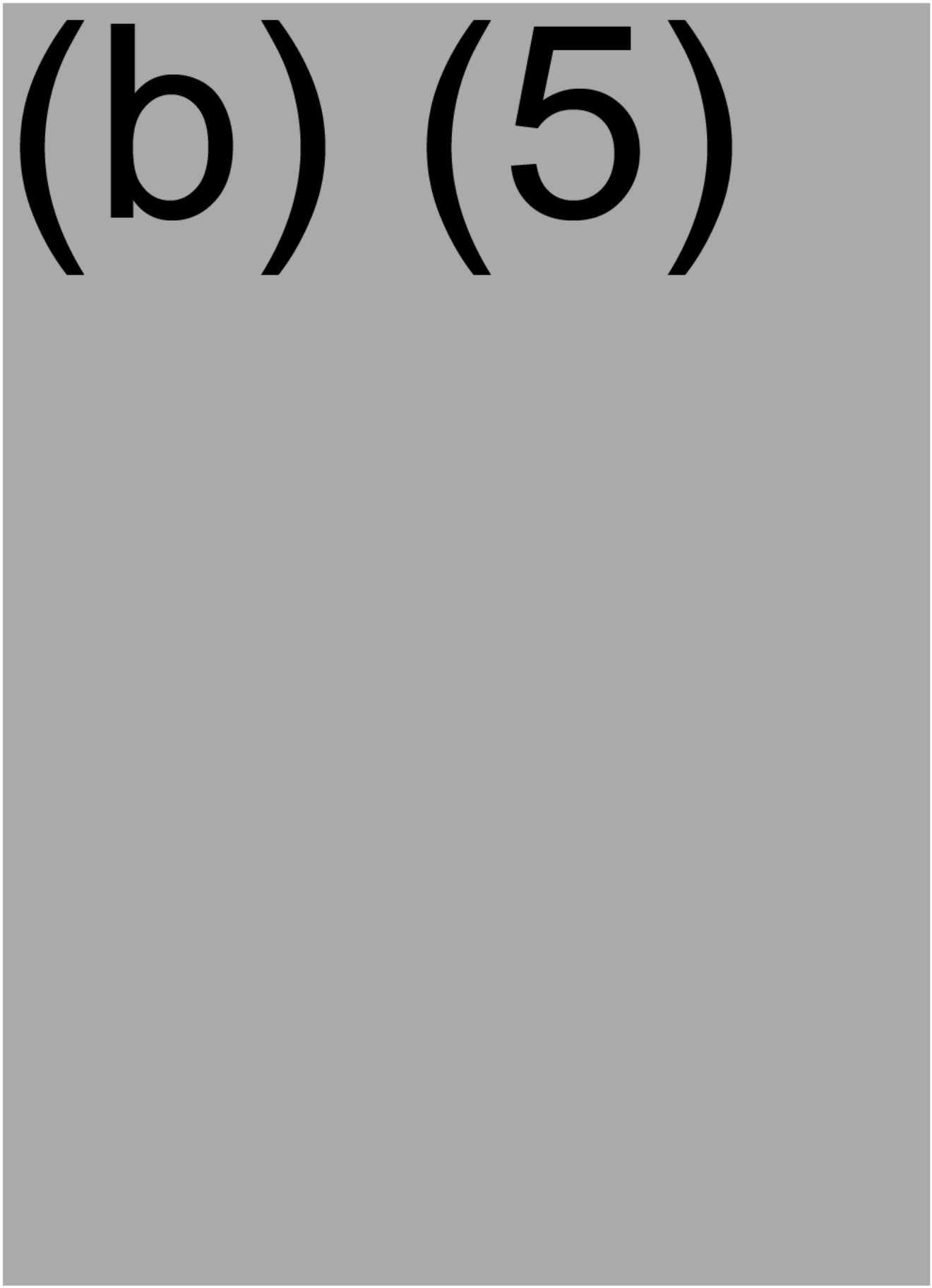
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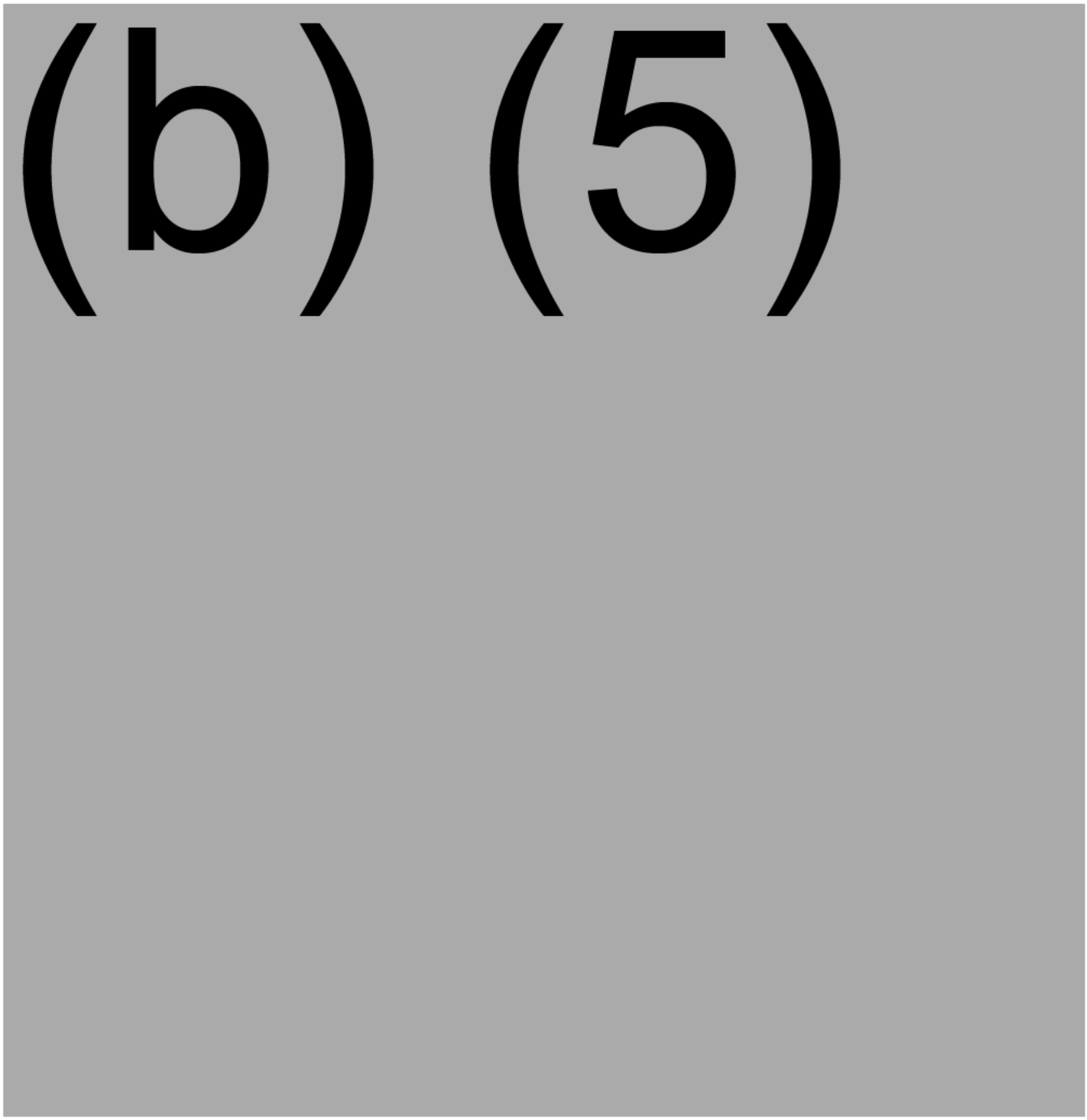
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CC: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: RE: New comms/potential hearing issue

Thanks for the heads up, Caitlin! I don't believe IGA has received the request you flagged below. I forwarded to the team and am double checking with them. IGA did receive a few inquiries last week and I think this team is aware of these. However, I am including them below:

- Wednesday (May 18th)
  - UT Governor's office re: helping a constituent with a specialty formula issue and also following up on expediting approval for other companies to start mfg formula. IGA is working with CFSAN on responding to both.
  - NAAG's Consumer Protection Project reached out to ask to host a briefing for AGs/AG staff with federal officials from FTC, USDA and FDA on IF shortage issues. IGA is working with CFSAN to identify SMEs and availability.
- Thursday (May 19th)
  - NC Governor's Fed Rep requested update on mapping infant formula availability and shortages. IGA working with CFSAN on a response.

Thanks!
Teresa

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Wednesday, May 25, 2022 6:37 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: New comms/potential hearing issue

Hi,

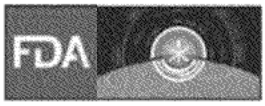
I wanted to flag new incoming for the Utah Governor's Office. I'm not sure if IGA is aware as it looks like this came in through the District.

Denver District Office received a call from our state partners in Utah – the Governor's Office. They have a request from someone that lives in Utah but is currently in Europe that wants to organize a shipment of infant formula to the US. The request states that "Ukrainian refugees in Poland have crowd-sourced an airplane full of baby formula and would like to send it direct". The request also said that they wanted to send it specifically to Utah. They are asking if Utah can accept the offer or if it would "be illegal per FDA regulations".

We don't know what types of formula are involved – it's likely many types that individuals picked up at retail. Can discuss more at the morning check-in.

Thanks,
Caitlin

Caitlin Boon, Ph.D.
Associate Commissioner for Food Policy and Response
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
(b) (6)
Caitlin.Boon@fda.hhs.gov



From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
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CC: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: URGENT -- Steve Solomon tweets

Importance: High

Hi both –

Dr. C will be announcing at the hearing today that Steve Solomon will be taking over the review. I just discussed with him and he's OK with doing so. Also adding him here for edits while he can still see. We need to time for when he mentions Steve at the hearing. This request is coming from the WH and HHS.

Julie/Tristan – If more needs to be added, please let me know.

(b) (5)

+++

Thank you,
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: (b) (6)
erica.jefferson@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Executive Assistant: Kristen.Tugwell@fda.hhs.gov (temporary)

From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 5/24/2022 6:58:37 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]
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Subject: Follow up: Calls to infant formula manufacturers
Attachments: SES Calls to IF Manufacturers_24May2022.xlsx

All,

Sharing work by Dayle's team today to make calls to infant formula manufacturers today and "test" the current state of play. Call times for key manufacturers, messaging and availability (where applicable) noted in the document.

Key takeaway: The current system is still imperfect. An opportunity exists to call on manufacturers to step up their game on how they communicate around access.

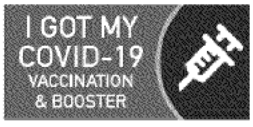
Dayle – Let us know if there is anything that you'd add.

Thank you,
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: (b) (6)
erica.jefferson@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Executive Assistant: Kristen.Tugwell@fda.hhs.gov (temporary)



From: Croce, Teresa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3ABF9312C3984913BDE628D5E6FA48D1-TERESA.CROC]
Sent: 5/25/2022 10:13:51 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: Readout from the WH Infant Formula Check-In (March 25th)

Hi All,

Below is a high-level readout on new items from the WH IF Check-In call this evening:

(b) (5)

Please feel free to reach out with questions.

Thanks!
Teresa

Teresa A. Croce, Ph.D. (she/her/hers)
Senior Advisor

Office of Policy, Legislation, and International Affairs
Office of the Commissioner
U.S. Food and Drug Administration
Mobile: (b) (6) Tel: 240-402-1281
teresa.croce@fda.hhs.gov

From: Goldstein, Mitchell (b) (6)
Sent: 5/26/2022 3:52:46 PM
To: (b) (6) ; CDER Executive Operations [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c68e582c3fb64e57963e510a97332f63-CDEREXSEC]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]; Kweder, Sandra L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dcee61a387b4de49117ed8a0a80eea5-KWEDER]; steve.morin@fda.hhs.gov
Subject: RE: [EXTERNAL] Re: Response to your email to Dr. Norman Sharpless

Phil,
Thank you. We have to stop this in its entirety. Medication insecurity has now progressed to food insecurity when it comes to our most at risk infants.
Regards,
MG

Mitchell Goldstein, M.D., M.B.A,, C.M.L.
Professor of Pediatrics, Loma Linda University School of Medicine
Director, Neonatal ECMO Program
Division of Neonatology, Department of Pediatrics
Loma Linda University Children's Hospital
11175 Campus Street, CP 11121
Loma Linda, CA 92354
Office: 909-558-7448 Fax: 909-558-0298 Cell: (b) (5)
Email: mgoldstein@llu.edu
LOMA LINDA UNIVERSITY
School of Medicine

From: (b) (6)
Sent: Thursday, May 26, 2022 12:27 PM
To: CDEREXSEC@cder.fda.gov
Cc: janet.woodcock@fda.gov; douglas.throckmorton@fda.hhs.gov; CommissionerFDA@fda.hhs.gov; sandra.kweder@fda.hhs.gov; steve.morin@fda.hhs.gov
Subject: [EXTERNAL] Re: Response to your email to Dr. Norman Sharpless

Dear Dr. Woodcock et al,
Here's my belated reply, which I posted on Linkedin yesterday, to your email of Nov. 8, 2019:

Wow! Finally, an FDA Commish who actually gets it! At today's hearing on the baby formula shortage before the House Energy & Commerce Committee, FDA Commissioner Robert M. Califf M.D. cited Sunday's 60 Minutes segment on how giant, for-profit hospital group purchasing organizations (GPOs) caused the chronic, deadly shortages and soaring prices of hundreds of lifesaving generic drugs. He declared: "We have to do something about

our supply chain issue."
https://lnkd.in/ghtCdyFm. (1:04:55)

That "something" is to end the bribes, kickbacks, and sharebacks of these buying cartels---notably #Vizient, #PremierInc and #HealthTrust---via congressional repeal of the misbegotten 1987 Medicare antikickback "safe harbor." Incredibly, that statute, enacted at the behest of well-heeled hospital lobbyists, exempted GPOs from CRIMINAL prosecution for taking kickbacks from suppliers. That enables them to literally sell market share, in the form of sole source contracts, to the HIGHEST bidder. THEY ARE A "LEGALIZED" FRAUD. ThEY ARE LITERALLY KILLING PEOPLE, INCLUDING BABIES! TIME TO TAKE AWAY THEIR "GET OUT OF JAIL FREE CARD!" #fda #ftc #doj #potus #HHS #nationalsecuritycouncil #nationaleconomiccouncil

* * * * * *

The bipartisan draft legislation, attached, that would have prevented this scandal by restoring competition and integrity to this broken marketplace was drafted in 2005 by Senators Herb Kohl (D-WI) and Mike DeWine (R-OH). They presided over four hearings on anticompetitive GPO business practices before the Senate Antitrust Subcommittee. Tragically, the bill was killed by the GPO and hospital lobby and their dominant supplier cohorts.

Your quality rating system plan is another non-starter. It's just another way for these corrupt cartels to kick the drug shortage can down the road again. I now have documentation on the MILLIONS GPO insiders and CEOs of GPO shareholder hospitals are raking in from this scam. [They're called "sharebacks," aka bribes, paid to maintain hospital compliance with the GPO system, which has inflated hospital drug, device, and supply expense by at least 30%, or roughly $100BB/yr.] Now that the 60 Minutes segment has aired, I will make that material public in due course. Incidentally, one of your predecessors, Scott Gottlieb, is on the Vizient payroll. Vizient appears to have "hired" him because, in a fleeting moment of forthrightness, he told the AP in July 2018 that GPOs were responsible for the shortages. I expect that you'll be reading more about that soon. If they can't buy you to silence you, they threaten to get you fired.

Finally, NASEM's "supply chain resilience project was hijacked by the GPO industry. The result was a useless 336 page tome. It omitted any documentation and articles (incl footnotes) that on their face were critical of the GPOs. Further, at least one of the members of the University of Michigan committee, Erin Fox, failed to declare her numerous, documented conflicts of interest with the GPO industry. She is a lobbyist, PR spokesperson and consultant to Vizient, the largest GPO. She is employed by University of Utah Medical Center, a major Vizient shareholder facility, meaning that top UUMC hospital executives almost certainly receive undisclosed "share backs" (aka "patronage fees") from Vizient. See attached documentation from her Nov. 2017 FTC presentation on drug market competition, which I attended. I alerted FTC staff to this a month before the conference and believe they forced her to make these disclosures. The media calls her everytime they're assigned to write a drug shortage story because she owns the data. She is a big part of the problem. Medical societies, nonprofits, academics, thought leaders, former top federal officials are also on the GPO payroll. I am filing research misconduct complaints with HHS, DOJ and other appropriate federal agencies on this.

For more documentation, visit our website: www.physiciansagainstdrugshortages.com. Feel free to contact me if you'd like to discuss this further.

All the best
Phil Zweig M.B.A.
Executive Director/Co-founder
Physicians Against Drug Shortages (PADS)
www.philliplzweig.com
(212) 490-0811
(b) (6) (cell)

-----Original Message-----
From: CDER Executive Operations <CDEREXSEC@cder.fda.gov>
To: (b) (6)
Sent: Fri, Nov 8, 2019 1:54 pm
Subject: Response to your email to Dr. Norman Sharpless

Dear Mr. Zweig,

Please see the attached response to your email to Dr. Sharpless.

Thank you,
CDER Executive Operations Team
U.S. Food and Drug Administration

From: Peter Pitts (b) (6)
Sent: 5/27/2022 4:19:58 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: [EXTERNAL] Baby Formula Idea

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Sure. I hear that.

Peter J. Pitts

> On May 27, 2022, at 4:14 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:
>
> Peter, this is not very helpful. CDER is assisting CFSAN. We notified a huge number of people and entities as soon as we did the recall, including AAP, WIC (that supports about half of all formula) and the media. The problem was lack of clear numbers on supply, and the media stoking people to stock up--we have grandparents, pregnant women and friends all buying formula. Could have been done better of course, if we had better intel. jw
>
> -----Original Message-----
> From: Peter Pitts (b) (6)
> Sent: Friday, May 27, 2022 2:34 PM
> To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
> Subject: [EXTERNAL] Baby Formula Idea
>
> CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.
>

From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 5/27/2022 2:31:09 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
Subject: FYI: Bubs news release was issued

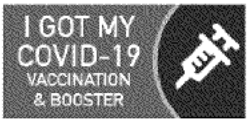
FYI. Our release on the Bubs Australia infant product enforcement discretion activity was issued a little awhile ago. Despite some data glitches internally, we were able to get this through our internal reviews, the company, HHS and WH in less than 24 hours. Thanks to Michael for navigating all this today.

https://www.fda.gov/news-events/press-announcements/fda-efforts-result-millions-additional-bottles-infant-formula-further-increase-us-supply

Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: (b) (6)
erica.jefferson@fda.hhs.gov

Executive Assistant: Kristen.Tugwell@fda.hhs.gov (temporary)



From: Peter Pitts (b) (6)
Sent: 5/27/2022 6:27:41 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: [EXTERNAL] Baby Formula Idea

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Wish Rib had shared this with the various committees. Can you share details so I can share more widely?

Peter J. Pitts

> On May 27, 2022, at 4:14 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:
>
> Peter, this is not very helpful. CDER is assisting CFSAN. We notified a huge number of people and entities as soon as we did the recall, including AAP, WIC (that supports about half of all formula) and the media. The problem was lack of clear numbers on supply, and the media stoking people to stock up--we have grandparents, pregnant women and friends all buying formula. Could have been done better of course, if we had better intel. jw
>
> -----Original Message-----
> From: Peter Pitts (b) (6)
> Sent: Friday, May 27, 2022 2:34 PM
> To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
> Subject: [EXTERNAL] Baby Formula Idea
>
> CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.
>

From: michael landa (b) (6)
Sent: 5/27/2022 12:18:56 AM
To: Califf, Robert (OLD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ed636c1d744f9a83d2cbbf53ec891c-Robert.Cali]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: [EXTERNAL] Infant Formula
Attachments: letter2drgottlieb.docx

Dear Commissioner Califf,

I am former Director and Deputy Director of CFSAN, and a former Acting Chief Counsel and Deputy Chief Counsel of the agency. I retired in January 2015, and generally make a point of staying out of the public eye and have not commented on agency matters for several years now.

I am writing because I worry that pressures surrounding the Abbott Infant Formula matter could cause the agency to proceed in a reckless manner. Accordingly, I urge you to avoid the rush to judgment the media, the Hill, and some of my former colleagues are calling for, and also to urge you to resist the cries for you to rearrange the deck chairs (resurrect the Office of Foods and Veterinary Medicine (OFVM)!; advocate for a single food agency!) or round up the usual suspects or scapegoats (e.g., Dr. Woodcock) on the theory there whatever mistakes were made, they had to have been the product of some fatal organizational flaw or official malfeasance – or both. Perhaps so, but one must first determine what happened, who did or didn't do what, who made – or failed to make -- what decisions, etc., before grappling the question of what might be done to minimize the risk of, if not prevent, a recurrence. In my own view, the inquiry should include the role of work-from-home policies and practices and how the agency does or does not use state officials and employees in conducting inspections of food manufacturing establishments.

I have taken the liberty of attaching a June 15, 2017 letter I wrote to Commissioner Gottlieb about OFVM, so that you know my view of it.

Sincerely,

Michael M. Landa
(b) (6)

May 27, 2022

(b) (6)

June 15, 2017

Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

I hope this letter finds you well. I am a former Director and Deputy Director of CFSAN, and a former Deputy Chief Counsel and Acting Chief Counsel. Our paths crossed during your previous tenure at FDA. I retired in January 2015.

I write in response to Executive Order 13871 "Comprehensive Plan for Reorganizing the Executive Branch" to improve its efficiency, effectiveness, and accountability. To these ends, I suggest that you abolish the Office of Foods and Veterinary Medicine (OFVM), and consider abolishing the other directorates. I suggest abolishing OFVM but only consider abolishing the others because I have direct knowledge of the activities and budgetary and other costs of OFVM alone.

Dr. Hamburg established the directorates to reduce the Commissioner's number of direct reports. I don't know whether the directorates accomplished that goal, but they did have the effect of putting a layer between the Commissioner and the centers. That always struck me as both odd and unfortunate, because without the centers, there would not be an FDA. I spent 19+ of my 29+ years at FDA in OCC (9+ in CFSAN), and have profound respect for the Office of the Commissioner and most of its component parts. But if they all disappeared tomorrow, FDA would continue to function, even if the work products would sometimes suffer. By contrast, if the centers disappeared tomorrow, FDA would come to a halt, as medical product approvals and withdrawals and implementation of FSMA and other statutes would cease. So, to my mind, the Commissioner, with or without a Principal Deputy, should be meeting on a regular basis with every center director, unaccompanied by the head of a directorate.

That aside, I think one must ask what a directorate adds, and at what cost. In the case of OFVM, Michael Taylor brought a wealth of food safety knowledge and expertise, and Stephen Ostroff brings deep public health experience and expertise, but that was (and is) hardly a reason to establish (or maintain) a directorate, especially one that housed 88 FTE and cost $20.3M in fy 2015, the most recent year for which I have information about the OFVM budget. With two or three exceptions, there was not and has not been any other person in

OFVM with food safety or public health expertise to speak of, or with nationally recognized nutrition expertise, and the only microbiologist or chemist in OFVM with expertise recognized outside FDA left last year.

To the extent there was a case for OFVM in 2011, when FSMA became law, that case has evaporated, as all the foundational rules have issued, and ORA's program alignment has been stood up.[1] I gather that a pending reorganization would reduce OFVM by roughly 50%, but that begs the question of what the remaining half adds to the food safety and nutrition endeavors. To take two examples: the research function in CFSAN is headed by its Deputy for Scientific Operations (a chemist who in 2016 received the Frances O. Kelsey Award for pioneering leadership in the application of whole genome sequencing to food safety, principally outbreak response (sequencing work opposed by OFVM at the time!); a senior advisor for microbiology (a microbiologist who was a professor and chair of the Department of Nutrition and Food Science at Maryland and a professor of Food Microbiology at the University of Florida); and a number of well-seasoned and highly credentialed office directors. What can a science unit in OFVM reasonably be expected to add to the team in question? In nutrition, CFSAN has both Dr. Mayne and a Senior Advisor for Nutrition Policy in her immediate office, and a highly credentialed expert with years of industry experience who heads the Office of Nutrition and Food Labeling. Again, what is it that nutritionists in OFVM can reasonably be expected to add?

My point is not that the OFVM employees are not able; my point is that in their current positions in OFVM there is not any significant value for them to add. Beyond that, much the structure they are in can and does imperil progress in CFSAN. That is in part because of the unavoidable confusion over roles and responsibilities and in part because of the transactional and other inescapable frictions when a layer is added. Other OFVM functions, e.g., communications, budget, and international, are conducted within both CFSAN and the Office of the Commissioner. What is it that necessitates another staff, or leaders or managers, in still another organization, i.e., OFVM?

I do not mean to suggest that CFSAN is without weaknesses; it has many of them. But the way to address them is by strengthening CFSAN, not by maintaining an oversight structure above it. That structure not only adds a layer and duplication of myriad functions -- which is bad enough; worse still, it diminishes CFSAN and every leader and manager in it, as every leader and

[1] Further, the nutrition and supplement facts labels and serving sizes regulations have been updated (notwithstanding the delays in implementation), the menu labeling final rule is in place (again, notwithstanding the delays in implementation), the food additive status of partially hydrogenated oils has been declared, and draft sodium guidance has issued.

manager moves down one slot. This includes the CFSAN director, who no longer reports and is accountable to the Commissioner but, instead, reports and is accountable to the head of OFVM.

Irrespective of who is running OFVM or CFSAN, the additional layer inevitably means less independence and authority throughout CFSAN. That, in turn, means less initiative, because "bottom up" is much harder when the bottom has been pushed down. Retaining and recruiting top notch senior people, always a challenge, become almost impossible, as the diminishment is felt by employees on board and eyed by potential hires. Recruiting of senior talent was more successful in CFSAN before OFVM, and OFVM itself recruited to OFVM almost no one of stature outside FDA.

I would be happy to discuss these suggestions and observations if you like. I may be reached at (b) (6) or by email at [HYPERLINK "mailto(b) (6)].

Sincerely,

Michael M Landa

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 2/24/2022 2:09:04 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Rawlings, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae46d13993dc46e190ae70b61e1d4871-KRawling]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
CC: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Mettler, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]

Subject: Canceled: Infant Formula Recall Informational Update
Location: Zoom details below.

Start: 3/1/2022 1:45:00 PM
End: 3/1/2022 2:00:00 PM
Show Time As: Free

Importance: High

Required Attendees: Tierney, Julia; Rawlings, Kimberly; Woodcock, Janet; Colonius, Tristan; Mayne, Susan; McMeekin, Judith; Yiannas, Frank; Jefferson, Erica; Rabin, Tara G.
Optional Attendees: Fristedt, Andi; Harris, Stic; Boon, Caitlin; Mettler, Erik; Rogers, Michael; Copeland, Jakea

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 3/5/2022 10:13:33 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]

Subject: [HOLD] Infant Formula Update (60 mins / 30 mins as alternate)

Start: 3/10/2022 9:30:00 AM
End: 3/10/2022 10:30:00 AM
Show Time As: Tentative

Required Attendees: Tierney, Julia; Woodcock, Janet

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 3/5/2022 10:12:37 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]

Subject: [HOLD] Infant Formula Update (60 mins / 30 mins as alternate)

Start: 3/10/2022 11:30:00 AM
End: 3/10/2022 12:30:00 PM
Show Time As: Tentative

Required Attendees: Tierney, Julia; Woodcock, Janet

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 3/5/2022 10:14:52 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]

Subject: [HOLD] Infant Formula Update (60 mins / 30 mins as alternate)

Start: 3/9/2022 3:30:00 PM
End: 3/9/2022 4:30:00 PM
Show Time As: Busy

Required Attendees: Tierney, Julia; Woodcock, Janet

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 3/5/2022 10:11:44 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Mettler, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]; Hermsen, Catherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a671332f224deea657d04b505eedf6-Catherine.H]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Dickinson, Elizabeth (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05cb143d66ed470ebe4dba5c54a88074-EDickins]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
CC: Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Hodnette, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]; Lockeed, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2fe9a22e8f940fa8761fad18ef37dd0-Matthew.Loc]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]

Subject: Infant Formula Update
Attachments: 1445-FDA Abbott infant formula timeline final.pptx
Location: Zoom, details below

Start: 3/9/2022 2:45:00 PM
End: 3/9/2022 3:30:00 PM
Show Time As: Busy

Required Attendees: Tierney, Julia; Woodcock, Janet; McMeekin, Judith; Yiannas, Frank; Mayne, Susan; Raza, Mark; Jefferson, Erica; Fristedt, Andi; Rogers, Michael; Mettler, Erik; Hermsen, Catherine; Stearn, Douglas; Harris, Stic; Boon, Caitlin; Dickinson, Elizabeth (FDA); Beckerman, Peter; Rabin, Tara G.; Colonius, Tristan

Optional Attendees: Trzeciak, Kimberlee; Hodnette, Jonathan; Lockeed, Matthew; Felberbaum, Michael

Hi there,

FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: +16692545252,,(b) (6) or +16692161590,,(b) (6)

Meeting URL: https://fda.zoomgov.com(b) (6)

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Passcode: (b) (6)

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H.323: (b) (6) (US West)
(US East)

Meeting ID: (b) (6)

Passcode: (b) (6)

SIP: (b) (6)

Passcode: (b) (6)

U.S. FOOD & DRUG ADMINISTRATION

FDA Timeline: Abbott Nutrition – Sturgis, MI Facility Inspection and Powered Infant Formula Recall

March 9, 2022, update

Abbott Nutrition – Sturgis 10-year History

Date of inspection	Inspection type	Classification
9/2021	Surveillance	VAI
9/2019	Surveillance	VAI
9/2018	Surveillance	NAI
9/2017	Surveillance	NAI
9/2016	Surveillance	NAI
3/2016	For-cause/consumer complaint (GI illness)	NAI
9/2015	Surveillance	NAI
6/2014	Surveillance	NAI
12/2013	For-cause/fortifier recall in Canada	NAI
6/2013	Surveillance	NAI
10/2012	For-cause/consumer complaint (foreign object)	NAI
6/2012	Surveillance	NAI

Five Complaints Received in Five Months

Date received	Issue	Determination
9/20/2021	• HAFW1 received a *Cronobacter* sakazakii complaint from the Minnesota Department of Health; infant taken to the hospital on 9/6 and diagnosed with Cronobacter sakazakii on 9/9; discharged on 9/28 • 9/20: Sturgis facility told FDA they did not have similar complaints from the lot • 9/23: HAFW1 collected 2 unopened cans and 1 opened can of Similac Sensitive Infant Formula Milk-Based Powder from hospital • 9/30: MDH sent open can to CDC for testing, along with opened container of distilled water • 10/11: MDH sent patient/clinical isolate to CDC	• Southeast Food and Feed Laboratory in Atlanta tested and found no Cronobacter sp. recovered in samples (10/6) • CDC testing recovered *Cronobacter sakazakii* from the infant formula; additional *Cronobacter* species were recovered from the infant formula and the opened water
10/26/2021	• Lawyer of confidential informant sent 34-page document detailing the informant's allegations of the firm's non-compliance with 21 CFR Parts 101, 106, and 117, and allegations of falsification of records and misleading an FDA investigator during an inspection • OCI informed due to possible criminal allegations; no case opened due to lack of specifics • 12/22: HAFE6 and national expert interviewed informant	• Team believed the information provided was very vague and there was nothing specific enough to follow up on during the inspection

Five Complaints Received in Five Months (con't)

Date received	Issue	Determination
11/17/2021	• DAL-DO received a complaint from the Texas Department of State Health Services regarding a positive *Salmonella* culture from an infant that was fed Similac Alimentum Infant Formula Powder • 11/19: HAFW3 collected one opened can from the consumer and five unopened cans from a different lot from the infant's pediatrician	• SFFL in Atlanta analyzed both samples for *Salmonella* and classified as negative
12/1/2021	• CIN-DO received a complaint from the Ohio Department of Health regarding the death of an infant that was fed Similac Pro-Total Comfort Infant Formula Powder • Post-mortem cerebrospinal fluid cultures grew *Cronobacter sakazakii* and *Proteus mirabilis*, and a post-mortem blood culture grew Group B streptococcus • 12/6-7: HAFE5 collected retain samples of the same lot from the Abbott Nutrition – Columbus, OH facility, 1 unopened can of the same lot from the health department, and 2 unopened cans of the same lot from the pediatrician's office	• ODH collected the opened can of formula from the health department and no *Cronobacter* was detected • SFFL analyzed the samples for *Cronobacter* and classified as negative
1/11/2022	• DAL-DO received a complaint from TDSHS regarding a confirmed positive case of *Cronobacter sakazakii* and bacterial meningitis in an infant that was fed Similac Advance Optigro powdered infant formula • Original sample had already been discarded by the hospital • Local health department collected one opened can and one unopened can from the hospital	• TDSHS analyzed the samples and no *Cronobacter* was detected

Current Case Counts and *Cronobacter* Surveillance

- **Total adverse events (to date)**
  - 5 (4 *Cronobacter*, 1 Salmonella)
  - All 5 were hospitalized, including 2 deaths (*Cronobacter* infection may have contributed to the cause of death for both infants)
  - The adverse events were reported between 9/16/2021 and 1/4/2022
  - States with Adverse Events: MN (1), OH (2), TX (2)
  - Product Distribution: Nationwide and International
- ***Cronobacter* surveillance**
  - *Cronobacter* infection surveillance is not handled the same way as infection with more common foodborne pathogens, such as *Salmonella* or *E. coli* O157:H7.
  - *Cronobacter* is not nationally notifiable and not reportable, except in one state.
  - FDA relies on consumer complaints of illness sent to the agency and on health care providers informing FDA directly about infants with *Cronobacter* infections.
  - Whole genome sequencing (WGS) is rarely performed on these isolates. To date, no outbreaks of *Cronobacter* have been detected using WGS.
  - When single cases of *Cronobacter* are reported, the FDA conducts a thorough review of each complaint, conducts sampling of products, and initiates inspections as appropriate.
  - FDA collaborates with CDC, which has developed a detailed questionnaire specifically for *Cronobacter* infections that is often used by state health departments in instances of *Cronobacter sakazakii* infection.

2022 For-Cause Inspection

- **12/30/2021:** ORA preannounced inspection to begin on 1/3/2022
  - Facility informed ORA of 12 COVID-positive employees
  - Inspection postponed until 1/31
  - **1/27:** ORA preannounced inspection for 1/31
    - Facility again informed ORA of COVID-positive employees
    - Received clearance to initiate inspection as scheduled with safety plan to ensure investigators' safety
  - **2/1-3:** Environmental swabbing for *Cronobacter* and *Salmonella*
    - 2/7: SFFL in Atlanta reported 14 environmental swabs as cannot rule out for *Cronobacter*
  - **2/8, ~10 p.m. ET:** ACRA notification
  - **2/9, ~7 a.m. ET:** ACRA notification sent to Foods Program; leadership meeting
  - **2/10:** CORE begins coordinating an outbreak response
  - **2/17:** CFSAN stood up a sit-rep report to complement the CORE report and capture ancillary activities (with AAP, USDA, supply chain, etc.)
  - **3/1:** ORA stands up IMT
  - Inspection wrap up planned for 3/16 or 3/17

FDA Lab Result Highlights

FDA Sample Status	As of March 7, 2022
Collected samples	**42** • 12 environmental samples (584 total swabs) • 1 sample consisting of 3 isolates from Abbott • 29 products samples (collected from firm and consumers, number of sub samples vary)
Samples completed	**29** • 2 environmental samples were positive for *Cronobacter sakazakii* and designated lab class 3 (4 swabs total were positive, resulting in 4 unique strains of the organism) • 16 product samples have been completed as designated Lab Class 1 • No samples have tested positive for *Salmonella* • None of the FDA product or environmental samples match by WGS to CDC samples
Samples pending	**13** • 4 product samples are in progress • 9 product samples have not begun testing

Initial Voluntary Recall

- **2/15 at 5 p.m. EST:** FDA recommended firm voluntarily recall powered infant formulas
  - During this call, FDA informed Abbott the agency was going to issue a consumer advisory about the safety of the product
  - FDA's recommendation was based on:
    - Positive samples found
    - Knowledge of positive product
    - Four consumer complaints related to *Cronobacter sakazakii* or *Salmonella* Newport in infants who had consumed powder infant formula manufactured in Sturgis facility
  - This recommendation came after FDA asked Abbott if they were concerned about the safety of their infant formula on 2/14; they saw no data to indicate a concern
- **2/17 (midnight call):** Abbott agreed to recall
- **2/17 at 5 p.m. EST:** FDA issued a press release and consumer advisory (with product images)
  - Alerted consumers to avoid Similac, Alimentum and EleCare powdered infant formula produced in the Sturgis facility
  - Distributed: Nationwide and international
  - Abbott's issued a press release the same day
- **Additional Stakeholder Outreach:**
  - **2/11:** CFSAN ONFL contacted USDA WIC (several follow ups have occurred)
  - **2/16:** White House, American Academy of Pediatrics
  - **2/18:** Other manufacturers to address potential shortages
  - **2/19:** 50-state call/email (follow up on 2/25)
  - **2/21:** Hospitals, insurers

Expanded Voluntary Recall

- **2/28:** Abbott expanded its voluntary recall to include one lot of Similac PM 60/40, also manufacturing in Sturgis, MI
  - Abbott agreed to expand the recall 2/28
  - Specialty formula for certain infants who would benefit from lowered mineral intake
  - Distributed: U.S. and Israel
  - This followed the death of an infant who tested positive for *Cronobacter sakazakii* who consumed Similac PM 60/40 from this lot
    - This case is under investigation, and the cause of the infant's *Cronobacter sakazakii* infection has not been determined
  - Abbott's press release stated: "… no distributed product has tested positive for the presence of *Cronobacter sakazakii*. Additionally, recently tested retained product samples of Similac PM 60/40 Lot # 27032K80 (can) / Lot #27032K800 (case) were negative for *Cronobacter.*"
- **Audit checks update**
  - **2/24:** Recall audit check assignments were issued
  - Product continued to be shipped after recall initiation; Abbott is following up with these consignees
  - To date: 5 recall audit checks have found the direct account did not receive notification from Abbott


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
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To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]

Subject: HOLD: Infant Formula

Start: 3/29/2022 3:00:00 PM
End: 3/29/2022 4:00:00 PM
Show Time As: Tentative

POC: Lindsay T.

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/17/2022 2:33:33 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]

Subject: HOLD: Infant Formula

Start: 3/28/2022 4:00:00 PM
End: 3/28/2022 5:00:00 PM
Show Time As: Tentative

POC: Lindsay T.

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/17/2022 2:32:35 PM
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Subject: HOLD: Infant Formula

Start: 3/29/2022 1:00:00 PM
End: 3/29/2022 2:00:00 PM
Show Time As: Tentative

POC: Lindsay T.

From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 2/17/2022 7:33:45 AM
To: Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Oxenham, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b682119aebb490b87abe0fc19b0c09d-Ann.Oxenham]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Weissinger, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50137b0c8c77450da27e941c2f69d16f-WWeissinger]; Irvin, Kari [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9fea0d41738d458282b5e0ab147de54d-Kari.Irvin]; Blickenstaff, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4804d4a3c9cc44be94f0ee65fa4d7d9a-Karen.Blick]; Newhart, Corinne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=656a525a42e547959efea21ab442bcd6-Corinne.New]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Farrar, Jeff A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c862ce01b6714d4c9c5057306240469e-Jeff.Farrar]; Prater, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=291b4eab842148baba96df3bd8c31058-DPRATER]; Christin, Charlotte - OC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcdfee4fbc934caf9a9557480f759d28-Charlotte.C]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]
CC: Smoot, Leslie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbebf67a5fa842c2bd91085804b2a087-Leslie.Smoo]; Klontz, Karl C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f034aab9aa2d44d5ab4a6a036be0686b-KKLONTZ]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Abbott Nutrition

Internal, Confidential

Thanks everyone. Right outcome.

Infant formula manufacturers have this down and a playbook on how to push back based on low probability end-product testing plans.

The fact that they agreed is, in my opinion, a direct result of the evidence we collected and the way the team laid this out.

It's the right public health outcome. I appreciate everyone's willingness to engage in such open discussion, with passion and conviction, over the past couple of calls.

Everyone…and I mean everyone….deserves recognition for a job well done.

But I also want to give a special shout-out to our subject matter experts, **Les Smoot** and **Karl Klontz**. I found their input to be extremely valuable, articulate, and persuasive. Thank you gentlemen.

Right outcome on behalf of one of the most sensitive consumer groups we serve.

Frank Yiannas
Deputy Commissioner, Food Policy & Response
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20993
Tel: 301-796-4665
frank.yiannas@fda.hhs.gov

From: Harris, Stic <stic.harris@fda.hhs.gov>
Sent: Thursday, February 17, 2022 1:03 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Weissinger, William <William.Weissinger@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Blickenstaff, Karen <Karen.Blickenstaff@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>
Subject: Abbott Nutrition
Importance: High

Good morning,

Just off an intimate midnight call with Monica from Abbott Nutrition, as well as Michael Rogers, Ann Oxenham, and the Division (Bill Weissinger and Darren Morgan). (b) (5) [redacted]

[redacted]::

All,

(b) (5) [redacted]

[redacted]

[redacted]

Certainly a lot to talk about later this morning.
And it appears I owe Doug a beer.

Thanks,

Stic

Stic Harris, DVM, MPH
Director

(he/him/his)

Coordinated Outbreak Response and Evaluation (CORE) Network
Cell: (b) (6)
Stic.Harris@fda.hhs.gov

From: Boon, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=11917EB34D5445C3802EEF2A3999E2E3-CAITLIN.BOO]
Sent: 2/16/2022 9:32:41 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Romano, Lisa M. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9653957f210f4febb1c12c64207346d4-LROMANO]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Prater, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=291b4eab842148baba96df3bd8c31058-DPRATER]; Farrar, Jeff A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c862ce01b6714d4c9c5057306240469e-Jeff.Farrar]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]
Subject: Food Safety Update #3 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation
Attachments: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

FOOD SAFETY UPDATE

U.S. FOOD & DRUG ADMINISTRATION

From the Office of Food Policy and Response

Internal, Privileged, & Confidential

We want to provide you with a brief update on the *Cronobacter* sakazakii illnesses associated with powdered infant formula as a suspect vehicle, as this remains an evolving situation.

Actions Today

- Two additional calls were held with the firm today to collect additional information on the possible scope of contaminated products and to encourage the firm again to implement a recall. The firm has yet to agree to a recall despite numerous environmental positives for C. sakazakii in the facility from FDA sampling and from the firm's own sampling, along with significant Good Manufacturing Practice deficiencies. This evening, a draft Consumer Advisory was shared with Abbott Nutrition to further encourage the firm to initiate a recall prior to issuance of the FDA Consumer Advisory tomorrow.

- FDA also learned that Abbott Nutrition discarded a previous production lot of powdered infant formula due to contamination with Cronobacter.

- FDA investigators are conducting additional swabbing of recently disassembled equipment in the Sturgis, MI facility.

- WGS continues for isolates from sub samples that were confirmed positive earlier in the week.

- Discussions continued with the WIC Program to prepare for the forthcoming announcement.

- FDA transmitted a briefing paper to the White House Supply Chain Taskforce to provide situational awareness.

Next Steps

- A draft Consumer Advisory is currently in clearance and will issue tomorrow. The advisory will inform consumers to avoid powdered infant formula from the Sturgis, MI facility with expiration dates after June 2022, and will include brands and specific label codes information to assist consumers in identifying the product manufactured at the Sturgis facility.

- A press release is also being prepared for issuance tomorrow.

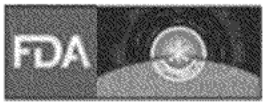
- We are preparing for further coordination with external groups such as the American Academy of Pediatrics to amplify messaging and prepare providers to give individualized advice to patients that may need to change feeding practices.

- We are preparing to do early morning outreach to retail stakeholders (e.g., Food Marketing Institute and National Grocers Association) to request that retailers implement measures to reduce hoarding (e.g., restricting the quantities of infant formula that can be purchased in a single shopping event).

As usual, we will keep you updated on any noteworthy developments as the investigation continues.

Caitlin Boon, Ph.D.
Associate Commissioner for Food Policy and Response

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
(b) (6)
Caitlin.Boon@fda.hhs.gov



From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
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Subject: HOLD: Infant Formula

Start: 3/29/2022 12:00:00 PM
End: 3/29/2022 12:30:00 PM
Show Time As: Busy

POC: Lindsay

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
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Subject: [HOLD] Congressional Briefing on Infant Formula/Medical Food Authorities and Needs

Start: 4/4/2022 3:30:00 PM
End: 4/4/2022 5:00:00 PM
Show Time As: Busy

POC: Shera Moxley

Parti

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
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Subject: [HOLD] PREP: Congressional Briefing on Infant Formula/Medical Food Authorities and Needs

Start: 4/4/2022 3:30:00 PM
End: 4/4/2022 5:00:00 PM
Show Time As: Busy

POC: Shera Moxley

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
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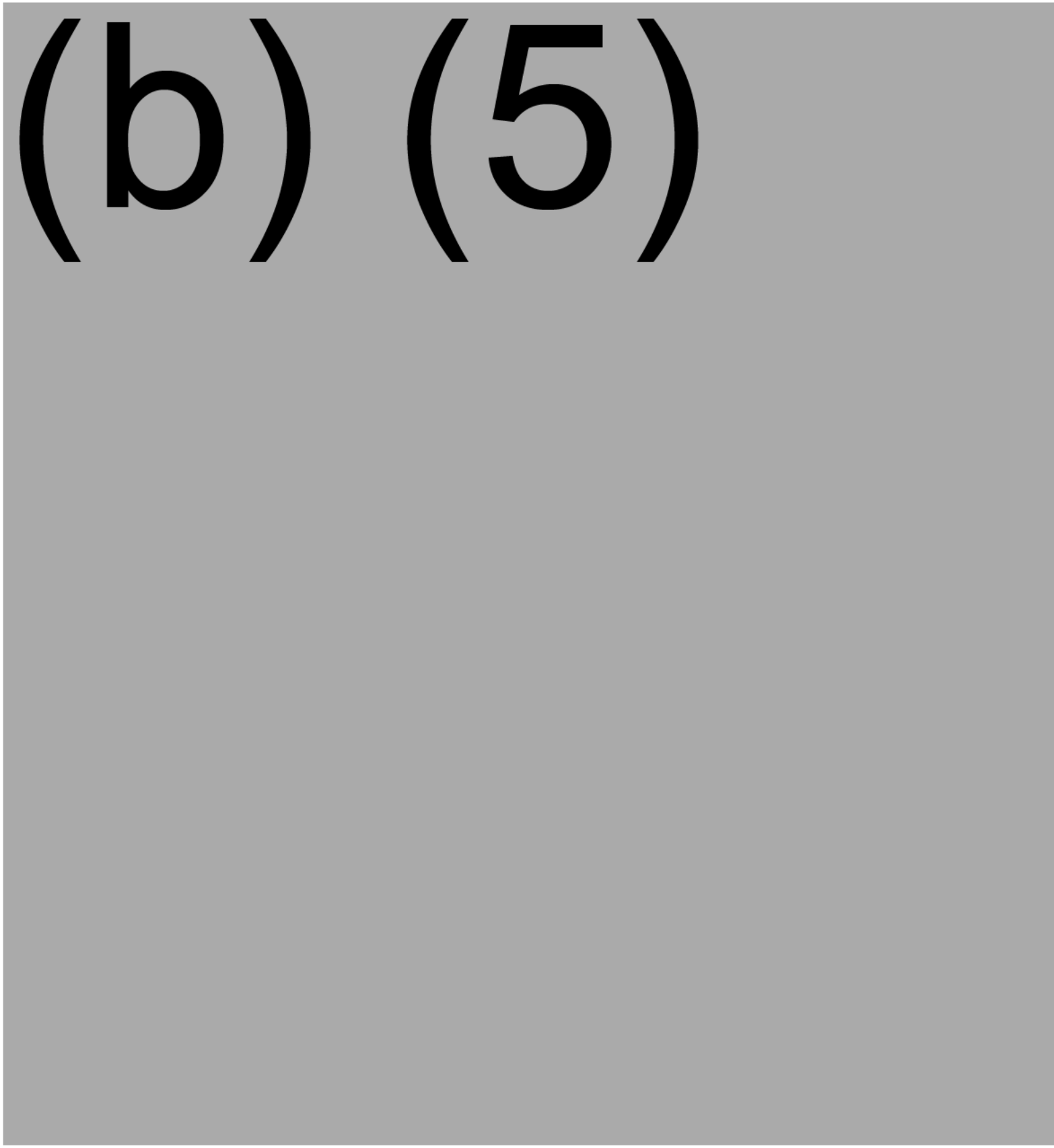
CC: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Mettler, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]

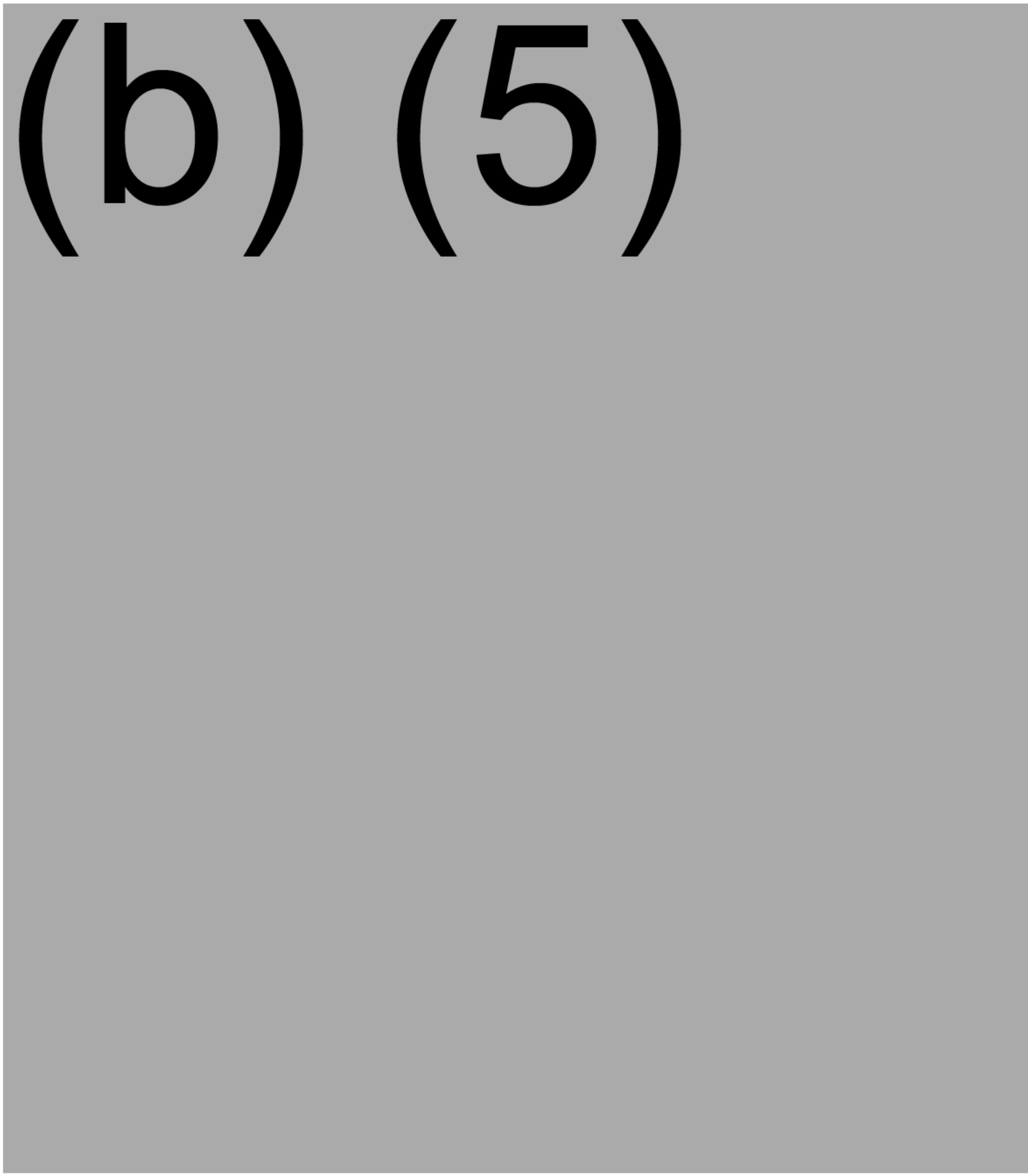
Subject: Canceled: Infant Formula Recall Informational Update
Location: Zoom details below.

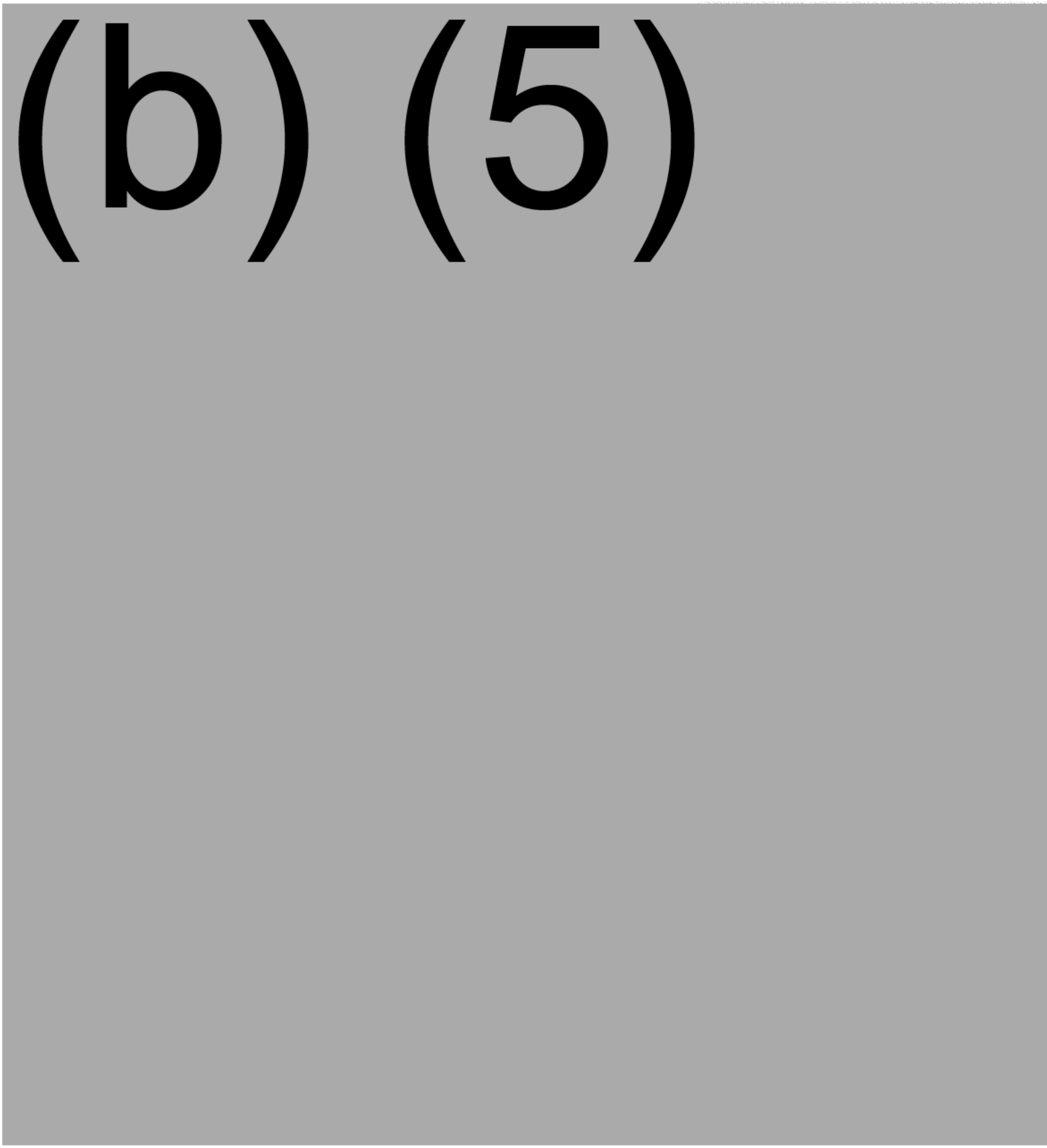
Start: 3/1/2022 1:45:00 PM
End: 3/1/2022 2:00:00 PM
Show Time As: Free

Importance: High

Required Attendees: Tierney, Julia; Rawlings, Kimberly; Woodcock, Janet; Colonius, Tristan; Mayne, Susan; McMeekin, Judith; Yiannas, Frank; Jefferson, Erica; Rabin, Tara G.
Optional Attendees: Fristedt, Andi; Harris, Stic; Boon, Caitlin; Mettler, Erik; Rogers, Michael; Copeland, Jakea


(b) (5)


(b) (5)


(b) (5)

From: Moxley, Shera [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2DBDDBF813674D38AC4A43176E2398E4-SHERA.MOXLE]
Sent: 3/28/2022 1:40:22 PM
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CC: Trzeciak, Kimberlee [Kimberlee.Trzeciak@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Goitom, Mahlet [Mahlet.Goitom@fda.hhs.gov]; Kehoe, Brian (OS) [Brian.Kehoe@hhs.gov]; Espinosa, Kimberly (OS) [Kimberly.Espinosa@hhs.gov]; ASLcalendar@hhs.gov

Subject: Zoom Briefing for HELP maj/Duckworth/Klobuchar staff on Infant Formula
Location: Zoom

Start: 4/5/2022 4:00:00 PM
End: 4/5/2022 4:30:00 PM
Show Time As: Busy

Required Attendees: Mayne, Susan; Woodcock, Janet
Optional Attendees: Trzeciak, Kimberlee; Tantillo, Andrew; Goitom, Mahlet; Kehoe Brian; Espinosa, Kimberly (OS); ASLcalendar@hhs.gov

Briefing for: Staff of HELP majority, Duckworth, Klobuchar
Topic: Infant Formula Regulation
Nature of their interest: General overview of how FDA regulates infant formula, particularly with regard to adequate nutritional content and safety assurance. (Not focused on the Abbott recall.)
Proposed scope of the engagement: (b) (5) [redacted]
OL Lead: Shera Moxley

Requested engagement date: April 5, 2022, 4:00-4:30p.
Phone or in-person: Zoom (audio/video)
FDA Briefers: Principal Deputy Commissioner Janet Woodcock, CFSAN Director Susan Mayne

[redacted]

Hi there,

Shera.Moxley@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: +16692545252,,(b) (6) [redacted] or +16468287666,,(b) (6) [redacted]

Meeting URL: https://fda.zoomgov.com(b) (6)
Meeting ID: (b) (6)

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Meeting ID: (b) (6)

International numbers

Join from an H.323/SIP room system

H.323: (b) (6) (US West)
(US East)

Meeting ID: (b) (6)

SIP: (b) (6)

From: Moxley, Shera [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2DBDDBF813674D38AC4A43176E2398E4-SHERA.MOXLE]
Sent: 3/28/2022 1:48:20 PM
To: Moxley, Shera [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dbddbf813674d38ac4a43176e2398e4-Shera.Moxle]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Goitom, Mahlet [Mahlet.Goitom@fda.hhs.gov]; CFSANEXECSEC [CFSANEXECSEC@fda.hhs.gov]; Carey, Emily Rose [EmilyRose.Carey@fda.hhs.gov]

Subject: Prep: Briefing for HELP maj/Duckworth/Klobuchar on Infant Formula
Location: Microsoft Teams Meeting

Start: 4/4/2022 3:30:00 PM
End: 4/4/2022 4:00:00 PM
Show Time As: Busy

Required Attendees: Mayne, Susan; Woodcock, Janet
Optional Attendees: Goitom, Mahlet; CFSANEXECSEC; Carey, Emily Rose

Materials forthcoming.

Microsoft Teams meeting

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From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/10/2022 10:02:29 AM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Smpokou, Patroula [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=361685f4efaa4d988bfafbe7d72c5228-Patroula.Sm]; Baer, Gerri [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dff3ad85ef047108db7d78fd1ce7893-Gerri.Baer]; Massaro, An [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45eac3f386c648c7b898f0341ca9ea12-An.Massaro]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Lotze, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e03cd80247c94486b9c4f4d1a0a9dfaf-Andrea.Lotz]; Yao, Lynne P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44c49d36f43f45f59347b5441ef45876-YAOLY]; Khurana, Mona [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6c995bded01e43c3a9a35a40d876d2b8-KHURANAMO]

Subject: Infant Formula
Location: Microsoft Teams Meeting

Start: 3/10/2022 11:30:00 AM
End: 3/10/2022 12:00:00 PM
Show Time As: Busy

Required Attendees: Mayne, Susan; Smpokou, Patroula; Baer, Gerri; Massaro, An; Boon, Caitlin; Kavanaugh, Claudine; Lotze, Andrea; Yao, Lynne P; Khurana, Mona

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Microsoft Teams meeting

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From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
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Subject: Canceled: [HOLD] Infant Formula Update (60 mins / 30 mins as alternate)

Start: 3/10/2022 9:30:00 AM
End: 3/10/2022 10:30:00 AM
Show Time As: Free

Importance: High

Required Attendees: Tierney, Julia; Woodcock, Janet

From: Smpokou, Patroula [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=361685F4EFAA4D988BFAFBE7D72C5228-PATROULA.SM]
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To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Infant formula recall

Yes, absolutely. would be good to get a sense of the background/context so I can think about who else may be helpful here. I am free to talk any time. Just let me know a good time for you and I can call you.

Thank you,

Patroula

~~~~~~

Patroula Smpokou, MD
Deputy Director
Division of Rare Diseases & Medical Genetics
Office of Rare diseases, Pediatrics, Urologic & Reproductive Medicine
Office of New Drugs | Center for Drug Evaluation & Research

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 10, 2022 8:36 AM
To: Smpokou, Patroula <Patroula.Smpokou@fda.hhs.gov>
Subject: FW: Infant formula recall

Also if you'd like to talk to see if there are any additional people you want to add, let me know we can have a quick call. JanetW

From: Stein, Peter <Peter.Stein@fda.hhs.gov>
Sent: Thursday, March 10, 2022 7:59 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: Infant formula recall

Janet, I'd suggest including Patroula Smpokou from DRDMG – she can then pull in any one else from that division needed based upon the specific info from CFSAN. I'm waiting for the name of a nutritionist from DHN, and will forward that name as once I get it,
peter

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 8:37 PM
To: Stein, Peter <Peter.Stein@fda.hhs.gov>
Subject: Fwd: Infant formula recall
~~~~~~

Could you advise?

Patrizia

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 6:10:53 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Green, Dionna <Dionna.Green@fda.hhs.gov>
Subject: Infant formula recall

FDA is working on a recall of infant formula made by Abbott at a single plant for potential bacterial contamination. Unfortunately this plant also makes a variety of special formulas for rare metabolic diseases. These have not been recalled and are of unknown risk. (b) (5) [redacted].

(b) (5) [redacted]. Some mitigation measures are available and are posted by CDC. (b) (5) [redacted].

(b) (5) [redacted] Does CDER and OPT have people who are versed in this area? I'd like to get a discussion together tomorrow. Thanks. Jw

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 3/5/2022 10:12:37 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]

Subject: Canceled: [HOLD] Infant Formula Update (60 mins / 30 mins as alternate)

Start: 3/10/2022 11:30:00 AM
End: 3/10/2022 12:30:00 PM
Show Time As: Free

Importance: High

Required Attendees: Tierney, Julia; Woodcock, Janet

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/17/2022 4:42:42 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: RE: Comms around infant formula

Will work on answers to these questions and get back to you. More to come.

Susan

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Thursday, March 17, 2022 4:21 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: RE: Comms around infant formula

Hi Susan,

(b) (5)

Best,
Erica

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 17, 2022 1:37 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Comms around infant formula

Just to provide some further explanation on the comment (that we ran out of time to discuss) on communicating the importance of risk of cronobacter in the home environment, this is an issue our infant formula SMEs raised since the very beginning of this incident. It is one of the reasons there exist recommendations on handwashing etc. while doing formula preparation or using products like baby bottles, breast pump parts, etc. (a whole section on CDC website on this topic in relation to cronobacter).

The other piece you probably are not aware of, is that CDC had a suspect cronobacter case that they had been evaluating for possible inclusion in this incident as the baby had consumed Abbott product (which would have given us 5 possible cases). But WGS demonstrated cronobacter on the breast pump surface that matched the clinical isolate for that baby; that breast pump had only been used in the home. For that reason, CDC is going to remove that case from the series of cases that were being considering associated with Abbott (leaving us with the 4 cases I mentioned, 3 of whom had isolates available for sequencing).

So, the comment about educating consumers about things they can do to prevent contamination in the home in our future comms is based on current (real-world?) evidence and common knowledge.

Hope that helps give context as we draft communications messages (and potentially even something Janet/Rob could say before we communicate broadly about the current situation?) Emphasizing cronobacter 101.

Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/17/2022 2:33:33 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]

Subject: HOLD: Infant Formula HHS Briefing

Start: 3/28/2022 4:00:00 PM
End: 3/28/2022 5:00:00 PM
Show Time As: Tentative

POC: Lindsay T.

From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 3/17/2022 6:11:23 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: RE: Comms around infant formula

DRAFT- DELIBERATE-CONFIDENTIAL

(b) (5)

In terms of education, I would be quite supportive. I can discuss with Jen as well; as I said earlier CDC already has a whole webpage on this as a start (scroll down on weblink): https://www.cdc.gov/cronobacter/infection-and-infants.html

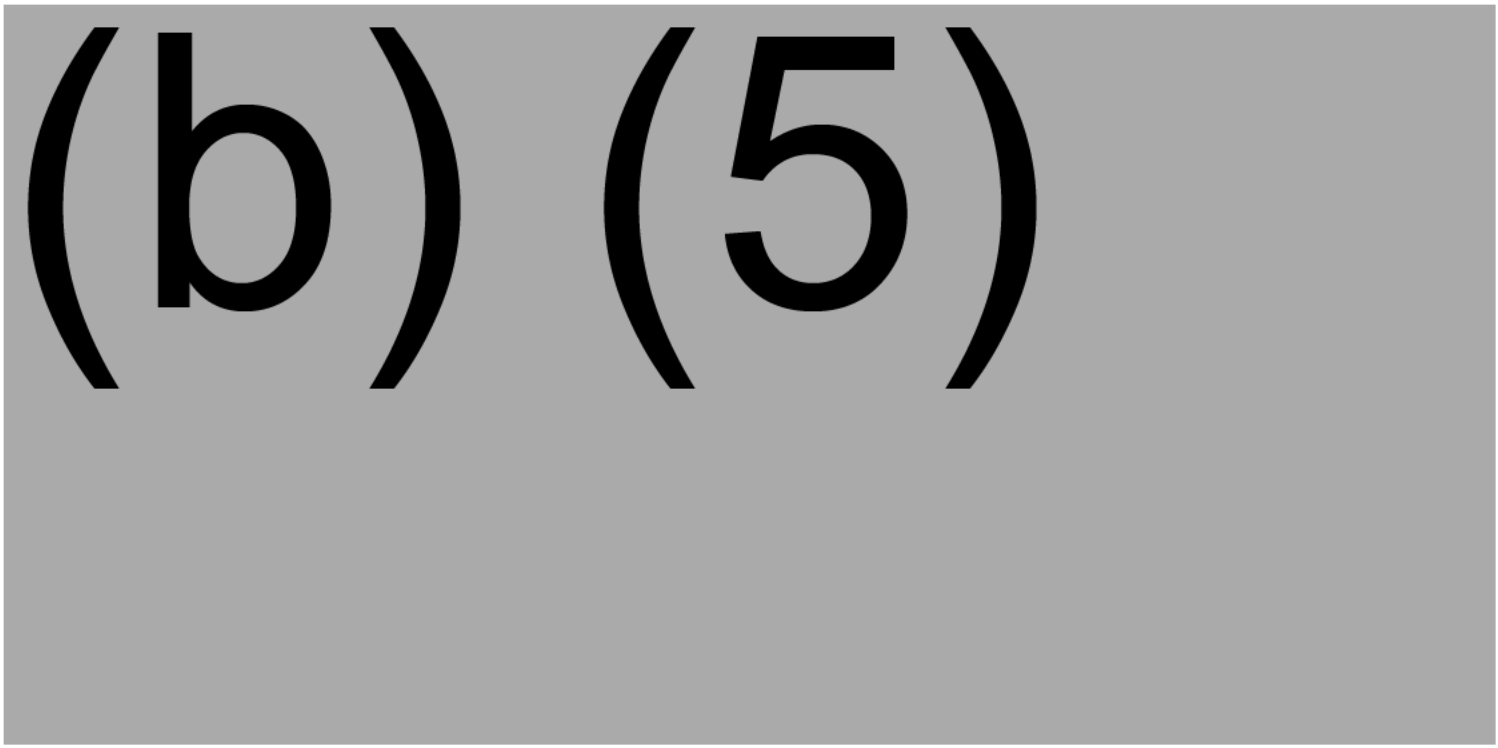
Happy to discuss data interpretation with anyone – as a reminder I am trained in epidemiology/causal inference so am very sensitive to differences in association vs causation and what WGS (which is essentially molecular epidemiology) can tell us.

A lot in there - Let me know if easier to discuss.

Susan

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Thursday, March 17, 2022 4:21 PM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: RE: Comms around infant formula

Hi Susan,



Best,
Erica

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 17, 2022 1:37 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Comms around infant formula

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Susan

Susan T. Mayne, Ph.D.
Director

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Tel: 240-402-1600
susan.mayne@fda.hhs.gov

Followme @https://twitter.com/drmaynefdafood

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 3/10/2022 7:36:58 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: Fwd: - unredacted 483s 2019 2021 Abbott Sturgis Facility
Attachments: Abbott Nutrition - FD483 9-16-24-2019 unapplied redactions pdf second review PJK.pdf; Abbott original FDA 483 issued 9-24-21.pdfunapplied redactions.pdf second review PJK.pdf; Abbott Nutritions - Amended 483 issued 9-24-21.pdfunapplied redactions.pdf second review PJK.pdf

Here are the 483s from the Abbott Sturgis inspections in 2019 and 2021. We are working with OMA and ORA on a strategic comms plan before we release.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	9/20/2021-9/24/2021
	FEI NUMBER 1815692

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TJ Hathaway , Site Director

FIRM NAME	STREET ADDRESS
Abbott Nutrition	901 N Centerville Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sturgis, MI 49091-9302	Infant Formula Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition.

Specifically, 09/20/2021 and 09/21/2021, in Building (b) (4) Dryer (b) (4) standing water was observed in the following locations: under and adjacent to the (b) (4) air handling unit, outside the (b) (4) door associated with the Dry Blending Room and in the clean-out-of-place (COP) area. On 09/23/2021, in the same room, standing water was observed on the floor below the (b) (4) .

On 09/23/2021, a forklift was observed moving ingredient pallets from the liquid processing mineral storage location to the Building (b) (4) Dryer (b) (4) location. The forklift was numbered (b) (4) and displayed a sign reading "Liquid Processing Room Only". Additionally, wooden pallets with ingredients for the liquid processing operation were stored in the same area. Finally, a box fan with a sign reading "Liquid Processing" was observed blowing in the direction of the (b) (4) cabinet in Building (b) (4) Dryer (b) (4) This fan was observed with extensive debris and dust-like build up.

OBSERVATION 2

You did not install a (b) (4) capable of (b) (4) when (b) (4) is used at a product filling machine.

Specifically, on Filler Lines (b) (4) the finished product is (b) (4) . On Filler Line (b) (4) (b) (4) is used at the following locations: filler (b) (4) , seamer (b) (4) , and seamer. On Filler Line (b) (4) is used at the following locations: filler/(b) (4) and seamer/(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Daniel B Arrecis, Investigator Elizabeth P Mayer, National Expert	X Daniel B Arrecis Investigator Signed By: Daniel B. Arrecis -S Date Signed: 09-24-2021 09:36:39	9/24/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	9/20/2021-9/24/2021
	FEI NUMBER 1815692

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TJ Hathaway , Site Director

FIRM NAME	STREET ADDRESS
Abbott Nutrition	901 N Centerville Rd
CITY, STATE, ZIP CODE, COUNTRY Sturgis, MI 49091-9302	TYPE ESTABLISHMENT INSPECTED Infant Formula Manufacturer

OBSERVATION 3

Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated.

Specifically, on 09/20/2021, in the Mineral Weigh Room, the Processing Operator did not sanitize nor change his gloves after touching non-food contact surfaces; immediately afterwards, he touched food contact surfaces including the inside of the potassium chloride ingredient bag and a clear plastic bag used to store weighed ingredient.

In addition, the Operator's exposed wrists, between the glove and smock cuff, were observed entering the inside of the potassium chloride ingredient bag when scooping ingredients.

OBSERVATION 4

An instrument you used to measure, regulate, or control a processing parameter was not properly maintained.

Specifically, your firm does not calibrate the following system components:

- The flow sensor for the (b) (4) system located on the product line between the (b) (4) pasteurizer and (b) (4) Dryer
- The pressure sensor for Tank (b) (4)
- The pressure sensors for Tanks (b) (4)
- The flow meters for the bulk oil silos into Tank (b) (4)

OBSERVATION 5

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Daniel B Arrecis, Investigator Elizabeth P Mayer, National Expert	X Daniel B Arrecis Investigator Signed By: Daniel B. Arrecis -S Date Signed: 09-24-2021 09:36:39	9/24/2021

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	9/20/2021-9/24/2021
	FEI NUMBER 1815692

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TJ Hathaway , Site Director

FIRM NAME	STREET ADDRESS
Abbott Nutrition	901 N Centerville Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sturgis, MI 49091-9302	Infant Formula Manufacturer

You did not monitor the temperature in a thermal processing equipment at a frequency as is necessary to maintain temperature control.

Specifically, review of Master Work Order 01-0X290-MWO (Alimentum Dryer) for the product Alimentum Advance (packaging dates 04/21/2021, 04/25/2021, 06/18/2021, 07/14/2021 and 07/17/2021) did not document the indicating thermometer temperature for the (b) (4) pasteurizer. Temperature is identified as a critical control point (CCP).

X Elizabeth P Mayer
National Expert
Signed By: Elizabeth P. Mayer -S
Date Signed: 09-24-2021 09:37:15

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Daniel B Arrecis, Investigator
Elizabeth P Mayer, National Expert

X Daniel B Arrecis
Investigator
Signed By: Daniel B. Arrecis -S
Date Signed: 09-24-2021
09:36:39

DATE ISSUED
9/24/2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	9/16/2019-9/24/2019* FEI NUMBER 1815692

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Patrick A. Cooper, Site Director

FIRM NAME	STREET ADDRESS
Abbott Nutrition	901 N Centerville Rd
CITY, STATE, ZIP CODE, COUNTRY Sturgis, MI 49091-9302	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

You did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards.

Specifically, on 09/16/2019, your firm was observed collecting 30 samples of Similac Pro Sensitive Batch No. (b) (4) during packaging on Packaging Line (b) (4). Your firm's document, Document ID: AN06-99-004, Global Microbiological Standards, Effective Date 26-Jun-2019, page 27 of 41, 5.5.6.1, notes sixty samples for Salmonella spp testing will be collected (b) (4) (b) (4).

*DATES OF INSPECTION

9/16/2019(Mon), 9/17/2019(Tue), 9/18/2019(Wed), 9/19/2019(Thu), 9/24/2019(Tue)

X Dariusz Galezowski
Investigator
Signed By: Dariusz Galezowski -S
Date Signed: 09-24-2019 14:28:11

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Daniel B Arrecis, Investigator Dariusz Galezowski, Investigator	X Daniel B Arrecis Investigator Signed By: Daniel B. Arrecis -S Date Signed: 09-24-2019 14:27:31	9/24/2019

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
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From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/17/2022 2:36:14 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]

Subject: HOLD: Infant Formula HHS Briefing

Start: 3/30/2022 12:00:00 PM
End: 3/30/2022 1:00:00 PM
Show Time As: Busy

POC: Lindsay T.

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/17/2022 2:32:35 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]

Subject: HOLD: Infant Formula HHS Briefing

Start: 3/29/2022 1:00:00 PM
End: 3/29/2022 2:00:00 PM
Show Time As: Tentative

POC: Lindsay T.

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/17/2022 2:32:55 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]

Subject: HOLD: Infant Formula HHS Briefing

Start: 3/29/2022 3:00:00 PM
End: 3/29/2022 4:00:00 PM
Show Time As: Tentative

POC: Lindsay T.

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/17/2022 2:37:30 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]

Subject: HOLD: Infant Formula HHS Briefing

Start: 3/31/2022 11:30:00 AM
End: 3/31/2022 12:30:00 PM
Show Time As: Tentative

POC: Lindsay T

From: Tobias, Lindsay [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4766773C717470BBC55D204B5F067B2-LINDSAY.STO]
Sent: 3/25/2022 11:07:09 AM
To: Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Boon, Caitlin; Harris, Stic; Rogers, Michael; Nichols, Megin C (CDC); Braden, Christopher R (CDC); Woodcock, Janet; Colonius, Tristan
CC: Tierney, Julia; Yiannas, Frank

Subject: FDA/CDC Connect Infant Formula Briefing
Location: Microsoft Teams Meeting

Start: 3/29/2022 10:30:00 AM
End: 3/29/2022 11:00:00 AM
Show Time As: Tentative

Required Attendees: Boon, Caitlin; Harris, Stic; Rogers, Michael; Nichols, Megin C (CDC); Braden, Christopher R (CDC); Woodcock, Janet; Colonius, Tristan
Optional Attendees: Tierney, Julia; Yiannas, Frank

Quick connect to go over run-of-show before HHS briefing on 3/31. Hopefully will just take 15 minutes.

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

Or call in (audio only)
+1 202-964-4011,(b) (6) United States, Washington DC
Phone Conference ID: (b) (6)
Find a local number | Reset PIN

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From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/24/2022 7:08:39 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]

Subject: [HOLD] PREP: Congressional Briefing on Infant Formula/Medical Food Authorities and Needs (30 min)

Start: 4/4/2022 3:30:00 PM
End: 4/4/2022 5:00:00 PM
Show Time As: Busy

POC: Shera Moxley

Briefing will be on 5 April @ 4pm