From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 3/9/2022 4:36:29 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]
Subject: FW: Infant Formula - CORE Advisory & Outbreak Table Update

FYI

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 4:30 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Infant Formula - CORE Advisory & Outbreak Table Update

Erica,

Flagging that CORE will update their advisory today and Outbreak Response Table to note the following, as the one suspected Salmonella illness was not found to be definitively linked to infant formula consumed:

The Salmonella Newport illness previously included in this investigation of complaints and illnesses has been removed. In the early stages of this investigation, FDA included all consumer complaints of illness with exposure to products from the Sturgis, MI, facility. After further investigation, the FDA has determined that there is not enough information to definitively link this illness to powdered infant formula. CDC confirmed that this single Salmonella illness is not linked to an outbreak. The FDA and CDC are continuing to monitor for Salmonella cases and consumer complaints may be related to this incident.

Sandy is seeking to update the Consumer Update with this information, and I believe the information included in the CORE post itself will serve as our media response should we get questions. Please let me know if any questions/concerns or if you'd like us to ask folks to hold.

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


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From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 3/9/2022 3:52:30 PM
To: 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]; 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: Re: comms strategy

I think you're asking some good questions.

rmc

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Date: Wednesday, March 9, 2022 at 3:49 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Califf, Robert (b) (6) @fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: comms strategy

I've alerted my team. We will quickly run through the key items for you all beyond the Foods program issues and everyone will drop off aside from Michael and myself.

The dynamics have been very challenging on this, but we've headed off premature disclosures here, including the 483s posting yesterday.

A few considerations/outstanding items for us on comms.

(b) (5)

Erica

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 3:28 PM
To: Califf, Robert (b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: comms strategy

Erica has offered to repurpose the comms check in at 4 to dig in further on this

Julia C. Tierney, JD (she/her)
Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(b) (6) (cell)
Julia.Tierney@fda.hhs.gov
Executive Assistant: Susan.Flowers@fda.hhs.gov

From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 3/17/2022 1:17:19 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]; 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]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]
CC: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]
Subject: Sharing: Follow up on infant formula recall Consumer Update metrics

All,

Following up on what Julie flagged regarding the Consumer Update earlier.

To date the Infant Formula Recall Consumer Update has 77,256 pageviews through 3/16. This makes it the 4th most popular Consumer Update in this time period, behind Delta 8 THC, ivermectin for COVID, and COVID Testing Basics. From the Govdelivery standpoint, the CU was also shared with 96,000 subscribers and had a 36% open rate, which in our experience is quite high. The current median federal open rate is at 14%.

Please note we have refrained from speculating, focused on the information in hand and provided specific recommendations to consumers. We have been somewhat conservative in how we've communicated around this recall because we recognize that this is an evolving situation. Given the high degree of interest in this topic, we recognize that we'll need to be mindful of how we frame future updates.

Erica

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/17/2022 10:01:34 AM
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]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; 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]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Singleton, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b70632897eee4a66a8e6bf7681210a85-Shannon.Chi]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; 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]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Dickinson, Elizabeth (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05cb143d66ed470ebe4dba5c54a88074-EDickins]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: 3/17, Materials: Commissioner Touch Base: Communications Strategy for Abbott
Attachments: Infant Formula Comms Plan Tick Tock 03.17.22.docx

Good morning,

Attached please find the materials for reference at today's "**11:30am - Commissioner Touch Base: Communications Strategy for Abbott**".

Thank you,

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

Infant Formula Comms Plan Tick Tock

Date	Action
Mon., March 21	Politico broad foods program interview briefing material provided in Dr. Califf/Dr. Woodcock homework packets
Tues., March 22	ORA posts 2019, 2021, 2022 Form 483s to FDA.gov after 2pm. *(Note: posting of 2022 Form 483 contingent on inspection closeout and availability, per ORA. To date, this is on track).* • OMA flags Politico for discussion on Wed., March 23 interview • Prepared media comment shared with press who receive 483s via FOIA (Consumer Reports, CNN, Bloomberg). Use reactive comment and QA for other inquiring media ○ Language regarding 2022 Form 483 will be high-level, noting ongoing nature of investigation
Wed., March 23	Morning: Politico interview prep session with Dr. Woodcock (Dr. Califf, TBD) Afternoon: Politico interview with Dr. Woodcock (Dr. Califf, TBD). Topics include: • Infant formula: public health prioritization, evaluation plan forthcoming, high-level contextualization of recently released 483s, taking appropriate action in the future, if warranted, as FDA continues to evaluate the inspectional findings • Foods program is a priority at FDA: notable strides in the foods program, but more could be done with additional resources and better authorities • Opportunities for improved processes/decision-making: intend to streamline decision-making with direct reporting to the Commissioner • Timing: why items could take long via regulatory processes, other potential factors • Prioritization of public health crises response: pandemic and toxic elements work vs. French dressing standard of identity, for example
~Wk. of April 4 (TBD per OCC/DOJ)	Abbott consent decree filed by court • Press release • Media call (TBD based on level of contextual information we can legally share, other broad developments on this issue at the time) • Social media amplification
Late April (TBD)	Announce details of evaluation plan (TBD per OCC/DOJ, if no criminal case in progress) • Press release • Media call • Social media amplification
TBD	Announce results of evaluation • Press release • Media call • Social media amplification

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/29/2022 5:15:30 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Final Proposal - Infant Formula IMG Memo and Org Chart

Seafood AI just came in, 511 pm. Jakea will include in RMC's materials, with his note we'll make sure it gets to him early enough to send the pre-meeting questions in.

Jakea will also distribute to all participants tonight, for tomorrow.

Thank you,
Frank

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Tuesday, March 29, 2022 4:57 PM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: FW: Final Proposal - Infant Formula IMG Memo and Org Chart

FYI and please let me know if this doesn't come through tonight.

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, March 29, 2022 3:44 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Prater, Donald <Donald.Prater@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Final Proposal - Infant Formula IMG Memo and Org Chart

Thanks Rob.

Yes, Don Prater on our team has been working with ORA and CFSAN on a background doc and a short deck to facilitate tomorrow's discussion and share what was done in Phase 1 and Phase 2.

We'll make sure to send the materials to Frank O, so it will be included in your homework tonight.

Yes, please feel free to send any questions you might have, so we can tackle them head-on. They've tried to answer questions they know you'll have on the data, models used, assumptions, and limitations.

The team is humble knowing that this is a new approach for the foods program, so they're excited about sharing what they've done and learning from you.

Frank

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, March 29, 2022 3:23 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Final Proposal - Infant Formula IMG Memo and Org Chart

Frank,

Thanks. Will review tonight.

For tomorrow's discussion of the seafood AI project, can I get the material tonight. I'd like to send you some questions. This concept is so important I want to make sure we'll all thinking about how to develop ML/AI data science as an integral part of all our operations.

rmc

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Date: Tuesday, March 29, 2022 at 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: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/25/2022 9:12:27 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]; 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]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: Updated Materials: 3/25, Materials: Biweekly OFPR Check-In with the Commissioner
Attachments: 1030-Biweekly OFPR Meeting_3.25.2022.pdf

Good morning,

Attached please find the updated slides for today's "10:30am - Biweekly OFPR Check-In with the Commissioner".

Jakea

From: Copeland, Jakea
Sent: Friday, March 25, 2022 5:40 AM
To: Woodcock, Janet Janet.Woodcock@fda.hhs.gov; Yiannas, Frank Frank.Yiannas@fda.hhs.gov; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Subject: 3/25, Materials: Biweekly OFPR Check-In with the Commissioner

Good morning,

Attached please find the materials for reference at today's "**10:30am - Biweekly OFPR Check-In with the Commissioner**". These materials have been shared with Dr. Califf.

Thank you,
Jakea

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


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Bi-Weekly OFPR Check-In with the Commissioner

3/25/2022

(b) (5)

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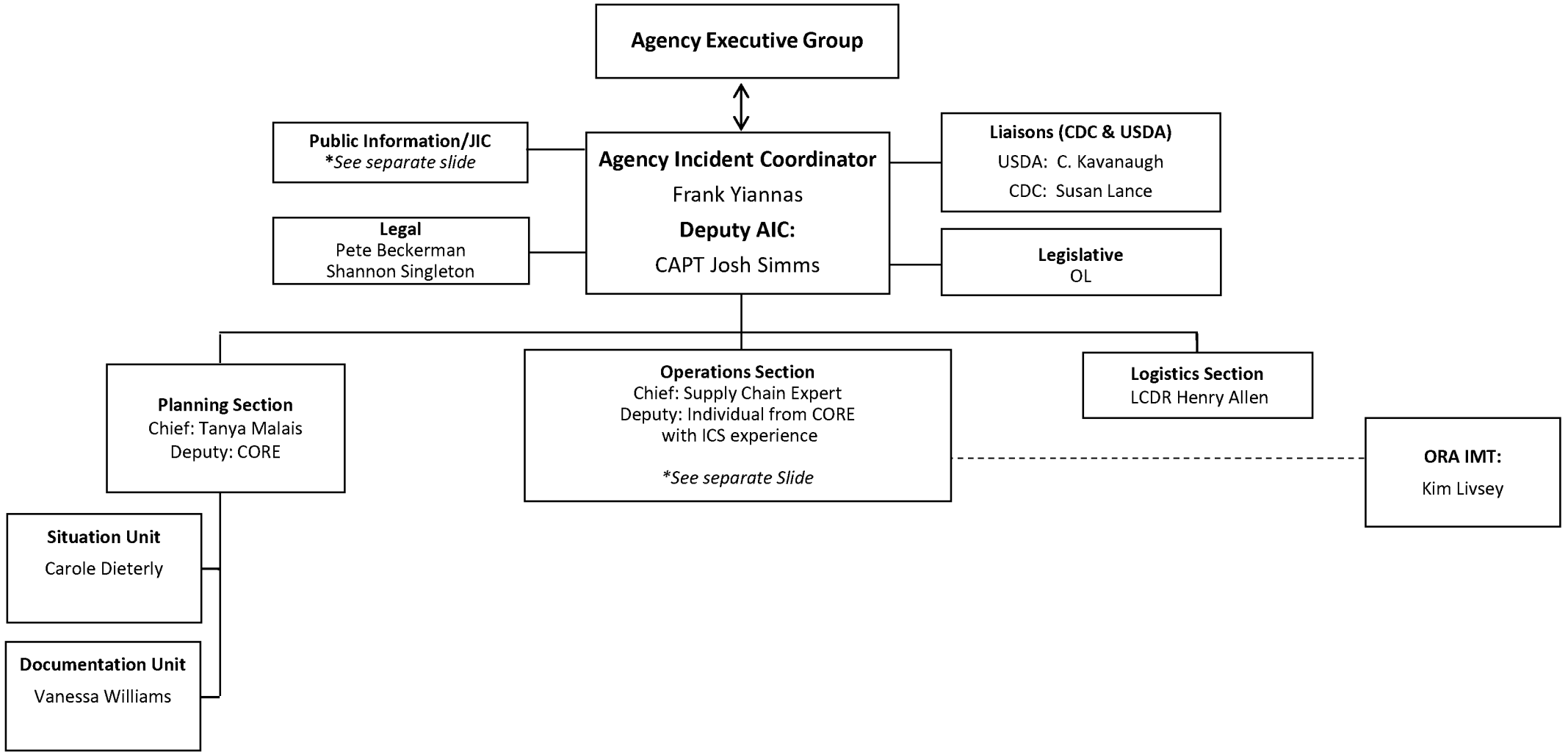
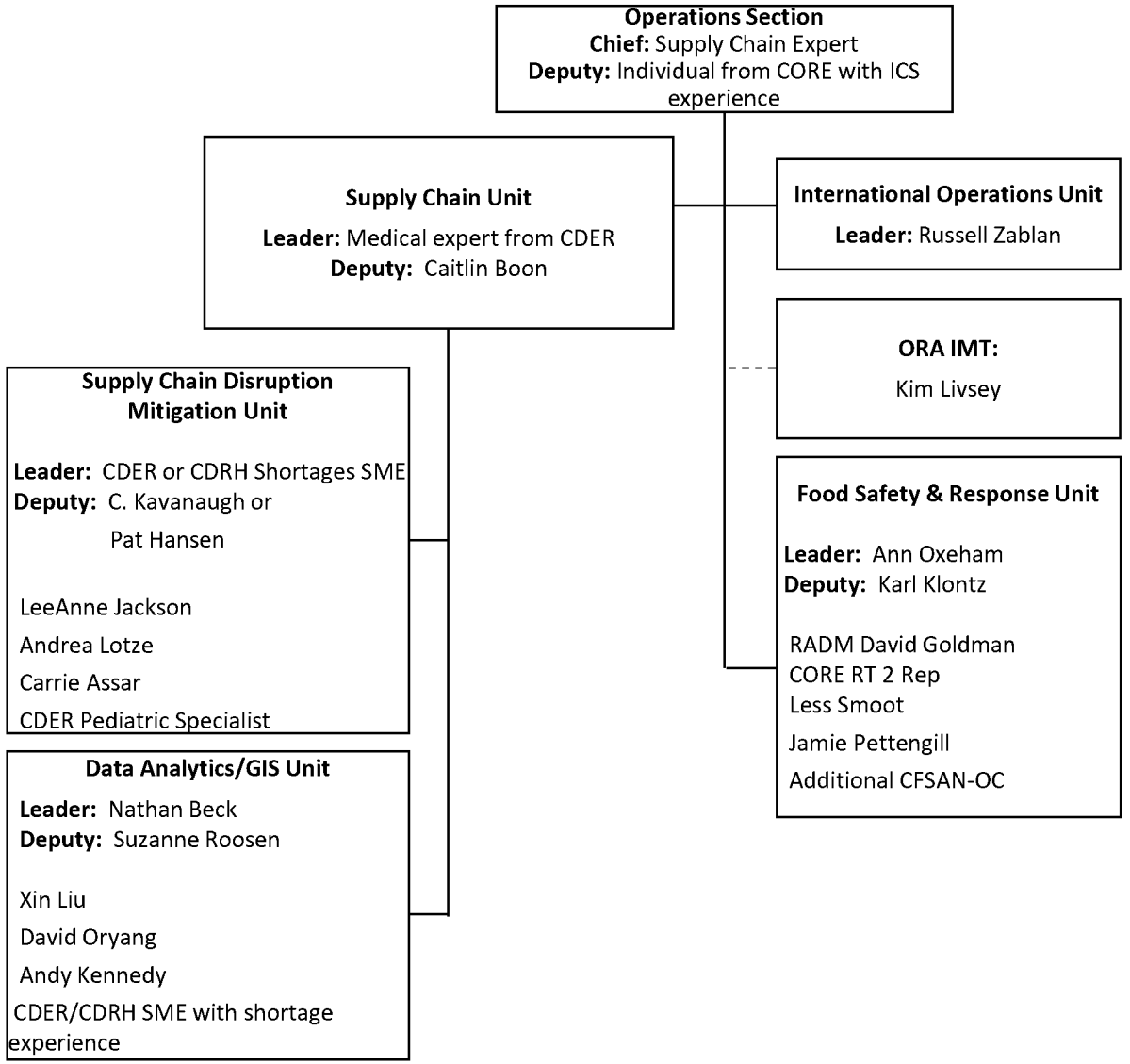
2022 Infant Formula

Incident Management Group



2022 Infant Formula - Incident Management Group
Operations Section



FDA Foods Program
Stakeholder Listening Sessions

National Association of State Departments of Agriculture (NASDA)	
Ted McKinney Chief Executive Officer NASDA (202) 296-9680 Ted.McKinney@nasda.org	Founded in 1916, NASDA is a nonpartisan, nonprofit association that represents the elected and appointed commissioners, secretaries, and directors of the departments of agriculture in all fifty states and four U.S. territories. NASDA's 2021 policy priorities are: food systems, food safety, infrastructure and capacity, climate resiliency, international trade and harmonization, and workforce development.

Food and Beverage Issue Alliance (FBIA)	
Robb MacKie President & CEO American Bakers Association Phone: (202) 789-0300 x114 RMacKie@americanbakers.org	FBIA represents 58 allied U.S. based Food and Beverage Trade Associations. FBIA, through collaboration with regulatory authorities, ensures that any regulations and guidance are justified by verifiable, peer reviewed, published science that is accessible through an open and transparent process and enhance consumer understanding. In addition, FBIA works to ensure regulation implementation timelines are reasonable, achievable and economically feasible for both small and large food and beverage manufacturer

Safe Food Coalition (SFC)	
James Kincheloe Food Safety Campaign Manager Center for Science in the Public Interest jkincheloe@cspinet.org	The SFC brings together consumer, public health and labor organizations to advocate for improvements to the food safety system, particularly with respect to meat and poultry. Since it was created in 1986, the Consumer Federation of America (CFA) has coordinated the coalition.

From: Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]
Sent: 4/4/2022 1:09:30 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Background Material for Today
Attachments: OCE Commissioner Briefing.r1.pptx; OCE Briefing Memo Informational Document FINAL 4-4-22.docx

I am sending background material for two meetings scheduled for today. I apologize if you received this material previously but I wanted to be certain that it was available to you.

2:00 p.m. Commissioner Informational Briefing - Oncology Center for Excellence Project Highlights (material above)

3:30 p.m. Prep: Briefing for HELP maj/Duckworth/Klobuchar on Infant Formula:
Please see draft key messages and talking points here: Talking Points - Infant Formula Briefing for HELP-Duckworth-Klobuchar 20220405.docx

Thank you.

Susan

Susan Flowers
Executive Assistant

Office of the Chief of Staff

Office of the Commissioner
U.S. Food and Drug Administration
Tel:240-402-4050
susan.flowers@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Colonius, Tristan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2B3590C046734A2E928858BD579ED852-TRISTAN.COL]
Sent: 4/14/2022 1:26:28 PM
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CC: Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]
Subject: RE: Potential Abbott Metabolic/Specialty Product Release & Comms Plan

I've asked that we are included in the process on the materials. Thanks

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, April 14, 2022 11:56 AM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Cc: Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Subject: RE: Potential Abbott Metabolic/Specialty Product Release & Comms Plan

Thanks, I would like to look at the materials if possible. jw

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Thursday, April 14, 2022 11:30 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Subject: FW: Potential Abbott Metabolic/Specialty Product Release & Comms Plan

FYSA

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Thursday, April 14, 2022 11:28 AM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@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>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Potential Abbott Metabolic/Specialty Product Release & Comms Plan

Tristan, Andi-

Providing an update on the situation and communications plan surrounding the potential release of metabolic and specialty product from the Abbott Nutrition Michigan facility.

- **Background:**
  - Next week, certain lots of specialty and metabolic infant formula products that have been on hold since the original recall may be released despite safety concerns that the products may still pose (e.g., have potential to be contaminated with Cronobacter). FDA has determined that the risk of not having these specialty products available could significantly worsen underlying medical conditions in the small population of individuals with rare diseases that these products serve. FDA has heard from the American Academy of Pediatrics and consumer groups that the supply for these products is dire and there are no alternatives available for these specific populations.
  - FDA will advise that although there is a need to release these products for this small population and safety concerns remain, parents and caregivers should work with their medical provider to consider whether comparable products or other changes to feeding practices may be an appropriate substitute for using this product. If comparable

alternative products are not available or appropriate, parents and caregivers should take extra care to follow the CDC's advice on how to reduce the risk of Cronobacter contamination of formula during preparation of powdered product.

- **Communications Plan:**
  - CORE advisory and Consumer Update revised to include information about this release and advice for healthcare providers, caregivers per CDC's existing web resource. Issued to list servs, posted via various social media channels.
  - FDA will develop an easy-to-read infographic leveraging CDC's advice to underscore the steps that can be taken to mitigate potential bacterial contamination in released product. The goal is to have the infographic ready for release in conjunction with the product release, which can be posted on FDA.gov assets (CORE advisory, Consumer Update) as well as disseminated for print use to stakeholder groups and via social media. Please note infographic release time is dependent on finalized recommendations in conjunction with FDA and CDC SMEs.
  - Stakeholder outreach to rare disease and pediatric groups.

With regard to clearances, we will follow the typical CORE clearance process for finalizing language that will be in the CORE advisory and Consumer Update. I don't believe this usually incudes the IO or OPLIA. Would you like to receive this language as a FYI once finalized or be part of the CORE clearance process for this event? These are typically concurrent reviews with rapid turnarounds.

Finally, OEA has given a head's up to HHS/ASPA about this activity and will be sure to provide continued update as the final recommendations are solidified by FDA. Please let me know if 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: Malais, Tanya [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F13699D67E9C491EAB11150A04F7FC6C-TANYA.MALAI]
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From: Baer, Gerri [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3DFF3AD85EF047108DB7D78FD1CE7893-GERRI.BAER]
Sent: 3/10/2022 10:02:21 AM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Smpokou, Patroula [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=361685f4efaa4d988bfafbe7d72c5228-Patroula.Sm]; Massaro, An [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45eac3f386c648c7b898f0341ca9ea12-An.Massaro]
Subject: RE: Meeting at 11:30

Jacque,
Please invite Lynne Yao and Mona Khurana from DPMH.
Thank you,
Gerri

Gerri R. Baer, M.D., F.A.A.P. (she/her)
Supervisory Medical Officer, Pharmacovigilance and Neonatology Team

Office of Pediatric Therapeutics
Office of Clinical Policy and Programs / Office of the Commissioner
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From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, March 10, 2022 10:01 AM
To: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@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

Please invite Claudine Kavanaugh, Andrea Lotze, and Caitlin Boon.

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: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 11/5/2021 7:54:45 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]; 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 for Monday, November 8, 2021
Attachments: 00-11.08.2021-Calendar.pdf; 0800-ORA Biweekly Meeting Agenda_11.08.2021.doc; 1430-CDER Weekly Meeting Agenda_11.08.2021.docx; 1500-CFSAN Weekly Meeting Agenda_11.08.2021.doc

Your first meeting is scheduled for 8 AM [*Biweekly ORA Meeting with the Acting Commissioner*]. Your final meeting is scheduled for 4:30 PM [Nancy Myers / Janet Woodcock].

8-8:30am Biweekly ORA Meeting with the Acting Commissioner
Materials: Agenda attached

8:30-9am Acting Commissioner Touchbase: PDUFA

9-9:30am TELECON ONLY: Commissioner's M/W/F Check-In

9:30-10am Smaller Group Daily Check-In

10-10:30am DESK TIME

10:30-10:50am On-Camera Print Interview: The Week Junior
Materials: Memo included in Read Ahead

11-11:30am Meet and Greet: Associate Commissioner for Legislative Affairs Candidate

11:30am-12pm Woodcock/Marks/Tierney

12-12:30pm LUNCH

12:30-1pm [EXTERNAL] Dr. Dzau call w/Janet WoodCock & Jacqueline O Shaughnessy (FDA) NAM Committee on Emerging Science, Technology, and Innovation in health and medicine

1-1:30pm Staff/Op Div Check In

1:30-2:30pm DESK TIME

2:30-3pm Weekly CDER Meeting with the Acting Commissioner
Materials: Agenda attached

3-3:30pm Weekly CFSAN Meeting with the Acting Commissioner
Materials: Agenda attached

3:30-4pm DESK TIME

4-4:30pm Telecon: Biweekly Check-In: A.Fristedt/Dr. Woodcock

4:30-5pm Nancy Myers / Janet Woodcock

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

November 8, 2021

Monday

November 2021

Su	Mo	Tu	We	Th	Fr	Sa
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December 2021

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MONDAY

8

(b) (5) GRx+Biosims 2021 (Virtual/Zoom/Pre-Record (11/02))

(b) (5) r, Victor Dzau (National Academy of Medicine) - Zoom

DECLINED: Collaboration Insights Run Through

7 AM

8

Biweekly ORA Meeting with the Acting Commissioner; See Zoom details below; FDA Commissioner

Acting Commissioner Touchbase: PDUFA ; Zoom, details below; Woodcock, Janet

9

TELECON ONLY: Commissioner's M/W/F Check-In; https://fda.zoomgov.com/(b) (6)

Smaller Group Daily Check-In; See Zoom details below; Woodcock, Janet

10

Desk Time

On-Camera Print Interview: The Week Junior; Zoom, link below; Woodcock, Janet

11

Meet and Greet: Associate Commissioner for Legislative Affairs Candidate; Please see Zoom below; Woodcock, Janet

Woodcock/Marks/Tierney; See Zoom details below.; Woodcock, Janet

12 PM

LUNCH

[EXTERNAL] Dr. Dzau call w/Janet WoodCock & Jacqueline O Shaughnessy (FDA) NAM Committee on Emerging Science, Technology, and Innovation in health and medicine; Zo

1

Staff/Op Div Check In; https://hhsgov.zoomgov.com/(b) (6)

Desk Time

2

Weekly CDER Meeting with the Acting Commissioner; See Zoom info below; FDA Commissioner

3

Weekly CFSAN Meeting with the Acting Commissioner; See Zoom info below; FDA Commissioner

Desk Time

4

Telecon: Biweekly Check-In: A.Fristedt/Dr. Woodcock; See Zoom details below.; FDA Commissioner

Nancy Myers / Janet Woodcock; Please see Zoom below; Woodcock, Janet

5

HOLD: Media

6

7

8

Weekly CFSAN Meeting with the Acting Commissioner
Monday, November 8, 2021
3:00-3:30 PM

Agenda Items

1. Infant Formula Review Timelines Update
2. HHS Office of Women's Health Activities in Endocrine-Disrupting Chemicals
3. Closer to Zero Public Meeting on November 18th
4. Update on Healthy Foods for All / Nutrition for Growth
5. Appropriations Briefings
6. Misc. Updates

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 11/8/2021 2:44:46 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]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: 3:00pm RE: Weekly CFSAN Meeting with the Acting Commissioner
Attachments: 1500-CFSAN Weekly Meeting Agenda_11.08.2021.doc

Hi there,

FDA Commissioner 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

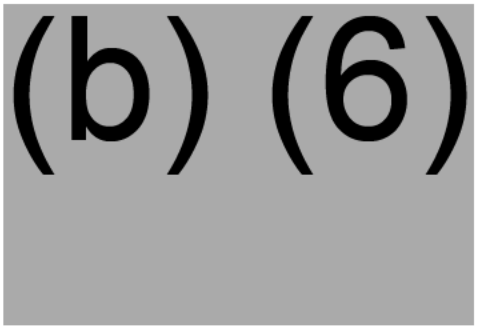
H.323:

Meeting ID:

Passcode

SIP:

Passcode



Weekly CFSAN Meeting with the Acting Commissioner
Monday, November 8, 2021
3:00-3:30 PM

Agenda Items

1. Infant Formula Review Timelines Update
2. HHS Office of Women's Health Activities in Endocrine-Disrupting Chemicals
3. Closer to Zero Public Meeting on November 18th
4. Update on Healthy Foods for All / Nutrition for Growth
5. Appropriations Briefings
6. Misc. Updates

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 11/19/2021 6:07:45 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]; 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 for Monday, November 22, 2021
Attachments: 00-11.22.2021-Calendar.pdf; 1230-1-Agenda for Touchbase with Lee Cohen & Dr. Woodcock_11.22.2021.docx; 1425-1-Run of Show_11.22.2021 - Biopharma Congress - Moderated by Kate Rawson, Senior Editor Prevision Policy LLC.pdf; 1500-CFSAN Weekly Meeting Agenda_11.22.2021.doc

Your first meeting is scheduled for 8 AM [*Update on Neurological Adverse Event Reports*]. Your final meeting is scheduled for 4 PM [Dr. Michelle McMurray-Heath (BIO) and Dr. Janet Woodcock (FDA)].

8-8:30am Update on Neurological Adverse Event Reports
Materials: Included in Read Ahead

8:30-9am DESK TIME

9-9:30am TELECON ONLY: Commissioner's M/W/F Check-In

9:30-10am Smaller Group Daily Check-In

10-10:30am DESK TIME

10:30-11am Telecon: Biweekly Check-In: A.Fristedt/Dr. Woodcock

11am-12pm Bimonthly ASH Briefing on NTP

12-12:30pm LUNCH

12:30-1pm Touch Base: Lee Cohen / Dr. Woodcock
Materials: Agenda attached; addt'l materials Included in Read Ahead

1-1:30pm Staff/Op Div Check In

1:30-2pm WEEKLY SENIOR COVID ADVISORS / SECRETARY BECERRA

2pm DNS- Prep for Camera

2:25-3pm Biopharma Congress with FOCR
Materials: Overview attached; addt'l material in Read Ahead

3-3:30pm Weekly CFSAN Meeting with the Acting Commissioner
Materials: Agenda attached

3:30-4pm DESK TIME

4-4:15pm Dr. Michelle McMurray-Heath (BIO) and Dr. Janet Woodcock (FDA)

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

November 22, 2021

Monday

November 2021

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28	29	30				

December 2021

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MONDAY

22

(b) (5) Dr. Michelle McMurray-Heath (BIO)

7 AM

8
- **Update on Neurological Adverse Event Reports**
  See Zoom details below.; Woodcock, Janet
- **DESK TIME**

9
- **TELECON ONLY: Commissioner's M/W/F Check-In**
  https://fda.zoomgov.com/(b) (6)
- **Smaller Group Daily Check-In**
  See Zoom details below; Woodcock, Janet

10
- **Desk Time**
- **Telecon: Biweekly Check-In: A.Fristedt/Dr. Woodcock**
  See Zoom details below.; FDA Commissioner

11
- **Bimonthly ASH Briefing on NTP**
  Zoom
  Levine, Rachel (OS)

12 PM
- **LUNCH**
- **Touch Base: Lee Cohen / Dr. Woodcock**
  Zoom, details below; Woodcock, Janet

1
- **Staff/Op Div Check In**
  https://hhsgov.zoomgov.com/(b) (6)
- **WEEKLY SENIOR COVID ADVISORS / SECRETARY BECERRA**
  Zoom ; OS Scheduling (HHS/OS)

2
- **DNS- Prep for Camera**
- **Biopharma Congress with FOCR**
  Virtual/Zoom/Pre-record Q&A (link below); Woodcock, Janet

3
- **Weekly CFSAN Meeting with the Acting Commissioner**
  See Zoom info below; FDA Commissioner
- **Desk Time**

4
- **Dr. Michelle McMurray-Heath (BIO) and Dr. Janet Woodcock (FDA)**
  Please see Zoom below; Woodcock, Janet

5

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8

Weekly CFSAN Meeting with the Acting Commissioner
Monday, November 22, 2021
3:00-3:30 PM

Agenda

Dr. Mayne will provide an update on the following areas:

1. Nutrition
2. Healthy
3. Allergen Framework
4. PBMA
5. Lead in Juice
6. CFSAN FOIA
7. Infant Formula

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 2/24/2022 4:59:25 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]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; 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]
Subject: 5 PM Link Re: OCC/OC Touch Base on Infant Formula

Please join, link below for 5 PM.

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
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Sent: 2/25/2022 8:36:58 AM
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]; 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]; 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]; 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]; 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]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]
Subject: RE: Update on Infant Formula Discussions with Abbott Nutrition

---

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Thursday, February 24, 2022 9:31 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; 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>
Subject: Update on Infant Formula Discussions with Abbott Nutrition

Good Evening,

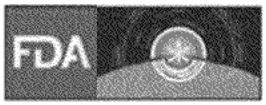
Given the potential for outreach by Secretary Beccera to Abbott tomorrow, we wanted to provide a brief update on a conversation held earlier this evening. Representatives from OFPR, CFSAN, and ORA held a call with Scott House, Senior Vice President of Quality Assurance, Regulatory and Engineering Services as well as Monica Wilkins, Corporate Vice President of Regulatory and Quality. We highlighted the need for Abbott Nutrition to prioritize responding to FDA's questions on the share of Abbott's infant formula production coming from the Sturgis manufacturing facility (overall and specific product lines) as well as additional information on product lines that are solely produced at this location. Mr. House and Ms. Wilkins committed to gathering this information as quickly as possible and stated that they have been overwhelmed with requests for information from government (U.S. and international), buyers, media, and consumer groups.

In addition, we had initial discussions on whether production for certain products, particularly the EleCare amino acid-based product, could be moved to an alternate facility. The initial assessment is that options are limited because the (b) (4) Abbott is currently considering next steps and appreciated our willingness to work with them as needed.

We will alert you immediately if the requested information comes in.

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
240-506-2292
Caitlin.Boon@fda.hhs.gov



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

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)

- Abbott announced the recall on Thursday night, Feb 21, but initial info available to retailers was vague.
- Abbott was eventually able to provide more specific info, such as product descriptions, UPCs affected, and batch codes. Thereafter, they also started to provide info about specific products and quantities received by customers, but it came in in sequential manner….and over time.
- Abbott's UPCs are unique to specific products, and as do all UPCs, they do not discriminate or identify where the product (UPC) was made. That information can be determined via the batch code on each container.
- It should be positively noted that Abbott does use appropriate case labels that identifies on the case the batch number, which does allow one to determine where the product was produced by simply looking at the case (without opening it).
- (b) (4)

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Recall Execution by Retailers

- As there was little detailed or specific info available early in the event, some retailers acted in an abundance of caution and pulled more Abbott product than was truly affected (e.g., UPCs for products produced at both the Sturgis and other Abbott facilities).
- In addition, as is customary, retailers with register lock-down capabilities, initiated scan-blocks of the affected UPCs to prevent sales. Again, because UPCs do not discriminate or identify where the UPC was made, for Abbott UPCs made at multiple plants, all product was prevented from being sold, until affected batches/lots were cleared from shelves and the register scan-blocks could be removed or lifted.
- As retailers received more detailed info from Abbott, they were able to sort through product and put those that were unaffected back on shelf.
- Also, it was consistently reported by retailers, that they had to execute at least a couple of waves of removals in stores, as data from Abbott of the products/lots affected came in in waves as opposed to all at once.
- As of yesterday, Feb 23, there was a general feeling that the recall was fully executed within the retail chains we contacted.

WIC

(b) (5)

Current Supply Chain Insights and Status

- FDA has been monitoring the infant formula supply chain status, as reports of shortages and bottlenecks had been previously reported prior to the recall.

(b) (5)

(b) (4), (b) (5)

(b) (5)

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: Tobias, Lindsay [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4766773C717470BBC55D204B5F067B2-LINDSAY.STO]
Sent: 2/25/2022 2:19:18 PM
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CC: 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]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; 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]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; 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]
Subject: Night Note for Monday, 2/28- Internal, Confidential, Deliberative

OTHER FLAGS:

- **Consumer Update: Infant Formula Recall: What to Know**

This article will offer information on what we know about the recall, symptoms of illness to be aware of and basic advice for consumers. *(may go today possibly)*

- **FDA Voices: Sharing Experiences in Rare Diseases Together**

By Janet Woodcock, Principal Deputy Commissioner and Sandra Retzky, Director, Office of Orphan Products Development, Office of Clinical Policy and Programs
This FDA Voices will amplify key messages of FDA's Rare Disease Day Public Meeting held on Friday, March 4, 2022. Rare Disease Day was created to raise awareness about the 7,000 known rare diseases, many of which have no treatment. As part of the observance, FDA will host a virtual public meeting with the theme, "Sharing Experiences in Rare Diseases Together."

Speaking Engagements

- **Remarks at Rare Disease Treatments: Regulatory and Policy Reform Event**

Principal Deputy Commissioner Janet Woodcock will deliver pre-recorded remarks during a virtual event hosted by The Hill news site on regulatory reforms needed for rare diseases. This virtual event is open press and will air Monday, Feb. 28 at noon.

- **Remarks at U.S. Public Health Service Engineer Change of Command Ceremony**

Principal Deputy Commissioner Janet Woodcock will deliver pre-recorded remarks at noon on the Commissioned Corps of the U.S. Public Health Service. This virtual event is closed press.

Lindsay R. Tobias
Special Assistant to the Chief of Staff

Office of the Commissioner
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Tel: 301-796-6743
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From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/25/2022 6:00:22 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: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; 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]; Rawlings, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae46d13993dc46e190ae70b61e1d4871-KRawling]
Subject: Two Week Look through 3/11: Comms on Upcoming Agency Actions

For your awareness, below is a list of upcoming anticipated agency actions and their associated planned communications for the next two weeks (through Fri., March 11).

COMMISSIONER SPEAKING EVENTS
Nothing to report at this time.

CONGRESSIONAL HEARINGS
Nothing to report at this time.

Monday, February 28
1. Sharing Experiences in Rare Diseases Together (FDA Voices by Janet Woodcock and Sandra Retzky)
2. U.S. Public Health Service Engineer Change of Command Ceremony (Janet Woodcock will deliver pre-recorded remarks at noon, closed press)
3. Rare Disease Treatments: Regulatory and Policy Reform event hosted by The Hill.com (Janet Woodcock will deliver pre-recorded remarks, event begins at noon, open press)
4. Infant Formula Recall: What to Know (Consumer Update)

Tuesday, March 1
1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. FDA provides guidance to support inclusion and efficiency in cancer clinical trials, expediting development of oncology treatments (Press Release, Social Media, Stakeholder Outreach)
3. FDA publishes a safety communication regarding a recall of an unauthorized version of a Celltrion COVID-19 test that was imported into the U.S. (FDA Roundup, MedWatch Safety Alert)
4. FDA publishes a safety communication regarding a recall of an unauthorized version of an ACON Laboratories COVID-19 test that was imported into the U.S. (FDA Roundup, Reactive QA, MedWatch Safety Alert)
5. FDA publishes the classification of a recall of an unauthorized version of an SD Biosensor COVID-19 test that was imported into the U.S. (FDA Roundup, MedWatch Safety Alert)

Wednesday, March 2

1. Device Good Manufacturing Practice Advisory Committee Meeting (CDRH, 9 a.m. to 6 p.m.)

Thursday, March 3

1. FDA urges companies to be "recall ready" to protect public health as part of final guidance for voluntary recalls (Press Release, Social Media)
2. Vaccines and Related Biological Products Advisory Committee - Influenza Virus (CBER, 9 a.m. to 3:30 p.m.)

Friday, March 4

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. CDER Continues to Make Rare Diseases a Priority with Drug Approvals and Programming to Speed Therapeutic Development (FDA Voices by Patrizia Cavazzoni)
3. FDA Rare Disease Day 2022 Public Meeting: "Sharing Experiences in Rare Diseases Together" (OOPD, 9 a.m. to 4:30 p.m., Janet Woodcock will deliver pre-recorded remarks at 1 p.m.)

Week of February 28 // Tentative:

1. District court to enter a consent decree against Salud Natural Entrepreneur, Inc. prohibiting the distribution of adulterated and misbranded dietary supplements (FDA Roundup)
2. Coronavirus Q&A: Updates for Consumers (Consumer Update)
3. Coronavirus Disease 2019 Testing Basics (Consumer Update)

Monday, March 7

N/A

Tuesday, March 8

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. FDA to grant EUA amendment to Moderna for a new presentation of COVID-19 vaccine booster dose (FDA Roundup, Stakeholder Outreach)
3. (b) (5) (Reactive Statement)

Wednesday, March 9

N/A

Thursday, March 10

1. Cellular, Tissue, and Gene Therapies Advisory Committee Meeting (CBER, 10 a.m. to 1:30 p.m.)

Friday, March 11

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)

Week of March 7 // Tentative:

1. FDA orders Philips Respironics to notify patients regarding the recall of certain breathing assistance machines (Press Release, Social Media, Stakeholder Outreach)
2. Nonprescription Drug Products for Mole and Skin Tag Removal Can Cause Injuries, Scarring (Consumer Update)

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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]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: Fwd: FYI - Consumer Update Live + Politico Story

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Friday, February 25, 2022 10:18 PM
To: Yiannas, Frank; Mayne, Susan; McMeekin, Judith; Jefferson, Erica; Boon, Caitlin; Rogers, Michael; Harris, Stic; Dooren, Jennifer; Colonius, Tristan; Burgess, Shelly; Newhart, Corinne
Cc: Walsh, Sandy; Felberbaum, Michael; Potash, Shana; Pfaeffle, Veronika
Subject: FYI - Consumer Update Live + Politico Story

FYI - Our new Consumer Update is live. Thank you to everyone who worked hard to get this posted today.

Also, below is the anticipated Politico Pro article published with a headline focused on a Hill letter to Abbott CEO. Highlight at bottom regarding today's supply related updates provided via the updated CORE post and new Consumer Update, public health focused message from Frank's quote in our press release last week, and anticipated notes we've shared to date on the timeline.

Senators demand answers from Abbott on infant formula recall

BY **HELENA BOTTEMILLER EVICH** | 02/25/2022 09:27 PM EST

Senate Health, Education, Labor and Pensions Chair Patty Murray (D-Wash.) talks to reporters at the U.S. Capitol. | Chip Somodevilla/Getty Images

Sens. Patty Murray (D-Wash.) and Bob Casey (D-Pa.) today demanded Abbott Nutrition hand over information and documents related to the company's sweeping infant formula recall last week, after POLITICO reported that FDA, CDC and Abbott were all informed of the first infant illness in September.

"It is completely unacceptable that manufacturing conditions allowed a contaminated product to reach babies, and that it took months for the company to act to warn parents and caregivers about this danger," the senators wrote Abbott CEO and chair Robert Ford, citing POLITICO's reporting.

The letter comes as CDC says it has received reports of more Cronobacter sakazakii cases that may be tied to the outbreak, beyond the four hospitalizations, including one death, initially reported (one with Salmonella Newport). West Virginia has since confirmed it had one infant sick with Salmonella tied to the formula, though this has not been reported by federal officials as part of the outbreak.

More reports from Texas and Maryland have been reported and moms have flooded social media with complaints and unconfirmed anecdotes of infant illnesses and hospitalizations. Federal health officials have not publicly updated their case counts in more than a week.

"CDC and FDA are conducting additional laboratory testing and investigation to better understand these cases," CDC said in an update Friday. The formula has been recalled in roughly three dozen countries.

Murray, chair of the Senate Health, Education, Labor & Pensions Committee, which oversees FDA, and Casey, one of the committee's top Democrats, are seeking answers from Abbott about the timeline.

The lawmakers are also seeking all internal documents and communications about complaints from consumers, including the initial September report of an illness. They want documents and information about the plants' testing and any destruction of product and audits, among other things, spanning back to 2017. The lawmakers gave the company until March 10 to respond.

Abbott Nutrition didn't have an immediate comment on the letter, but the company says it took swift action.

"Abbott conducts extensive quality checks on each completed batch of infant formula, including microbiological analysis prior to release," Jonathon Hamilton, a spokesperson for Abbott, said. "All infant formula products are tested for Cronobacter sakazakii, Salmonella and other pathogens and they must test negative before any product is released."

FDA also said Friday it's working to ease supply chain issues, as parents have faced shortages across the country. The brands recalled by Abbott Nutrition — Similac, Alimentum and EleCare — are major parts of the infant formula market. The agency is also working with USDA because so much of the recalled formula was part of the WIC program, which provides nutrition to millions of low-income parents and young children. The recall sent dozens of state agencies scrambling.

"We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible," said Frank Yiannas, deputy commissioner for food policy and response, in a statement last week.

As POLITICO first reported, the timeline from the first illness to the sweeping recall spans months. When pressed about the specific dates, FDA said the agency was told about the first illness Sep. 21.The next day, the agency notified Abbott Nutrition.

The agency has said the next two Cronobacter cases, plus one Salmonella case linked to the same Sturgis, Mich., facility, came through in November, December and January, without specifying when. The infants in all four cases were hospitalized. One infant died, though FDA has said it's not clear whether it was solely due to the Cronobacter infection.

The FDA initiated an inspection of the facility Jan. 31, the agency told POLITICO. Inspectors found Cronobacter sakazakii in several environmental samples taken at the plant. They also found records suggesting the company had previously found the bacteria in the plant and had destroyed product because of the issue. Product was recalled Feb. 17, about three weeks after the inspection kicked off.

One detail that's been missed in all the confusion: FDA was actually in the plant for a routine inspection a few days after the first case was reported to FDA and CDC but it doesn't appear inspectors were looking for Cronobacter. The FDA has so far declined to answer POLITICO's questions about the September inspection and whether inspectors were told about the reported illness.

The plant was not inspected in 2020, likely due to Covid-19. Infant formula plants are usually inspected once a year because they serve such a vulnerable population. The agency has also not answered questions about whether all routine infant formula inspections were skipped in 2020 due to the pandemic.

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Subject: Infant Formula Recall Informational Update
Location: Zoom details below.

Start: 3/4/2022 5:00:00 PM
End: 3/4/2022 5:15:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Monday, Wednesday, Thursday, and Friday from 5:00 PM to 5:15 PM
Required Attendees: Tierney, Julia; Woodcock, Janet; Rawlings, Kimberly; Colonius, Tristan; Mayne, Susan; McMeekin, Judith; Yiannas, Frank; Jefferson, Erica; Rabin, Tara G.; Boon, Caitlin; Mettler, Erik; Rogers, Michael; Harris, Stic
Optional Attendees: Copeland, Jakea; Fristedt, Andi

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Subject: Infant Formula Recall Informational Update
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From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 2/28/2022 2:03:33 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]; 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]; 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]; 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]; 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]
CC: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]

Subject: Infant Formula Recall Informational Update
Location: Zoom details below.

Start: 2/28/2022 5:00:00 PM
End: 2/28/2022 5:15:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Monday, Wednesday, Thursday, and Friday from 5:00 PM to 5:15 PM
Required Attendees: Yiannas, Frank; Woodcock, Janet; Tierney, Julia; Rawlings, Kimberly; Colonius, Tristan; Mayne, Susan; McMeekin, Judith; Jefferson, Erica; Rabin, Tara G.; Harris, Stic; Boon, Caitlin; Mettler, Erik; Rogers, Michael
Optional Attendees: Copeland, Jakea; Fristedt, Andi

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SIP: (b) (6)@sip.zoomgov.com

Passcode (b) (6)

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 2/28/2022 2:03:27 PM
To: 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]; 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]; 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]; 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]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]
CC: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]

Subject: Infant Formula Recall Informational Update
Location: Zoom details below.

Start: 3/2/2022 5:00:00 PM
End: 3/2/2022 5:15:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Monday, Wednesday, Thursday, and Friday from 5:00 PM to 5:15 PM
Required Attendees: Tierney, Julia; Woodcock, Janet; Rawlings, Kimberly; Colonius, Tristan; Mayne, Susan; McMeekin, Judith; Yiannas, Frank; Jefferson, Erica; Rabin, Tara G.; Boon, Caitlin; Mettler, Erik; Rogers, Michael; Harris, Stic
Optional Attendees: Copeland, Jakea; Fristedt, Andi

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Passcode (b) (6)

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Passcode (b) (6)

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 2/28/2022 9:18:18 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]; 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: Schedule for Tuesday, March 1, 2022
Attachments: 00-03.01.2022-Calendar.pdf; 1050-2022-03-01_FDA_Tech_Council_Agenda.docx; 1130-1-Email Prep Pre-record FDA Rare Disease Day.pdf; 1500-OPLIA customer interview questions 2.15.2022.docx

Your first meeting is scheduled for *8:45 AM [Small OC Executive Team]*. Your final meeting is scheduled for *5:15 PM [Strategy for 4th Dose of mRNA Vaccines]*.

8:45-9:00am Small OC Executive Team

9:00-10:00am DIVERSITY IN CLINICAL TRIALS BRIEFING

10:00-10:50am DNS - Prep for Camera

10:50-11:00am Join the Technology Council Meeting for support of an award being given
Materials: Agenda attached

11:00am DNS- Prep for camera

11:30am-12:00pm FDA Studios Recording with Janet Woodcock for RDD 2022
Materials: Overview attached; addt'l material included in Read Ahead

12:00-12:30pm COVID Part 2 Briefing (CBER) on Tuesday, March 1, 2022

12:30-1:45pm LUNCH/DESK TIME

1:45-2:00pm Infant Formula Recall Informational Update

2:00-3:00pm Meeting with the Strategic Initiatives Team

3:00-3:30pm Sandra Tibbs / Janet Woodcock (OPLIA Customer Interview)
Materials: Attached

3:30-4:00pm DESK TIME

4:15-4:30pm Internal Prep for RMC call with CMS Administrator

4:30-5:15pm DESK TIME

5:15-6:15pm Strategy for 4th Dose of mRNA Vaccines

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

March 1, 2022

Tuesday

March 2022

Su	Mo	Tu	We	Th	Fr	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

April 2022

Su	Mo	Tu	We	Th	Fr	Sa
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3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

	TUESDAY
	1
7 AM	**DNS**
8	**Small OC Executive Team;** Zoom details below; FDA Commissior
9	**DIVERSITY IN CLINICAL TRIALS BRIEFING** OS Scheduling (HHS/OS)
10	**DESK TIME** **DNS - Prep for Camera** **Join the Technology Council Meeting for support of an awarc**
11	**DNS- Prep for camera** **FDA Studios Recording with Janet Woodcock for RDD 2022;** Zoom: https://fda.zoomgov.com, (b) (6)
12 PM	**COVID Part 2 Briefing (CBER) on Tuesday, March 1, 2022;** https://fda.zoomgov.com (b) (6) **LUNCH**
1	**DESK TIME** **Infant Formula Recall Informational Update;** Zoom details below.; Califf, Robert
2	**Meeting with the Strategic Initiatives Team** Microsoft Teams Meeting Woodcock, Janet
3	**Sandra Tibbs / Janet Woodcock (OPLIA Customer Interview);** Microsoft Teams Meeting; Woodcock, Janet **DESK TIME**
4	**Internal Prep for RMC call with CMS Administrator;** MS Teams; Califf, Robert **DESK TIME**
5	**Strategy for 4th Dose of mRNA Vaccines** Please see Zoom below Califf, Robert
6	
7	
8	

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/4/2022 5:40:55 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; 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]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: 3/4, Agenda: Weekly Check-In: Legislative Forecast
Attachments: 0800-Legislative Comms Meeting Agenda_03.04.2022.docx

Good morning,

Attached please find the agenda for reference at today's "**8:00am - Weekly Check-In: Legislative Forecast**". This agenda has been shared with Dr. Califf.

Thank you,

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

Weekly Check-In: Legislative Forecast
Friday, March 4, 2022 - 8:00-8:15am
Virtual/Zoom
Materials: none

AGENDA

1. Member Outreach Plan Update/Harris reminder

2. FY 22/supplemental update

3. FY 23 release and hearing update/Qs
   - Testimony

4. DeLauro GAO Infant Formula request

5. Synthetic Nicotine

6. UFA Engagement with EC/HELP

7. PREVENT Pandemic Intro and Markup

8. Member Meeting - Krishnamoorthi

From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 3/6/2022 4:38:23 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]; 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: RE: [EXTERNAL] 'I almost lost my baby': Parents demand answers from FDA

With Helena at times, yes. She's particularly prone to the dramatic. It's better with a few of the other Politico reporters.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Saturday, March 5, 2022 9:12 AM
To: Califf, Robert <(b) (6)fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: Re: [EXTERNAL] 'I almost lost my baby': Parents demand answers from FDA

+Erica who can comment further. They tend towards the sensational at times.

From: Califf, Robert <(b) (6)fda.hhs.gov>
Sent: Saturday, March 5, 2022 7:33:02 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Re: [EXTERNAL] 'I almost lost my baby': Parents demand answers from FDA

Is this representative of our relationship with Politico?

rmc

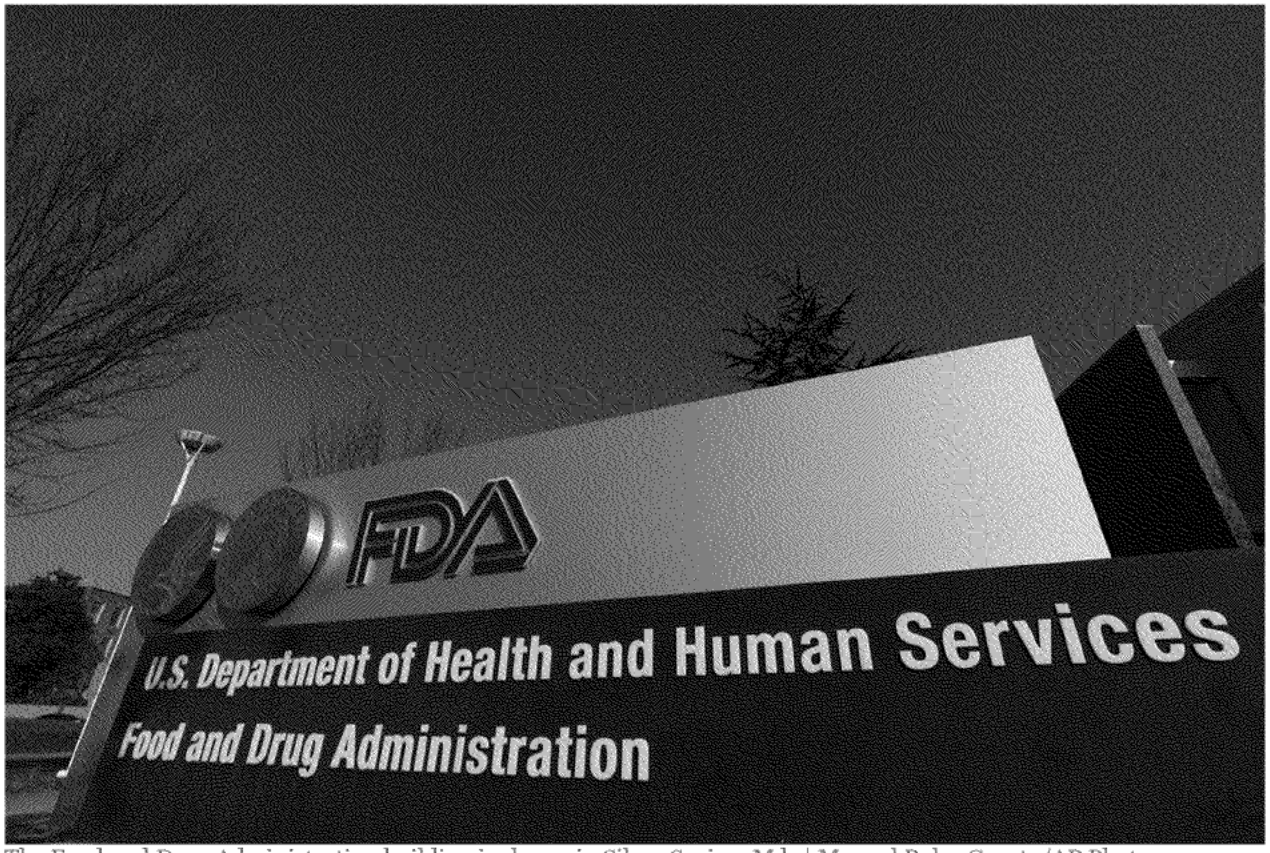
From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Date: Friday, March 4, 2022 at 10:18 PM
To: Califf, Robert <(b) (6)fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Fwd: [EXTERNAL] 'I almost lost my baby': Parents demand answers from FDA

From: POLITICO Pro <alert@email.politicopro.com>
Sent: Friday, March 4, 2022 9:33:55 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: [EXTERNAL] 'I almost lost my baby': Parents demand answers from FDA

POLITICOPRO

‘I almost lost my baby’: Parents demand answers from FDA

BY HELENA BOTTEMILLER EVICH | 03/04/2022 09:33 PM EST



The Food and Drug Administration building is shown in Silver Spring, Md. | Manuel Balce Ceneta/AP Photo

Two weeks after a nationwide recall of infant formula tied to five hospitalizations and two deaths, the FDA is refusing to answer questions about why it took months to take action, while parents, lawmakers and advocates ratchet up pressure on the agency.

As POLITICO recently reported, the FDA, CDC and formula maker Abbott Nutrition knew about the first infant seriously sickened by Cronobacter sakazakii, a rare bacteria, in September. It was more than four months before FDA sent inspectors to investigate the plant where the formula was made. It took another three weeks to order a recall. The

timeline has raised questions about the government's response and whether quicker action could have prevented illnesses and deaths.

"It's kind of alarming that we know more about Russian military tactics in Ukraine than we do about FDA's actions regarding the Abbott facility," said Brian Ronholm, director of food policy at Consumer Reports.

POLITICO has repeatedly asked the FDA to explain why there was a monthslong lag between illnesses being reported, an inspection and then ultimately pulling products off the market. The agency has repeatedly declined to do so.

"We know there have been questions about the timeline," FDA said in a statement. "However, this remains an open inspection with many moving parts. Our top priority is ensuring that any recalled product produced at this facility is taken off the market."

The FDA said it would conduct a review once the investigation is over.

A handful of Democrats on Capitol Hill are raising concerns about the incident Sen. Patty Murray (D-Wash.), chair of the Senate Health, Education, Labor and Pensions Committee, and Sen. Bob Casey (D-Pa.), a senior member on the committee, wrote to Abbott Nutrition demanding documents and other information by March 10. House Appropriations Committee Chair Rosa DeLauro (D-Conn.) on Thursday asked the Health and Human Services office of the inspector general to investigate whether the FDA "took prompt, appropriate, and effective action" in the lead-up to the massive recall.

The three brands that were recalled — Similac, Alimentum and EleCare — are all major players in the infant formula market. Similac is also a top supplier to the WIC program, which provides millions of low-income parents with formula and nutritious food staples. The illnesses tied to Abbott Nutrition's products, all manufactured at a single plant in Sturgis, Michigan, include four cases of Cronobacter and one of Salmonella Newport. All five infants were hospitalized between September and January.

The FDA has shared details on which lots of formula have been recalled here.

As pressure builds on FDA, throngs of parents have taken to social media to express their anger toward Abbott, toward the government and in many cases to report that their babies also got sick. While CDC's official count is that there are five hospitalizations as part of this outbreak, a spin through Instagram and TikTok reveals dozens of unconfirmed yet detailed and heartbreaking reports of babies hospitalized for Salmonella and other bacterial infections after reportedly consuming recalled formula, using hashtags like #similac #screwyou.

POLITICO spoke with several families who believe contaminated formula sickened their baby, in some cases almost killing them.

Deborah Rossick, a mother of two in Lakeland, Florida, said she started buying EleCare late last summer because her then 4-month-old baby Arya was showing signs of dairy intolerance. (EleCare is hypoallergenic.) When Arya started getting sick in late August, Rossick said, she quickly started consulting doctors to try to figure out what was wrong. By early October Arya was diagnosed with Salmonella, Rossick said. After weeks of being sick, in and out of the hospital, Arya got much worse. She ended up with meningitis — a

type that is caused by Salmonella — she started seizing, stopped breathing, had a stroke and was intubated. She was in a coma for nine days.

"Doctors told me she wasn't going to make it," Rossick said. When Arya woke up, doctors learned she had suffered severe neurological damage. She is also now blind and deaf.

"I have my baby," Rossick said, choking back tears. "I almost lost my baby — I still have her. But she is a completely different baby."

When Rossick saw the news about the recall Feb. 17, she said she was "completely appalled." Every single can of formula that Rossick had fed Arya has now been recalled, she said. She said she's planning legal action to cover hundreds of thousands of dollars in medical bills and extensive care that will be needed for Arya over her lifetime.

Abbott Nutrition said in a statement, "We are very sympathetic to the families. We value the trust parents and caregivers place in us and ensuring the safety and quality of our products is our top priority."

Rossick's tragedy also raises questions about the country's public health surveillance system. Cronobacter sakazakii is a rare bacteria and it has not been deemed a notifiable disease, which means that health providers aren't required to report cases to CDC. Salmonella is a notifiable disease, however, which means every case is supposed to reported into CDC's surveillance system. Arya's case was reported and the Polk County Health Department interviewed Rossick in October. She said she told health officials that her daughter only consumed EleCare formula and she only used bottled water, so she could not figure out how she could possibly contract Salmonella.

"I know cross contamination," said Rossick, a trained pastry chef. "I'm not going to cut raw chicken and touch my baby's bottle. I'm thinking: my dog ate a frog and then kissed her on the mouth. I'm thinking of every possible alternative as to how my baby got salmonella. And it has everything to do with me giving it to her."

A Florida Health Department spokesperson told POLITICO the state has no cases connected to the outbreak. An FDA complaint coordinator, however, told Rossick there are several reports currently being investigated in Florida, she said. Arya's case is among them.

In epidemiology, it's long been known that for every case of foodborne illness that's detected and linked to an outbreak, there are many others that will not be accounted for. CDC estimates that for every lab-confirmed case of Salmonella there are 30 that go undetected. In the current outbreak, CDC has connected one case of Salmonella Newport to the outbreak. The infant was hospitalized.

There are many more parents wondering if their childrens' recent illnesses might be explained by contaminated formula.

Paige Goitia, a mother of two in Sparta, New Jersey, said she woke up at 3 a.m. in late January to find her 7-month-old baby Adrien was completely covered in vomit. He was violently — and silently — vomiting on himself in a way that alarmed her. She got him out of his crib and gave him a bath. Soon thereafter, he started having diarrhea. Another bath. Adrien was extremely sick like this for several days, Goitia said. He ended up in the hospital and was put on fluids, but doctors chalked it up to a virus and told Goitia to

prepare for the rest of her family to catch it, too, they said. She was skeptical. No one else got sick. Adrien slowly recovered, but it was a horrific ordeal.

Three weeks later, when Goitia saw the recall announcement and it included Adrien's formula — Similac Pro-Sensitive — she was furious. She called Abbott's phone line they set up for consumers and waited what seemed like forever to talk to a representative. "I asked, where is everybody getting off that this just affected a couple babies? Where is that coming from?" she recalled, noting that a scroll through the company's social media account uncovered numerous parents with similar complaints.

Goitia said she is still traumatized by the incident. She shudders to think what might have happened if she hadn't found Adrien the first night he got sick.

"It scares me to this day and I actually have him sleep right by me now by the bed because this incident has terrified me," she said. "He could have choked on his own throw-up. He couldn't roll over to his side yet. I was livid. I blamed myself — he could have died."

After she learned about the recall, Goitia decided to get Adrien tested for Salmonella. She has not yet gotten the results.

Parents are increasingly turning to lawyers. A pre-suit petition has been filed in Texas on behalf of a baby that was hospitalized for weeks with Cronobacter, racking up hundreds of thousands in medical bills. A class action with 18 cases so far, from parents across several states, has been filed in the U.S District Court Southern District of Florida.

Abbott Nutrition responded in a statement, saying "the cases are under investigation and at this time the cause of the infants' infections have not been determined. All infant formula products are tested for Cronobacter sakazakii, Salmonella and other pathogens and they must test negative before any product is released. The company keeps retained samples of each batch. We tested retained product samples related to the complaints for Cronobacter sakazakii and Salmonella, and they tested negative."

The day after the sweeping recall was announced, FDA answered a few of POLITICO's questions about the investigation timeline, but after that did not address several specific follow up questions about why the recall took months.

Last September, the Minnesota Department of Health investigated a case of an infant who was sickened by Cronobacter sakazakii. State health officials in Minnesota — a state known for its diligence in investigating foodborne illnesses — ascertained that the infant had consumed powdered formula produced at an Abbott Nutrition facility in Sturgis, Michigan, and shared this information with FDA and CDC in September, the state agency said, as POLITICO previously reported.

"It often takes time to gather enough information to put the pieces of a puzzle together — or at least enough pieces to make clear the actions needed to protect public health," said Doug Schultz, a spokesperson for the Minnesota Department of Health, explaining why one illness might not spark a recall. State agencies can't institute national recalls; only the FDA has that power.

The FDA initiated an inspection of the facility on Jan. 31, a spokesperson told POLITICO. Inspectors found Cronobacter sakazakii in several environmental samples taken at the plant, FDA said. They also found records suggesting the company had been finding the

bacteria in the plant and had destroyed product because of the issue, according to the agency. The FDA issued its warning to consumers and a voluntary recall from Abbott Nutrition the evening of Feb. 17, nearly three weeks after initiating the inspection.

In 2017, an inspector general report found that FDA had serious deficiencies with its food recall process. "Recalls were not always initiated promptly because FDA does not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary food recalls," the report concluded.

The agency has since tried to shore up its foodborne outbreak response. In December, the agency released a plan aimed at solving outbreaks faster and said it had expanded its rapid response teams to help federal and state officials work better together, among other changes.

Lawmakers and consumer advocates are also raising questions about FDA's inspection history of the Sturgis, Michigan plant. FDA was actually in the plant for a routine inspection a few days after the first case was reported to FDA and CDC in September, but it doesn't appear inspectors were looking for Cronobacter. During that inspection, FDA uncovered several issues, including lapses in basic plant sanitation and handwashing. The agency has so far declined to answer specific questions about the September inspection and whether inspectors were told about the reported illness.

"The FDA's ongoing inspection of the Abbott facility in Sturgis, Michigan is part of an open investigation, which we cannot comment on," the agency said in a statement.

Infant formula plants are usually inspected once a year because they serve such a vulnerable population. The Michigan plant was not inspected in 2020, likely due to Covid-19.

As questions about the government's timeline in the infant formula recall have intensified, the FDA has largely clamped down. Key congressional aides in the House and Senate said their questions have not been answered. Consumer advocates have not gotten responses, either.

"The recent infant illnesses and deaths with exposure to certain recalled powdered infant formulas produced at an Abbott facility is tragic and of great concern to us all," said Frank Yiannas, deputy commissioner for food policy and response at FDA. "Our first and foremost priority is ensuring that any recalled product is taken off the market and working with the USDA and manufacturers to ensure that parents have access to alternative, safe infant formula."

Consumer advocates are pressing for a clearer explanation of why the timeline spans months.

"There are many more questions here than answers," said Michael Taylor, former FDA deputy commissioner for foods and veterinary medicine, who is now a board member of Stop Foodborne Illness, which works with victims of foodborne illness. "It's urgent for the health of babies and consumer trust that FDA get to the bottom of what happened internally and at Abbott, fix the problem, and be transparent with the public."

View this article online.

Politico Transaction: correlation=3c9fd4d0-e9b8-429d-9382-4d9d11e50a64, doc=0000017f-57c6-d8c0-a97f-ffef72cd0001, send=a0030989-64e0-4120-8bff-44bd645422b7, user=00000159-94ce-d592-a55d-ffef1ec80000

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/8/2022 8:51:12 PM
To: 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]; 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]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: 03/09, Materials: Infant Formula Update
Attachments: 1445-FDA Abbott infant formula timeline final.pptx

Good evening,

Attached please find the materials for reference at tomorrow's "**2:45pm - Infant Formula Update**". These materials have been shared with Dr. Califf.

Thank you,

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

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.]
Sent: 3/24/2022 8:44:51 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: IMPORTANT: Updated Materials for Media Prep/Interview - Thurs., March 24, 2022

You're welcome.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 24, 2022 8:44 AM
To: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Subject: RE: IMPORTANT: Updated Materials for Media Prep/Interview - Thurs., March 24, 2022

Thx Jacque. jw

From: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Sent: Wednesday, March 23, 2022 11:43 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: IMPORTANT: Updated Materials for Media Prep/Interview - Thurs., March 24, 2022
Importance: High

SCHEDULE

9 AM - Media Prep: Politico, FDA Foods Program

10 AM - Media Interview: Helena Bottemiller Evich, Politico

ATTACHED MEETING MATERIALS

1. **Talking Points, Politico Interview on FDA Foods Program**
2. **Technical Written QAs, Politico FDA Foods Program Story**
3. **Attached Media Comment & Responsive QAs, Abbott Nutrition FDA Form 483s**

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, March 23, 2022 10:01 AM
To: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@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>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: OEA/OMA Homework Materials for PDC - Tue., March 22, 2022

All of this looks fine. However several things come to mind. The "Foods Program" TPs are very CFSAN centric. Last time I looked, which admittedly was a while ago, the bulk of the foods program, by resourcing, resided in ORA. Do we not want to point out the split of resources?

Basically as far as I can parse it out, ORA and Frank's group work mainly on adulteration/outbreak/recall issues, focused primarily on microbial/virus contamination issues and FSMA. CFSAN in contrast has to do that in addition to literally dozens of additional important programs such as the heavy metal and chemical contamination issues brought up in the

backgrounder, as well as the standards of identity and other matters. CFSAN appears to draft all the rules although I'm not sure about that.

(b) (5)

jw

From: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Sent: Tuesday, March 22, 2022 5:58 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: OEA/OMA Homework Materials for PDC - Tue., March 22, 2022
Importance: High

PLEASE REVIEW ATTACHED: Background & Talking Points, Politico Interview on FDA Foods Program

- Requesting feedback by: Wed., Mar. 23, 10 am
- **Interview date: Thu. Mar. 24, 10am**
- Note: Preparation material for Politico interview on FDA's foods program, including discussion on infant formula
- **OEA POC: Tara Rabin**

PLEASE REVIEW ATTACHED: Technical Written QAs, Politico FDA Foods Program Story

- Requesting feedback by: Wed., Mar. 23, 10 am
- Anticipated release: Wed., Mar. 23
- Note: Written responses to reporter questions to be provided to Politico in advance of interview
- **OEA POC: Tara Rabin**

FYI: Attached Media Comment & Responsive QAs, Abbott Nutrition FDA Form 483s

- Requesting feedback by: Wed., Mar. 23, 5 pm
- Anticipated release: Thu. Mar. 24
- Note: Cleared material to address media when Abbott Nutrition FDA Form 483s posted on Tues., Mar. 22. Providing as additional background in preparation for Politico interview.
- **OEA POC: Tara Rabin**

NOTE: (b) (5) related to Abbott Nutrition for Drs. Califf and Woodcock was obtained by Emily Helms Williams on 3/21.

Jacqueline Thomas
Executive Assistant
Immediate Office, Office of the Principal Deputy Commissioner

U.S. Food and Drug Administration
Mobile: (b) (6)
Email: Jacqueline.Thomas@fda.hhs.gov

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/28/2022 10:03:44 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]; Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; 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]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: 3/28, Agenda: Weekly CFSAN Meeting with the Commissioner
Attachments: 2022.03.28_CFSAN Agenda.doc

Good morning,

Attached please find the agenda for reference at today's "**3:00pm - Weekly CFSAN Meeting with the Commissioner**". This agenda has been shared with Dr. Califf.

Thank you,

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 CFSAN Meeting with the Commissioner
Monday, March 28, 2022
3:00-3:30 PM

Agenda

1. Follow-up from Commissioner attendance at CLT - questions?
2. Susan WFA form
3. Impact of Russia/Ukraine situation on food supply chain
4. Abbott Nutrition cronobacter incident
5. Politico story - next steps and impact on CFSAN staff? How can commissioner's office support
6. Nutrition updates

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 3/30/2022 10:38:16 AM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: Final Proposal - Infant Formula IMG Memo and Org Chart

Frank, thanks for all the work that has gone into this so that we can pull together all of the folks with the right expertise. One comment, though, we need to make sure that this is fit for purpose and, for example, I don't think we need a JIC as part of this (and I understand it's not necessary). I understand that OEA was asked for 7 staff for this and that just is not doable - and also not necessary as they are very coordinated on messaging. Will follow up separately with you, Mark, and Erica.

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Tuesday, March 29, 2022 6:53:01 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: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 4/6/2022 7:02:48 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]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: FLAG: CDC request for FDA to develop infant formula resource for consumers

All,

Just making you aware that CDC reached out to us looking for help developing an infographic or alternative visual to demonstrate safe infant formula preparation inspections. They've developed a resource for consumers, but recognize that a visual would be more impactful. There information is highlighted on the following CDC webpage under the section titled, "Follow These Five Guidelines to Protect Your Baby From Cronobacter" - https://www.cdc.gov/cronobacter/infection-and-infants.html. Apparently CDC's editorial/graphics team cannot assist is due to competing COVID priorities.

The team and I believe this would be a helpful resource for FDA as well should/when the Abbott facility come back online for production and start releasing product to the public. Our press team has also heard from a few reporters that the CDC guidance is a bit confusing and hard to find. Obviously this is something that OEA will support them in developing. Will keep you all looped in on the end result.

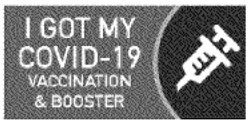
But wanted to make you all aware CDC is now giving us more work. 😊

Have a good evening,
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: Kristen.Tugwell@fda.hhs.gov (temporary)



From: Safford, Melissa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=662886BBFBC7441DAE59DE74071CEC71-MELISSA.SAF]
Sent: 4/6/2022 4:24:12 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Draft IF Evaluation Plan

Great! It's nice to hear that my brain is still capable of writing something that makes sense.

Melissa Safford

Senior Advisor
Office of the Commissioner
(240) 447-9379
melissa.safford@fda.hhs.gov
FDA U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, April 06, 2022 4:19 PM
To: Safford, Melissa <Melissa.Safford@fda.hhs.gov>
Subject: RE: Draft IF Evaluation Plan

Very nice, thanks. You are better at this than I am! jw

From: Safford, Melissa <Melissa.Safford@fda.hhs.gov>
Sent: Tuesday, April 5, 2022 2:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Draft IF Evaluation Plan

Dr. Woodcock – Attached is a draft infant formula evaluation plan for your review and input. I don't know if you saw a prior version, but this is what I worked up using the version I received upon my return last week. We can discuss during our check in later today. Once this is aligned with your thinking, next steps I've identified include:

(b) (5)

Talk soon,
Melissa

Melissa Safford

Senior Advisor
Office of the Commissioner
(240) 447-9379
melissa.safford@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: 4/7/2022 8:16:50 PM
To: 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]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Flowers, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9418b62ec07642d7bc53c564e008f5ce-Susan.Flowe]
Subject: 4/8, Materials: Biweekly OFPR Check-In with the Commissioner
Attachments: 0800-Biweekly OFPR Meeting_04.08.2022.pdf

Good evening,

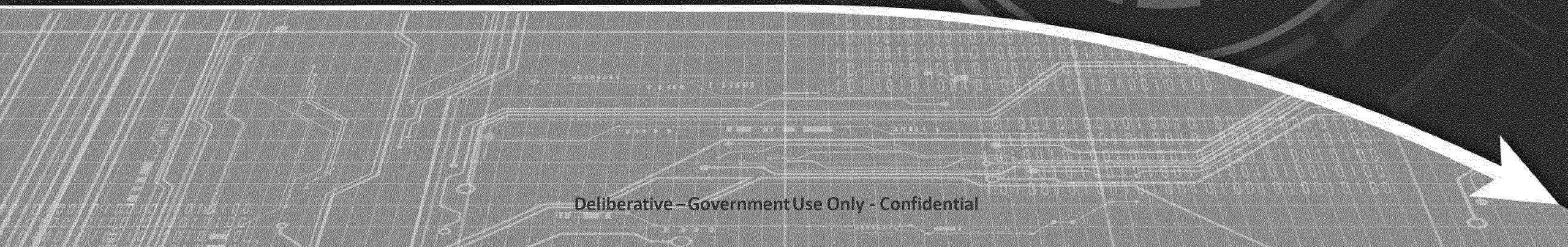
Attached please find the materials for reference at tomorrow's "**8:00am - Biweekly OFPR Check-In with the Commissioner**". These materials have been shared with Dr. Califf.

Thank you,

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 with the Commissioner

4/8/2022



(b) (5)

(b) (5)

FDA Foods Program
Stakeholder Listening Sessions

National Association of State Departments of Agriculture (NASDA)	
Ted McKinney Chief Executive Officer NASDA (202) 296-9680 Ted.McKinney@nasda.org	Founded in 1916, NASDA is a nonpartisan, nonprofit association that represents the elected and appointed commissioners, secretaries, and directors of the departments of agriculture in all fifty states and four U.S. territories. NASDA's 2021 policy priorities are: food systems, food safety, infrastructure and capacity, climate resiliency, international trade and harmonization, and workforce development.

Food and Beverage Issue Alliance (FBIA)	
Robb MacKie President & CEO American Bakers Association Phone: (202) 789-0300 x114 RMacKie@americanbakers.org	FBIA represents 58 allied U.S. based Food and Beverage Trade Associations. FBIA, through collaboration with regulatory authorities, ensures that any regulations and guidance are justified by verifiable, peer reviewed, published science that is accessible through an open and transparent process and enhance consumer understanding. In addition, FBIA works to ensure regulation implementation timelines are reasonable, achievable and economically feasible for both small and large food and beverage manufacturer

Safe Food Coalition (SFC)	
James Kincheloe Food Safety Campaign Manager Center for Science in the Public Interest jkincheloe@cspinet.org	The SFC brings together consumer, public health and labor organizations to advocate for improvements to the food safety system, particularly with respect to meat and poultry. Since it was created in 1986, the Consumer Federation of America (CFA) has coordinated the coalition.

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 4/5/2022 8:40:58 AM
To: 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: Re: Incident Management Group Activation Notice- Infant Formula Incident

Talking with Frank this morning.
rmc

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Date: Tuesday, April 5, 2022 at 7:22 AM
To: Califf, Robert (b) (6)fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Fwd: Incident Management Group Activation Notice- Infant Formula Incident

Rob - I know we've been busy with other things this past weekend, wanted to re-up this since the IMG is moving forward. Happy to discuss. Thanks.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Saturday, April 2, 2022 9:23:52 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Califf, Robert (b) (6)fda.hhs.gov>
Subject: RE: Incident Management Group Activation Notice- Infant Formula Incident

Looks fine to me. The supply chain issues include things like need for additional inspections of other facilities, review of reformulations, medical decisions about releasing specialty product to prevent shortages and of course tracking availability. jw

---

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, April 1, 2022 11:52 PM
To: Califf, Robert (b) (6)fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: Incident Management Group Activation Notice- Infant Formula Incident

Draft email to Frank re the IMG below. Janet, please feel free to add any comments.

Frank,

(b) (5)

rmc

From: Russo, Mark <Mark.Russo@fda.hhs.gov>
Sent: Tuesday, March 29, 2022 5:53 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>
Cc: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>
Subject: Incident Management Group Activation Notice- Infant Formula Incident
Importance: High

All:
The purpose of this message is to advise you that an FDA Incident Management Group (IMG) is being activated in response to illnesses possibly associated with infant formula, and to solicit your assistance in staffing key IMG positions. FDA has been investigating consumer complaints of infant illness related to products from Abbott Nutrition's Sturgis, Michigan facility. As a result of this investigation, FDA issued an advisory to alert consumers to avoid purchasing or using certain powdered infant formula produced in the Sturgis, MI facility, and Abbott Nutrition has recalled a number of products produced at the facility. The Sturgis, MI facility has not been producing product since the initial recall was issued, and FDA has conducted extensive inspectional activities at the firm.
The Abbott Nutrition facility that produces recalled infant formulas also produces metabolic and other medical specialty infant formulas for infants with inborn errors of metabolism and other medical needs, as well as medical foods. These products, with the exception of one lot of Abbott Similac PM 60/40, have not been recalled because the FDA has determined that the risk of not having these specialty products available could significantly worsen underlying medical conditions. For many of these patients, the risk of life-threatening adverse events from restricted access to these critically needed products is likely greater than the risk from consuming products that have been produced at the facility. FDA has alerted caregivers and consumers who use specialty metabolic formulas and medical food products to be aware that there may be some risk of *Cronobacter* contamination.
Given the magnitude of the recall, the length of time that this facility has not been in production, and the contribution that the Sturgis, MI facility makes to the overall supply of certain products, there are ongoing concerns about the availability of infant formula and medical food products. There are also continuing efforts needed to provide for safe resumption of production at the Sturgis, MI facility.
Because of the impact on infant health, product supply, and in accordance with the FDA Emergency Operations Plan (https://www.fda.gov/media/79493/download), at the request of the Office of Food Policy and Response I am activating an IMG to coordinate FDA's response to the incident, effective at 8:30 a.m. on Friday, April 1, 2022. Initial operating hours for the IMG will be 8:30 a.m. - 5:00 p.m. EDT, Monday through Friday. Hours and/or days of operation are subject to change, depending on the needs of the incident, at the discretion of the Agency Incident Coordinator (AIC). **The AIC for this incident will be Frank Yiannas, Deputy Commissioner, Food Policy & Response.**
Initial objectives for the IMG are as follows:

- Coordinate any product or firm actions that may be warranted (e.g., compliance actions, exploration of any additional cases/complaints, recall scope, consent decree).
- Evaluate the severity of public health need for Abbott product to be released from storage.
- Track the availability of infant formula and medical food products through analysis of market data and contact with infant formula manufacturers.
- Explore temporary policies and mitigation strategies to address supply shortages.
- Coordinate with federal, state, local, and international partners.
- Collaborate with the FDA Incident Management Team(s) (IMT) on consumer complaints received.
- Outreach to patient groups, provider groups, and consumers.

An initial organization chart for the IMG is attached for reference. A complete listing of positions on the IMG can be found below. A number of positions have already been filled using Office of Food Policy and Response (OFPR), Center for Food Safety and Applied Nutrition (CFSAN), and Office of Emergency Management (OEM)/Office of Emergency Operations (OEO) staff. Those positions are indicated in black font below. A number of additional positions are listed, along with recommended staff/organizations to fill them. These positions are indicated in blue font below. Finally, a number of positions have been identified as needed for our response but have not yet been staffed. These positions are indicated in red font below. I am requesting that the organizations indicated below identify staff who can serve in the positions indicated. All positions indicated below will work on the IMG from their virtual work locations. We are requesting that personnel designated from all organizations listed below be available to participate virtually for IMG duty ***beginning on Friday, April 1st.*** Initial staffing commitment is anticipated to be 4 weeks.

1. **Agency Incident Coordinator**- Frank Yiannas, OFPR
2. Deputy Agency Incident Coordinator- CAPT Joshua Simms, OEM/OEO
3. CDC LNO: Susan Lance, CFSAN
4. USDA LNO: Claudine Kavanaugh, CFSAN
5. Legal – Peter Beckerman, Shannon Singleton and Carrie James, OCC
6. **Planning Section Chief**- CAPT Dominic Frasca, OEM/OEO
7. Planning Section Deputy - CORE
8. Situation Unit Leader- Carole Dieterly, OEM/OEO
9. Situation Unit Specialist – CFSAN
10. Documentation Unit Leader- Vanessa Williams, OEM/OEO
11. Documentation Unit – ORA
12. Documentation Unit – CFSAN
13. **Operations Section Chief – Supply Chain Expert, CDER**
14. Operations Deputy - Individual from CORE with ICS experience
15. Supply Chain Chief – Pediatric Medical Expert, CDER
16. Supply Chain Deputy – Caitlin Boon
17. Supply Chain Disruption Mitigation Unit Leader – CDER Shortage SME
18. Supply Chain Disruption Mitigation Unit Deputy – Claudine Kavanaugh or Pat Hansen, CFSAN/ONFL
19. Supply Chain Disruption Mitigation Unit Specialist – LeeAnne Jackson, CFSAN
20. Supply Chain Disruption Mitigation Unit Specialist – Andrea Lotze, CFSAN
21. Supply Chain Disruption Mitigation Unit Specialist – Carrie Assar, CFSAN
22. Supply Chain Disruption Mitigation Unit Specialist – Pediatric Specialist, CDER
23. Data Analytics/GIS Leader - Nathan Beck, OEM/GIS Team
24. Data Analytics/GIS Deputy – Suzanne Roosen, OFPR
25. Data Analytics/GIS Specialist – Xin Liu, OFPR
26. Data Analytics/GIS Specialist – David Oryang, CFSAN
27. Data Analytics/GIS Specialist – Andy Kennedy, OFPR
28. Data Analytics/GIS Specialist – Adam Friedlander, OFPR
29. Data Analytics/GIS Specialist – CDER Shortage Staff
30. International Operations Unit, Leader – Russell Zablan, OEM/OEO
31. International Operations Specialist – CFSAN/OIE
32. Food Safety & Response Leader – Ann Oxenham, CFSAN
33. Food Safety & Response Deputy – Karl Klontz, CFSAN/OAO/DPHIA
34. Food Safety & Response Specialist – RADM David Goldman, OFPR
35. Food Safety & Response Specialist – CORE Response Team 2
36. Food Safety & Response Specialist – CFSAN OC
37. Food Safety & Outbreak Response Specialist – Less Smoot, CFSAN

38. Food Safety & Outbreak Response Specialist – Jamie Pettengill, CFSAN

39. **Logistics Section Chief** – LCDR Henry Allen, OEM/OEO

A Joint Information Center (JIC) is also being established within the IMG. The size and complexity of the incident necessitates a robust public information/external affairs function. The purpose of the JIC is to develop and deliver coordinated intra-agency and interagency messages; develop, recommend, and execute public information plans and strategies; advise the IMG on public affairs issues that could affect a response effort; and correct inaccurate information, to the degree possible, that could undermine public confidence in the incident response effort.

In light of the above, I am requesting that the organizations indicated below provide staff for full-time assignment to the following positions:

Joint Information Center

1. JIC Lead — Office of Media Affairs (OMA)/Office of External Affairs (OEA)
2. Social Media Specialist — OMA
3. Communications Specialist(s) — affected Centers and Offices and representatives for a variety of stakeholders. You can add as many of these personnel as you need.
4. External Affairs Specialist (stakeholders) — OEA
5. Call Center Liaison – Liz Ortuzar, OEM
6. Call Center Liaison- CFSAN
7. Consumer Communications Specialist(s) — OEA
8. Two Web Communications Specialists (one writer/content manager, one for technical posting support) - OMA
9. Legislative Affairs Specialist—Office of Policy, Legislation and International Affairs /Office of Legislation
10. Graphic Designer - OMA

At this time, I am also asking each of the following Centers/Offices to designate a representative to serve on an **Agency Executive Group (AEG)**, in the event one is needed as the incident unfolds:

1. Office of the Commissioner
2. Center for Food Safety and Applied Nutrition
3. Office of Regulatory Affairs
4. Office of External Affairs,
5. Office of Chief Counsel
6. Office of Global Policy and Strategy
7. Office of Security and Emergency Management

As indicated in the FDA Emergency Operations Plan, an AEG may be utilized to provide guidance on policy issues and resolve issues involving competing resources. AEG members should represent senior leadership within their organizations.

Please e-mail the names and contact info (office and cell phone) of the designated representative(s) from your organization to emergency.operations@fda.hhs.gov, cc: Frank Yiannas, ***at your earliest convenience, preferably by noon on Thursday, March 31, 2022.***

Thank you.

--Mark

Mark R. Russo
Director

Office of Emergency Management
U.S. Food and Drug Administration
Office: 301-796-9655
24-hour Emergency: 866-300-4374
mark.russo@fda.hhs.gov

From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 4/11/2022 9:22:33 AM
To: Frasca, Dominic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5975945e67674e19b4f4a02025c5b6b5-Dominic.Fra]; Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dcce89b861b673-JOS]
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]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Infant Formula IMG sitrep

Captain Dominic:

Can you please add those cc'd on this note to the Mon, Weds, and Fri Infant Formula sitrep distribution list?

Also, can we please send them the reports they've missed?

Thanks

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: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 4/14/2022 2:59:55 PM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
CC: Russo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2b18c46a7bc4938a0609c76747e7456-Mark.Russo]; 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]
Subject: RE: Ad Hoc Infant Formula AEG Special Focus Meeting

sure

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Thursday, April 14, 2022 2:53 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; Califf, Robert (b) (6)fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ad Hoc Infant Formula AEG Special Focus Meeting

Frank – would you also include me for the IO on tomorrow's invite? Thanks!

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: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 4/11/2022 9:34:52 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]; Pillsbury, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=962a7ed1a2a24b308cb6ccc3673c53ae-Laura.Pills]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: 4/11, Materials: Weekly CFSAN Meeting with the Commissioner
Attachments: 1500-1-2022.04.11_CFSAN Agenda.doc; 1500-2-Dairy Standards of Identity.pptx

Good morning,

Attached please find the materials for reference at today's "**3:00pm - Weekly CFSAN Meeting with the Commissioner**". These materials have been shared with Dr. Califf.

Thank you,

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 CFSAN Meeting with the Commissioner
Monday, April 11, 2022
3:00-3:25 PM

Agenda

1. Meeting with the Alliance for a Stronger FDA – 4/12
2. COVID-19, Ukraine, and Impacts on the Food Industry
3. Budget Briefings Around FY23
    a. Dairy Standards of Identify and Formal Rulemaking
    b. Nutrition Education Campaign
4. Status of Documents
5. Seafood AI/ML Pilot
6. Infant Formula
7. COVIDtrakr

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 4/15/2022 7:09:58 AM
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]
CC: Russo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2b18c46a7bc4938a0609c76747e7456-Mark.Russo]; 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

Glad to hear this.
rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>
Date: Thursday, April 14, 2022 at 1:27 PM
To: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Cc: "Russo, Mark" <Mark.Russo@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Robert Califf (b (6)) (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.

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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: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 4/18/2022 8:25:45 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]
CC: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: Re: Infant Formula IMG/ AEG meeting 4/15/2022 DECISIONAL (meeting minutes enclosed)

Thanks Frank. Seems like progress.

rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>
Date: Monday, April 18, 2022 at 8:01 AM
To: Robert Califf (b (6)fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>
Cc: Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Subject: Infant Formula IMG/ AEG meeting 4/15/2022 DECISIONAL (meeting minutes enclosed)

Internal, Confidential

(b) (5)

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: Frasca, Dominic <Dominic.Frasca@fda.hhs.gov>
Sent: Friday, April 15, 2022 7:39 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; James, Carrie <Carrie.James@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Smoot, Leslie <Leslie.Smoot@fda.hhs.gov>; Pettengill, James <James.Pettengill@fda.hhs.gov>
Cc: Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Morris, Larry <Larry.Morris@fda.hhs.gov>; Williams, Vanessa <Vanessa.Williams@fda.hhs.gov>; Elassar, Sana <Sana.Elassar@fda.hhs.gov>
Subject: Infant Formula IMG/ AEG meeting 4/15/2022 meeting minutes enclosed.

Good evening;

Enclosed please find a copy of the meeting minutes from today's AEG meeting; as well as a copy of the combined recommendations paper. If approved, I will send to the AEG members as well.

-----Original Appointment-----
From: Frasca, Dominic
Sent: Thursday, April 14, 2022 2:42 PM
To: Frasca, Dominic; Yiannas, Frank; Abdoo, Mark; Mayne, Susan; McMeekin, Judith; Beckerman, Peter; Jefferson, Erica; Felberbaum, Michael; Carter, Lionel; Russo, Mark
Cc: Williams, Vanessa; Elassar, Sana; Morris, Larry; Colonius, Tristan; Malais, Tanya; Woodcock, Janet; Rogers, Michael; Cave, Carol; Oxenham, Ann; Toerner, Joseph; Rabin, Tara G.; Hetlage, Daniel; Sigg, Jim; Howard King, Vinetta; Mignone, Alfred; Barringer, Amy; James, Carrie; Singleton, Shannon; Smoot, Leslie; Pettengill, James
Subject: AEG meeting request-- Infant Formula Investigation IMG (invite updated with the Recommendations paper)
When: Friday, April 15, 2022 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fda.zoomgov.com(b) (6)
Importance: High

Good afternoon;

The Infant Formula Investigation requests that the Agency Executive Group (AEG) be convened to discuss options/ recommendations regarding the held products at Abbot. Enclosed in this invite, please find the Recommendations paper from the IMG's Supply Chain Unit and its Food Safety & Response Unit.

- FDA has determined that for the 12 specialty/metabolic products on hold at Abbott Nutrition for individuals under 2 years of age, there are: 4 products for which there are no comparable products, 1 products for which there are limited comparable products, 6 products for with there is limited availability of comparable product, and 1 product for which comparable products are available. For the 11 Abbott products on hold for individuals over 2 years of age, FDA has determined there are 3 products for which there is no comparable product, 6 products with limited comparable products, and 4 products for which there are multiple comparable products.
- The FDA's Infant Formula Incident Management's Team Supply Chain Unit and Food Safety and Response Unit are collaborating on a recommendation for the partial release of specialty/metabolic products on hold at Abbott Nutrition, with specific testing requirements. A copy of the recommendation paper will be provided to the AEG members prior to the call, for review , and for discussion during the call. FDA will share the final recommendation with the US Dept. of Justice prior to presenting the recommendation to Abbott Nutrition, which FDA hopes can occur early next week.

V/r
CAPT Dominic Frasca
Deputy Agency Incident Coordinator
FDA Infant Formula Investigation IMG
301798246
BB (b) (6) .

Hi there,

Dominic.Frasca@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 +1 669 216 1590 or +1 551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode: (b) (6)

International numbers

Join from an H.323/SIP room system

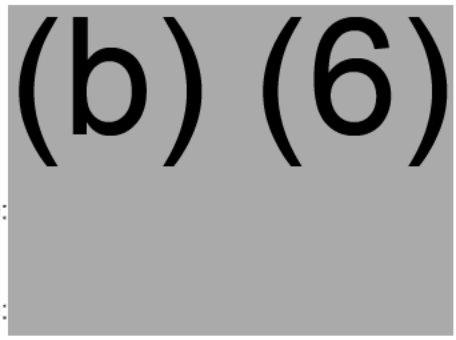
H.323:

Meeting ID:

Passcode:

SIP:

Passcode:



From: Rabin, Tara G. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D6E14C0D07AD46CA812A39A72C751BFE-TARA.GOODIN]
Sent: 4/19/2022 9:33:44 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]; 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]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; 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]
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]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Burgess, Shelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5beb691d4bac4848945f6039974b29fa-Shelly.Burg]
Subject: FYI - Politico, "'What else have they been missing?' Massive infant formula recall raises questions about FDA inspections"

Good evening,

Passing along an anticipated Politico story on our infant formula inspections. It will post outside the paywall tomorrow. As was discussed in IMG calls and reported via the SITREP last week, we provided several responses to the reporter's questions that are reflected in the article, although many did reference our ongoing investigation (including questions specific to timeline). There is also a quote from Dr. Woodcock pulled from our interview with the same reporter for her other, broader foods program piece.

We'll be brainstorming more with OCC tomorrow to understand how/if we might be able to move the needle a bit forward on some "ongoing investigation" responses when/if a Consent Decree is signed.

Best,
Tara

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 4/19/2022 9:41:53 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: brainstorming on portfolio messaging

I haven't talked to Rob yet about timeline, but can do so tomorrow. Or he seems to think you all are going to get a lot of work done at the conference lol

---

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Tuesday, April 19, 2022 9:24:31 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: brainstorming on portfolio messaging

I'm planning to have talking points from our discussion to both of you by tomorrow morning. If this is the case, yes, we'll probably need to accelerate plans. Julie, are you going to speak with Rob about the timeline?

I still think we need to make sure the CFSAN and OFPR teams are aware. We might be able to do an email all hands and then follow up with the town halls. I'll think on this tonight.

Tara is sending around Politico story specific to infant formula that popped tonight…

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Tuesday, April 19, 2022 9:21 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: RE: brainstorming on portfolio messaging

I know we talked about(b) (5) [redacted] Happy to chat in the morning.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, April 19, 2022 8:37 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: RE: brainstorming on portfolio messaging

That sounds good. I'll send you folks the split I proposed to him that he (vaguely) agreed to. It is not cast in stone, but I don't want to be involved on the medical product side routinely, only as consult! jw

---

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, April 18, 2022 6:14 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Flowers, Susan <Susan.Flowers@fda.hhs.gov>; Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>; Tugwell, Kristen <Kristen.Tugwell@fda.hhs.gov>
Subject: brainstorming on portfolio messaging

Hi there – can the three of us get together this week to brainstorm messaging around how the portfolio will be divided between Janet and Rob? Thinking 15-30 minutes, we can be efficient if 15 minutes is all we can land.

FYI I asked that he maybe say a word or two about Janet leading the work on concept of operations and organizational excellence tomorrow before we dive into the Budget and WCF process discussions with the CDs and DCs – and that there will be more to come – so that folks start to get used to it. (open to alternative ways for him to frame)

Thanks,
Julie

Julia C. Tierney, JD (she/her)
Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(b) (6) (cell)
Julia.Tierney@fda.hhs.gov
Executive Assistant: Susan.Flowers@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

I GOT MY COVID-19 VACCINATION

From: Colonius, Tristan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2B3590C046734A2E928858BD579ED852-TRISTAN.COL]
Sent: 4/20/2022 1:16:20 PM
To: 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]; 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]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: RE: FOR REVIEW: Infographic on reducing cronobacter risk when prepping infant formula

Agree – this looks really great!

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Wednesday, April 20, 2022 12:57 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Califf, Robert (b) (6) fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: FOR REVIEW: Infographic on reducing cronobacter risk when prepping infant formula

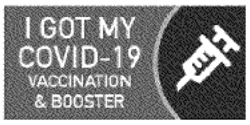
Thanks! This looks great to me. Will it be translated (at some point)?

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

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
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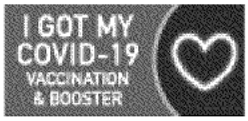
Phone: 301-796-5758 & (b) (6)
Anna.Staton@fda.hhs.gov



From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 4/20/2022 1:17:21 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]; 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]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: RE: FOR REVIEW: Infographic on reducing cronobacter risk when prepping infant formula

Yes, we are planning to translate.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Wednesday, April 20, 2022 12:57 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Califf, Robert <(b) (6)fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: FOR REVIEW: Infographic on reducing cronobacter risk when prepping infant formula

Thanks! This looks great to me. Will it be translated (at some point)?

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
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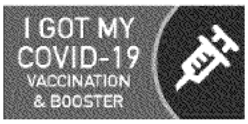
erica.jefferson@fda.hhs.gov

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

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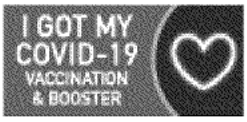

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 4/22/2022 4:33:16 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; 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]; 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]
Subject: Two Week Look through 5/6: Comms on Upcoming Agency Actions

For your awareness, below is a list of upcoming anticipated agency actions and their associated planned communications for the next two weeks (through Fri., May 6).

COMMISSIONER SPEAKING EVENTS

- 4/29: Association of Health Care Journalists Conference (open to press, noon)

CONGRESSIONAL HEARINGS

- 4/26: There will be a full HELP committee hearing, "FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients, FDA Center Directors." FDA Center Directors testifying include Drs. Cavazzoni, Marks and Shuren. Begins at 10 a.m.
- 4/27: FDA Commissioner Dr. Califf will testify in the "Agriculture Hearing" before the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee. Begins at 10 a.m.

Monday, April 25

1. FDA approves first COVID-19 treatment for young children (Press Release, Social Media)

Tuesday, April 26

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. FDA authorizes tobacco-flavored NJOY Ace products (FDA Roundup, Social Media, Stakeholder Outreach)
3. Digital health policies and public health solutions for COVID-19 web update (FDA Roundup)

Wednesday, April 27

Nothing to report at this time

Thursday, April 28

1. FDA issues proposed product standards to ban menthol in cigarettes and characterizing flavors in cigars (Press Release, Social Media, Stakeholder Outreach)

2. FDA issues third-party program questions and answers guidance (FDA Roundup)

Friday, April 29

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. FDA limits use of Janssen COVID-19 Vaccine to certain populations (Press Release, Social Media)

Week of April 25//Tentative:

1. FDA authorizes first lab tests that can determine COVID-19 mutation (FDA Roundup, Stakeholder Outreach)
2. FDA allows Abbott Nutrition to release certain metabolic infant formula products from Michigan facility (FDA Roundup, Stakeholder Outreach)
3. FDA finalizes question and answer guidance on Orange Book (FDA Roundup)
4. FDA issues an order requiring Philips Respironics to submit a plan for device repair, replacement and/or refund of certain breathing machines (Reactive QA)
5. FDA updates home COVID test webpage to include expiration information (FDA Roundup, Stakeholder Outreach)
6. FDA revokes emergency use authorization (EUA) for point of care antigen test manufactured by GenBody Inc. (Reactive QA)
7. FDA revokes emergency use authorization (EUA) of over-the-counter Access Bio, Inc. CareStart COVID-19 Antigen Home Test (Press Release, Social Media, Stakeholder Outreach)
8. FDA makes updates to Aduhelm drug label (Reactive Statement)
9. Caution: Bodybuilding Products Can Be Risky (Consumer Update)
10. Vaccines and Babies (Consumer Video)
11. What is That Sound? Video on Pertussis (Consumer Video)

Monday, May 2

Nothing to report at this time

Tuesday, May 3

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. FDA issues warning letters to companies illegally selling delta-8 tetrahydrocannabinol (THC) products to treat medical conditions (Press Release, Social Media, Stakeholder Outreach)

Wednesday, May 4

Nothing to report at this time

Thursday, May 5

Nothing to report at this time

Friday, May 6

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. FDA holds advisory committee meetings to discuss multiple potential actions on COVID-19 vaccines (Press Release, Social Media)

Week of May 2//Tentative:

1. FDA permits marketing for new test to improve diagnosis of Alzheimer's Disease (Press Release, Social Media, Stakeholder Engagement)
2. FDA denies Section 804 Importation Program proposal from state of New Hampshire (Reactive QA)

From: Safford, Melissa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=662886BBFBC7441DAE59DE74071CEC71-MELISSA.SAF]
Sent: 4/26/2022 1:54:26 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Infant Formula Evaluation

Thanks. Makes sense. I will request those documents.

Melissa Safford

Senior Advisor
Office of the Commissioner
(240) 447-9379
melissa.safford@fda.hhs.gov
FDA U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, April 26, 2022 1:48 PM
To: Safford, Melissa <Melissa.Safford@fda.hhs.gov>
Subject: RE: Infant Formula Evaluation

Looks fine to me. You will probably need to get ahold of all the SOPs governing these processes in ORA and CFASN. jw

From: Safford, Melissa <Melissa.Safford@fda.hhs.gov>
Sent: Tuesday, April 26, 2022 12:04 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Infant Formula Evaluation

Dr. Woodcock – The attached document includes the following:
1. A draft email requesting participation in the IF evaluation (currently with OCC for feedback)
2. A list of staff by Center/Office I propose including in the evaluation
3. A list of general discussion topics to provide in advance to each person who agrees to participate in the evaluation.

Not sure if you'll have time to take a look before our check in this afternoon, so happy to walk through it then.

-Melissa

Melissa Safford

Senior Advisor
Office of the Commissioner
(240) 447-9379
melissa.safford@fda.hhs.gov
FDA U.S. FOOD & DRUG ADMINISTRATION

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 5/6/2022 8:26:03 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]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
CC: Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]
Subject: Fwd: Recall Standards
Attachments: Recall Standards.docx

Thanks to Kim for compiling this quickly last night - it's a helpful reference.

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Thursday, May 5, 2022 9:57:01 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Recall Standards

I pulled this together quickly. Hopefully this is helpful.

Controlled Substances (FDCA 569D)	Devices (FDCA 518)	Biologics (PHS 351(d)(1))	Food (FDCA 423)
(a) Order To Cease Distribution and Recall.-- ``(1) In general.--If the Secretary determines there is a reasonable probability that a controlled substance would cause serious adverse health consequences or death, the Secretary may, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such controlled substance. ``(2) Hearing.--An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify an amendment to the order, and what actions are required by such amended order pursuant to subparagraph (3). ``(3) Order resolution.--After an order is issued according	Recall Authority (e)(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)— (A) to immediately cease distribution of such device, and (B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for	(d)(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code. (2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the	SEC. 423. MANDATORY RECALL AUTHORITY. (a) VOLUNTARY PROCEDURES.—If the Secretary determines, based on information gathered through the reportable food registry under section 417 or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402 or misbranded under section 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in section 417) with an opportunity to cease distribution and recall such article. (b) PREHEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE.—(1) IN GENERAL.—If the responsible party refuses to or does not voluntarily cease distribution or recall such article within the time and in the manner prescribed by the Secretary (if so prescribed), the Secretary may, by order require, as the Secretary deems necessary, such person to— (A) immediately cease distribution of such article; and (B) as applicable, immediately

to the process under paragraphs (1) and (2), the Secretary shall, except as provided in paragraph (4)-- ``(A) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order; ``(B) continue the order ceasing distribution of the controlled substance until a date specified in such order; or ``(C) amend the order to require a recall of the controlled substance, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall. ``(4) Risk assessment.--If the Secretary determines that the risk of recalling a controlled substance presents a greater health risk than the health risk of not recalling such controlled substance from use, an amended order under subparagraph (B) or (C) of paragraph (3) shall not include	such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order. (2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall. (B) An amended order under subparagraph (A)— (i) shall— (I) not include recall of a device from individuals, and (II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device	nearest 1⁄10 of 1 percent. For purposes of this paragraph, the term ''base quarter'', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.	notify all persons— (i) manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (ii) to which such article has been distributed, transported, or sold, to immediately cease distribution of such article. (2) REQUIRED ADDITIONAL INFORMATION.— (A) IN GENERAL.—If an article of food covered by a recall order issued under paragraph (1)(B) has been distributed to a warehouse-based third party logistics provider without providing such provider sufficient information to know or reasonably determine the precise identity of the article of food covered by a recall order that is in its possession, the notice provided by the responsible party subject to the order issued under paragraph (1)(B) shall include such information as is necessary for the warehousebased third party logistics provider to identify the food. (B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed— (i) to exempt a warehouse-based third party logistics provider from the requirements of this Act, including the requirements in this section

either a recall order for, or an order to cease distribution of, such controlled substance, as applicable. ``(5) Action following order.--Any person who is subject to an order pursuant to subparagraph (B) or (C) of paragraph (3) shall immediately cease distribution of or recall, as applicable, the controlled substance and provide notification as required by such order.  ``(b) Notice to Persons Affected.--If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to paragraph (1) or an amended order pursuant to subparagraph (B) or (C) of paragraph (3) to provide either a notice of a recall order for, or an order to cease distribution of, such controlled substance, as applicable, under this section to appropriate persons, including persons who manufacture, distribute, import, or offer for sale such product that is the subject of an order and to the public. In providing such notice,	from use, and (ii) shall provide for notice to individuals subject to the risks associated with the use of such device. In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b). (3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).		and section 414; or (ii) to exempt a warehouse-based third party logistics provider from being the subject of a mandatory recall order. (3) DETERMINATION TO LIMIT AREAS AFFECTED.—If the Secretary requires a responsible party to cease distribution under paragraph (1)(A) of an article of food identified in subsection (a), the Secretary may limit the size of the geographic area and the markets affected by such cessation if such limitation would not compromise the public health. (c) HEARING ON ORDER.—The Secretary shall provide the responsible party subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible, but not later than 2 days after the issuance of the order, on the actions required by the order and on why the article that is the subject of the order should not be recalled. (d) POST-HEARING RECALL ORDER AND MODIFICATION OF ORDER.— (1) AMENDMENT OF ORDER.—If, after providing opportunity for an informal hearing under subsection (c), the Secretary determines that removal of the article from commerce is necessary, the

the Secretary may use the assistance of health professionals who prescribed or dispensed such controlled substances. ``(c) Nondelegation.--An order described in subsection (a)(3) shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated under this section unless the official is the Director of the Center for Drug Evaluation and Research or an official senior to such Director. ``(d) Savings Clause.--Nothing contained in this section shall be construed as limiting-- ``(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, any drug under any other provision of this Act or the Public Health Service Act; or ``(2) the ability of the Secretary to request any person to perform a voluntary activity related to any drug subject to this Act or the Public Health Service Act.''.			Secretary shall, as appropriate—(A) amend the order to require recall of such article or other appropriate action; (B) specify a timetable in which the recall shall occur; (C) require periodic reports to the Secretary describing the progress of the recall; and (D) provide notice to consumers to whom such article was, or may have been, distributed. (2) VACATING OF ORDER.—If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, or that such actions should be modified, the Secretary shall vacate the order or modify the order. (e) RULE REGARDING ALCOHOLIC BEVERAGES.—The Secretary shall not initiate a mandatory recall or take any other action under this section with respect to any alcohol beverage until the Secretary has provided the Alcohol and Tobacco Tax and Trade Bureau with a reasonable opportunity to cease distribution and recall such article under the Alcohol and Tobacco Tax and Trade Bureau authority. (f) COOPERATION AND CONSULTATION.—The Secretary shall work with State and local

			public health officials in carrying out this section, as appropriate. (g) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Secretary shall— (1) ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, in order to provide notification— (A) of the recall to consumers and retailers to whom such article was, or may have been, distributed; and (B) that includes, at a minimum— (i) the name of the article of food subject to the recall; (ii) a description of the risk associated with such article; and (iii) to the extent practicable, information for consumers about similar articles of food that are not affected by the recall; (2) consult the policies of the Department of Agriculture regarding providing to the public a list of retail consignees receiving products involved in a Class I recall and shall consider providing such a list to the public, as determined appropriate by the Secretary; and (3) if available, publish on the Internet Web site of the Food and Drug Administration an image of the article that is the subject of the press release described in (1). (h) NO

			DELEGATION.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner. (i) EFFECT.— Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this Act or under the Public Health Service Act. (j) COORDINATED COMMUNICATION.— (1) IN GENERAL.—To assist in carrying out the requirements of this subsection, the Secretary shall establish an incident command operation or a similar operation within the Department of Health and Human Services that will operate not later than 24 hours after the initiation of a mandatory recall or the recall of an article of food for which the use of, or COSMETIC ACT.XML As Amended Through P.L. 117-103, Enacted March 15, 2022 147 Sec. 501 FEDERAL FOOD, DRUG, AND COSMETIC ACT 48See footnote for section 403(h)(3) regarding the stylistic use of a list consisting of ''(a)'', ''(b)'', etc. sure to, such

			article will cause serious adverse health consequences or death to humans or animals. (2) REQUIREMENTS.—To reduce the potential for miscommunication during recalls or regarding investigations of a food borne illness outbreak associated with a food that is subject to a recall, each incident command operation or similar operation under paragraph (1) shall use regular staff and resources of the Department of Health and Human Services to— (A) ensure timely and coordinated communication within the Department, including enhanced communication and coordination between different agencies and organizations within the Department; (B) ensure timely and coordinated communication from the Department, including public statements, throughout the duration of the investigation and related foodborne illness outbreak; (C) identify a single point of contact within the Department for public inquiries regarding any actions by the Secretary related to a recall; (D) coordinate with Federal, State, local, and tribal authorities, as appropriate, that have responsibilities related to the recall

			of a food or a foodborne illness outbreak associated with a food that is subject to the recall, including notification of the Secretary of Agriculture and the Secretary of Education in the event such recalled food is a commodity intended for use in a child nutrition program (as identified in section 25(b) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769f(b))); and (E) conclude operations at such time as the Secretary determines appropriate. (3) MULTIPLE RECALLS.—The Secretary may establish multiple or concurrent incident command operations or similar operations in the event of multiple recalls or foodborne illness outbreaks necessitating such action by the Department of Health and Human Services.

From: Rabin, Tara G. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D6E14C0D07AD46CA812A39A72C751BFE-TARA.GOODIN]
Sent: 5/6/2022 5:41:11 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]; 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: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Hetlage, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1356d75869e43ffad945d0deb85598c-Daniel.Hetl]
Subject: RE: Flagging, Politico on Abbott specialty/metabolic IF products

Good afternoon – Flagging that the anticipated Politico story just published. It includes our statement that the FDA has not delayed the release of any specialty and metabolic infant formula products and strongly disagrees with any assertations that the agency may have done so. Abbott notes that it's phone lines for case-by-case release opened on Fri., 4/29. The story also points out our Congressional request to consider giving the agency new authorities requiring that companies notify the agency if there are anticipated interruptions.

Best,
Tara

'I don't know how my son will survive': Inside the dangerous shortage of specialty formulas

BY **HELENA BOTTEMILLER EVICH** | 05/06/2022 04:39 PM EDT

Remainder of article removed due to copy right.

Remainder of article removed due to copy right.

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Thursday, May 5, 2022 11:01 AM
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>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Cc: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
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

FDA U.S. FOOD & DRUG ADMINISTRATION

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

From: Safford, Melissa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=662886BBFBC7441DAE59DE74071CEC71-MELISSA.SAF]
Sent: 5/4/2022 12:58:56 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: (b) (6), (b) (7)(C), (b) (7)(D)

Thanks.

Melissa Safford

Senior Advisor
Office of the Commissioner
(240) 447-9379
melissa.safford@fda.hhs.gov
FDA U.S. FOOD & DRUG ADMINISTRATION

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, May 04, 2022 12:57 PM
To: Safford, Melissa <Melissa.Safford@fda.hhs.gov>
Subject: FW: (b) (6), (b) (7)(C), (b) (7)(D)

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

Internal, Deliberative, & Confidential

Janet

FYI – as you'll be leading the review, incoming on (b) (6), (b) (7)(C), (b) (7)(D)

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,

(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: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 5/10/2022 12:47:20 PM
To: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
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: URGENT REVIEW REQUEST: PR, FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products

Tara,

I had a chance to read it. I think its just fine. Agree its good for the public to understand that a lot of work is going on.

rmc

From: "Rabin, Tara G." <Tara.Rabin@fda.hhs.gov>
Date: Tuesday, May 10, 2022 at 12:33 PM
To: Robert Califf (b) (6) @fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Cc: Erica Jefferson <Erica.Jefferson@fda.hhs.gov>, Michael Felberbaum <Michael.Felberbaum@fda.hhs.gov>, "Hetlage, Daniel" <Daniel.Hetlage@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Andi Fristedt <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

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

From: Colonius, Tristan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2B3590C046734A2E928858BD579ED852-TRISTAN.COL]
Sent: 5/11/2022 6:27:52 PM
To: Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]
CC: McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; 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]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Availability for Appropriations Briefing on IF

Hey Kate - Dr. Woodcock indicated to me earlier she is interested in joining and I believe she can make these times work Monday. I'm looping in Jacque to assist on scheduling, as well as Melissa for awareness. Dr. Woodcock is on leave Friday - flagging in terms of any prep session/materials planning.

From: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Sent: Wednesday, May 11, 2022 6:20 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: McBride, Maren <Maren.McBride@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>
Subject: Availability for Appropriations Briefing on IF

Hi Dr Woodcock,

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, background on shortage issues, timelines, and how they can help us, resources or otherwise.

Per the conversation at the this morning's leg check-in, I wanted to inquire if you were interested and available to participate? If you are able to attend, we thought you could weigh in on the program resource needs and connect to our FY23 request/data modernization. We are currently looking for a time in the 10-12pm window on Monday, May 16th. Dr Mayne will participate for CFSAN, Frank for OFPR—both are available in that window.

Please let us know if you would like to join.

Thanks,
Kae

Kate Klimczak
(b) (6)

From: Fristedt, Andi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8EBCDC6531394636A5AFCB391A6C0CC3-ANDI.FRISTE]
Sent: 5/12/2022 1:31:51 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; 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]
CC: 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]; 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]
Subject: Re: E&C Hearing

Indeed. Hard to overstate the swirl on this over the last 24 hours. Lots to catch up on in the morning.

Thanks to Kim, Andy and team for landing this witness panel. Took some finesse on their part.

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Wednesday, May 11, 2022 10:06 PM
To: Trzeciak, Kimberlee; Woodcock, Janet; Fristedt, Andi; Tierney, Julia
Cc: Tantillo, Andrew; Flahive, James; Colonius, Tristan; Safford, Melissa
Subject: Re: E&C Hearing

Thanks, this is a good lineup; kind of amazing the way this swirls. Got second hand message from the Speaker just a minute ago.

rmc

From: Kimberlee Trzeciak <Kimberlee.Trzeciak@fda.hhs.gov>
Date: Wednesday, May 11, 2022 at 10:04 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Andi Fristedt <Andi.Fristedt@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>
Cc: Andrew Tantillo <Andrew.Tantillo@fda.hhs.gov>, "Flahive, James" <James.Flahive@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, "Safford, Melissa" <Melissa.Safford@fda.hhs.gov>
Subject: E&C Hearing

Dr. Califf and Dr. Woodcock –

I wanted to follow up regarding the E&C hearing on infant formula with a quick update.

The Committee will be inviting Dr. Woodcock, Deputy Commissioner Yiannas, and Dr. Mayne to testify. We will receive formal invitations tomorrow.

We have begun work within OL on written testimony and prep materials, and can keep you updated as we move forward.

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
U.S. FOOD & DRUG ADMINISTRATION

Sent: 2/17/2022 8:33:25 AM
To: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: RE: FYI - PR, FDA Announces Investigation of Bacterial Infections Possibly Associated with Certain Powdered Infant Formula

I

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: Colonius, Tristan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2B3590C046734A2E928858BD579ED852-TRISTAN.COL]
Sent: 5/12/2022 3:32:48 PM
To: 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]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: WH Press Release is up

https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/12/fact-sheet-president-biden-announces-additional-steps-to-address-infant-formula-shortage/

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: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 5/12/2022 9:57:17 PM
To: 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]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: Draft Responses to Rep. DeLauro on Infant Formula

Thanks. Definitely agree with the strategy—she is trying to help, but some of the communications (I don't know from whom) have led so many people down the wrong path.

rmc

From: Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Date: Thursday, May 12, 2022 at 9:55 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Cc: Julie Tierney <Julia.Tierney@fda.hhs.gov>
Subject: Draft Responses to Rep. DeLauro on Infant Formula

Hi,

Rep. DeLauro's appropriations staff sent questions following your call today that they would like back in the morning.

For your review/input, if interested, the responses are here: Draft responses to Rep DeLauro.docx

Our responses aim to focus Rep. DeLauro on bolstering FDA's formula program as opposed to her idea to federally fund a mass purchase of imported formula.

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: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 5/12/2022 9:58:22 PM
To: 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]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: Draft Responses to Rep. DeLauro on Infant Formula

Will read with aa clear head in early am.

rmc

From: Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Date: Thursday, May 12, 2022 at 9:55 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Cc: Julie Tierney <Julia.Tierney@fda.hhs.gov>
Subject: Draft Responses to Rep. DeLauro on Infant Formula

Hi,

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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: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 5/14/2022 11:12:46 AM
To: 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]
CC: Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]
Subject: RE: RUF annual meeting

OK. I'll handle

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, May 13, 2022 10:22 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Subject: RE: RUF annual meeting

Happy to have Frank raise. jw

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Friday, May 13, 2022 10:21 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Subject: RUF annual meeting

Janet & Frank – are either of you planning to say something on infant formula at the RUF event? Given the moment, I'd advise one of us raise. No strong feelings here on who does so.

From: Hattis, Daniel [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EEA12BDAA04F42F0AFB9DD6ABF39793A-DANIEL.HATT]
Sent: 5/15/2022 12:49:25 AM
To: 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]; 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]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; 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]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Wade, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbc3da04754040b6bd8107a700959e17-Jennifer.Wa]
Subject: RE: REVIEW: Responses to Approps Infant Formula Supplemental Funding Questions

Thanks, Tristan! We really appreciate your help on this busy Saturday. Per our conversation, OCA is planning to send this to the Committee at 9am tomorrow so it gets there in time for them to consider our input while drafting the bill. We're happy to receive any feedback up until then.

Best,
Dan

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Sunday, May 15, 2022 12:29 AM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Wade, Jennifer <Jennifer.Wade@fda.hhs.gov>
Subject: RE: REVIEW: Responses to Approps Infant Formula Supplemental Funding Questions

Dan and I just caught up. Will let him take things from here but will add my appreciation for Dan, Kate, Maren, and OB's weekend work on this too.

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Saturday, May 14, 2022 11:47 PM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Wade, Jennifer <Jennifer.Wade@fda.hhs.gov>
Subject: RE: REVIEW: Responses to Approps Infant Formula Supplemental Funding Questions

Nothing else from me. Thanks for the quick work on this!

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Saturday, May 14, 2022 11:24 PM
To: Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Wade, Jennifer <Jennifer.Wade@fda.hhs.gov>
Subject: RE: REVIEW: Responses to Approps Infant Formula Supplemental Funding Questions

Hi – Two questions and a comment.

(b) (5)

From: Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>
Sent: Saturday, May 14, 2022 10:51 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Wade, Jennifer <Jennifer.Wade@fda.hhs.gov>
Subject: REVIEW: Responses to Approps Infant Formula Supplemental Funding Questions
Importance: High

All,

As many of you are aware, the House is drafting an emergency supplemental funding bill this weekend to address the current infant formula situation. They requested that FDA provide information to support their effort, and they have asked that we respond tonight if possible.

OCA has worked with the Centers/Offices to develop two documents answering some of the Committee's questions and providing both short-term (immediate) funding needs to address the current situation, and long-term investments which will help FDA to improve its work on infant formula and help avoid/mitigate future shortages.

We are requesting review of these documents ASAP since, as mentioned above, we are hoping to provide these to the Committee tonight. Apologies in advance for the late hour and the quick turnaround.

Links are below and I have also provided offline copies in case anyone prefers those or has trouble with the links.

Infant Formula Supplemental--FDA Info.docx
Infant Formula Resource Needs.docx

Thanks,
Dan

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: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 5/16/2022 9:12:12 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: FW: Follow up: Broadcast TV hits tomorrow am

Here are the talkers that Rob used on the morning shows today.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Sunday, May 15, 2022 10:03 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: RE: Follow up: Broadcast TV hits tomorrow am

General

- **The FDA recognizes that many consumers have been unable to access infant formula and critical medical foods they are accustomed to using and are frustrated by their inability to do so.**

- **The FDA is leaving no stone unturned to further increase the availability of infant formula and I am personally committed to continuing to do everything in our power as part of the all-of-government efforts to ensure there's adequate product available wherever and whenever parents and caregivers need it.**

- **The FDA expects that the measures and steps it is taking with infant formula manufacturers and others will mean more and more supply is on the way or on store shelves moving forward.**

- **Data from IRI indicate that in-stock rates in retail stores are improving and FDA's actions are expected to continue to increase product availability. While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80% in-stock rates at the week ending May 8.**

- **Per FDA custom research definitions based on IRI data, national infant formula sales by volume for the month of April were up more than 13% compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5% compared to the month prior to the recall.**

- **What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall.**

- **Increased sales are a good indicator of formula available to the general population of infants, but the agency understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern.**

- **The FDA has already taken steps with Abbott Nutrition to make product available to those with life-threatening conditions on a case-by-case basis and will continue its efforts to make these products even more readily available.**

- **The FDA's best current assessment is that with all of the actions we're taking, and the potential for Abbott Nutrition's Sturgis, Michigan, facility to safely resume production in the near-term, the supply of infant formula will continue to improve over the next couple of months.**

- We 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.

Abbott Facility/Consent Decree

- The plant remains voluntarily closed as the company works to rectify findings related to the processes, procedures, and conditions that the FDA observed during its inspection of the facility that began in late January and ended in mid-March, which raised concerns that powdered infant formula produced at this facility prior to the FDA's inspection carry a risk of contamination.

- We're working closely with Abbott and have made significant progress. We are very close to having a path forward to safely reopening the facility.

- I anticipate will have news to share here very soon.

Importation Guidance

- We're moving as quickly as possible to safely bring in additional product intended for other countries so there's more product on the shelves.

- I anticipate that as soon as today, we will be able to make an announcement on the expedited process to bring additional safe product to American store shelves.

Asleep at the Wheel?

- **We take seriously our obligation to ensure the availability of safe infant formula, which is the sole source of nutrition for many infants.**

- As is true for all foods, the ultimate responsibility for a product's safety lies with the manufacturer and we need to make sure they comply.

- The FDA received consumer complaints in September, November, December and January, which raised concern for the agency and on January 31, 2022, we initiated an inspection at the Abbott Nutrition facility in Michigan.

- While our inspection was ongoing, we issued a warning and Abbott voluntarily recalled their product. At the close of our inspection, we found operational deficiencies at the facility that need to be corrected in order to ensure product safety.

- Throughout the pandemic, the FDA has been monitoring potential supply chain risks for this category of products and was working to address supply chain issues associated with the pandemic including those impacting the infant formula industry.

- As Abbott Nutrition was initiating its recall, the FDA intensified this work.

- We know there have been questions about the timeline. However, this remains an open investigation with many moving parts.

- Our first priority right is ensuring that parents have access to safe infant formula and once the immediate risk to the public has been addressed, we will conduct a review.

Border

- This is not an FDA-specific topic, but fact checkers have dismantled this claim.

- **A 1997 law requires adequate food and elsewhere specifies age appropriateness – hence formula for kids under 1.**

- **CBP is following the law to feed people in custody, which I hope we can all agree is the right thing to do.**

- **This law has been followed under every administration since then, regardless of party.**

- **What I can tell you is that FDA has been doing everything in our power as part of the all-of-government efforts to ensure there's adequate infant formula available wherever and whenever parents and caregivers need it.**

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Sunday, May 15, 2022 9:27 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Re: Follow up: Broadcast TV hits tomorrow am

Were some more bullets going to come?

How would you answer the direct question: was FDA asleep at the wheel?

rmc

From: Michael Felberbaum <Michael.Felberbaum@fda.hhs.gov>
Date: Sunday, May 15, 2022 at 7:10 PM
To: Erica Jefferson <Erica.Jefferson@fda.hhs.gov>, Robert Califf <(b) (6) @fda.hhs.gov>
Cc: Frank Olivarria <Frank.Olivarria@fda.hhs.gov>, Janice Sheehy <Janice.Sheehy@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Subject: RE: Follow up: Broadcast TV hits tomorrow am

From WH on the border Q:

- This is not an FDA-specific topic, but fact checkers have dismantled this claim.
- A 1997 law requires adequate food and elsewhere specifies age appropriateness – hence formula for kids under 1.
- CBP is following the law to feed people in custody, which I hope we can all agree is the right thing to do.
- This law has been followed under every administration since then, regardless of party.
- What I can tell you is that FDA has been doing everything in our power as part of the all-of-government efforts to ensure there's adequate infant formula available wherever and whenever parents and caregivers need it.

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, May 15, 2022 12:06 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Follow up: Broadcast TV hits tomorrow am
Importance: High

Hi Rob –

Circling back following our conversation with Kate B. last evening. I connected with WH comms this morning and they would like to get you placed on a few morning shows tomorrow/Monday. The major networks. They'd like to at least get a few in. Here is what they are proposing in the way of a schedule, subject to your availability.

6:30am – Broadcast morning (CBS, NBC or ABC)
6:40am – Broadcast morning (CBS, NBC or ABC)
7:00am – Broadcast morning (CBS, NBC or ABC)
If possible to squeeze in:
7:10am – NPR
7:20am – Cable Morning (CNN or MSNBC)
7:30am – Cable Morning (CNN or MSNBC)

The focus will be on infant formula. Note: The broadcast outlets have been provided with the 1-pager you saw debunking the 43% and what in stock rate means. I've attached the final version that was provided to us.
Toplines:

(b) (5)

It is also possible that they will ask about vaccines for kids under 5 as well. I think you are well-versed here as well, but focus on:
Toplines:

(b) (5)

Happy to discuss.
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: Kristen.Tugwell@fda.hhs.gov (temporary)

From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 5/16/2022 9:50:27 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Working

Yes, will do. Thank you!

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, May 16, 2022 9:50 AM
To: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Subject: RE: Working

I also have an 11 AM hill briefing (short) and I have to sit in on the HHS staff meeting, so can you tell my timekeeper I'm working the whole day? Thx jw

From: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Sent: Monday, May 16, 2022 8:02 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Working
Importance: High

Good morning,

I hope you're doing well and had a nice visit with your guest on Friday.

To recap your meetings for today, and to make sure that I'm tracking, I have you attending the following meetings:

- **9:00 a.m.** - CMO Interview #3
- **11:30a.m**. - House/Senate Ag Approps Staff Briefing on Infant Formula
- **2:45 p.m.** - [EXTERNAL] Reagan-Udall Foundation for the FDA Annual Public Board Meeting - FDA Leadership Invite (Zoom window opens at 2 p.m. for an optional mic check)

Thank you,
Jacque

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, May 15, 2022 6:45 PM
To: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Subject: Working

I'll be working at least half a day tomorrow. Jw

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 5/13/2022 4:29:45 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; 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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: [EXTERNAL] USDA Letter
Attachments: Abbott Labs_Ford_5-13-2022_USDA_signed.pdf

Thanks

+JW

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Sent: Friday, May 13, 2022 4:29 PM
To: 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>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>
Subject: FW: [EXTERNAL] USDA Letter

FYI – letter from USDA Secretary Vilsack to Abbott CEO

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Friday, May 13, 2022 4:22 PM
To: Infant Formula FDA IMG Leadership <InfantFormulaFDAIMGLeadership@fda.hhs.gov>; Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Infant Formula FDA IMG <InfantFormulaFDAIMG@fda.hhs.gov>
Cc: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: FW: [EXTERNAL] USDA Letter

Sharing letter USDA sent to Abbott CEO today

USDA United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

May 13, 2022

Robert B. Ford
Chairman and CEO
Abbot Laboratories
100 Abbott Park Road
Abbott Park, IL 60064

Dear Mr. Ford,

I am writing to express my grave concern regarding the accessibility of safe infant formula to our Nation's most vulnerable families, and request your meaningful engagement in ensuring the health, safety, and nutrition security of these populations in the short and long term.

As you know, Abbott holds infant formula contracts in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) with states, territories, and tribes representing nearly half of the program's infants. These contracts allow Abbott to serve as the primary provider of WIC infant formula to participants in these areas, putting Abbott in a privileged position, one of critical responsibility to the national supply of infant formula.

While USDA appreciates the work you have done to replace impacted Abbott products and shift production to non-impacted facilities to attempt to mitigate supply impacts, we believe that Abbott can do more to ensure that WIC participants in states that have contracted with Abbott have access to formula.

Since the recall began, Abbott has provided rebates for alternative products, including competitive brands, so that WIC participants have continued access to safe formula. We are concerned, however, that you have extended this flexibility to states on a month-by-month basis setting up uncertainty each month for the WIC program and its participants.

In order to allow states to plan and reassure participants that they will have reliable access to formula for their babies, we ask that you extend these rebate commitments for all contracted products through at least August 31, 2022. We further request that you continue these commitments until Abbott's formula supply meets demand across the country. I believe Abbott must take these additional actions to support vulnerable WIC families during this challenging time.

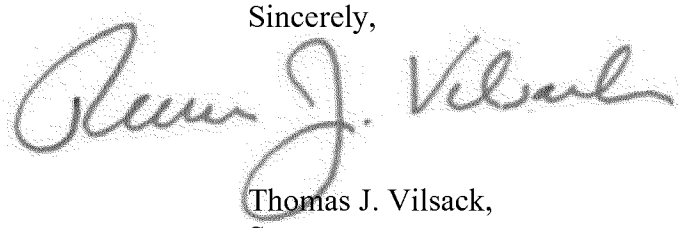
Recent reports of parents who have been unable to access life-sustaining formula for their medically fragile infants are also of significant concern to me. While we recognize that you have taken recent steps to address demand for metabolic formulas on a case-by-case basis, I urge you to redouble your efforts to reach out to populations in need of specialty formulas to ensure their immediate nutrition security.

In addition, my expectation is that you will continue to work with the Food and Drug Administration (FDA) and utilize all options available to you to resume production and distribution of specialty formulas. USDA stands ready to ensure that parents of medically fragile infants can access these special formulas.

Going forward, Abbott must take every measure possible to ensure safe production of infant formula as well as a reliable supply, even in the face of disruption.

Please direct your response to Stacy Dean, Deputy Under Secretary of the Food, Nutrition, and Consumer Services at Stacy.Dean@usda.gov.

Sincerely,



Thomas J. Vilsack,
Secretary

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 5/16/2022 6:32:46 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]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
Subject: Consent Decree has been entered
Attachments: ECF 008 Consent Decree.pdf

Please see attached, just entered by Judge Jarbou.

Julia C. Tierney, JD (she/her)
Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(b) (6) (cell)
Julia.Tierney@fda.hhs.gov
Executive Assistant: Susan.Flowers@fda.hhs.gov

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 1:22-cv-441

Hon. Hala Y. Jarbou

ABBOTT LABORATORIES, a corporation doing business as ABBOTT NUTRITION, and KEENAN S. GALE, TJ HATHAWAY, and LORI J. RANDALL, individuals,

Defendants.
_____/

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel and on behalf of the United States Food and Drug Administration ("FDA"), having filed a Complaint for Permanent Injunction ("Complaint") against Abbott Laboratories, a corporation doing business as Abbott Nutrition, and Keenan S. Gale, TJ Hathaway, and Lori J. Randall, individuals, (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. ("Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into

interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3), 21 U.S.C. § 350a(b)(2), and 21 C.F.R. Part 106.

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

6. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 350a(a)(3).

7. For purposes of this Decree, the following definitions shall apply:

A. "Associated Persons" shall refer collectively to each and all of Defendants' officers, agents, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, and "doing business as" entities) who are involved with the manufacture, processing, preparing, packing, labeling, holding, or distribution of articles of food covered by paragraph 7(F) or paragraph 7(G) at or from the Sturgis Facility;

B. "CGMP Regulations for Human Food" shall refer to the current good manufacturing practice requirements in Subpart B of 21 C.F.R. Part 117 (Current Good

Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food);

C. "Days" shall refer to business days;

D. "Infant Formula CGMP Regulations" shall refer to the current good manufacturing practice requirements in Subpart B of 21 C.F.R. Part 106 (Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications);

E. "Inventory Products" shall refer only to the non-recalled powdered finished products manufactured at the Sturgis Facility and in Defendants' possession, custody, or control as of March 18, 2022, the close of FDA's inspection at Defendants' facilities located at 901 North Centerville Road, Sturgis, Michigan 49091;

F. "Other Operations" shall refer to Defendants' manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any infant formula, as that term is defined in 21 U.S.C. § 321(z), in powdered form, except for Inventory Products defined in paragraph 7(E) and products subject to Specialty Operations described in paragraph 7(G);

G. "Specialty Operations" shall refer to Defendants' manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any article of food that is:

(1) Any powdered infant formula covered by 21 U.S.C. § 350a(h)(1); or

(2) Any powdered product for non-infants (older than 12 months of age) that serves similar nutritional purposes as any formulation of powdered infant formula covered by 21 U.S.C. § 350a(h)(1); and

H. "Sturgis Facility" shall refer to the facilities located at 901 North Centerville Road, Sturgis, Michigan 49091.

Specialty Operations

8. Subject to paragraph 11(A), upon entry of this Decree, Defendants and each and all of their Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from conducting Specialty Operations, unless all the following conditions are met:

A. Defendants, at their expense, shall retain or continue retention of an independent person or persons ("Expert") who is without any personal or financial ties (other than a retention agreement or agreements to satisfy the requirements of this Decree and/or to perform other consulting or testing work for Abbott Nutrition) to Defendants or their families, and who, by reason of training, education, and experience, is qualified to:

(1) Evaluate the facilities, methods, processes, and controls at the Sturgis Facility to ensure that Defendants' products are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, the CGMP Regulations for Human Food, and the Infant Formula CGMP Regulations; and

(2) Inspect the Sturgis Facility to determine whether Defendants' facilities, methods, processes, and controls are continuously operated and administered in conformity with this Decree, the Act, and its implementing regulations;

B. Defendants shall notify FDA in writing of the identity and qualifications of the Expert within two days after retaining the Expert, and, in coordination with the Expert, Defendants shall:

(1) Verify the dry-out procedures (including time and temperature controls) 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. Where applicable, Defendants may rely on completed action described in Defendants' response(s) to the FDA Form-483 issued on March 18, 2022 ("Form-483 Response");

(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. Where applicable, Defendants may rely on completed actions already conducted in coordination with the Expert or as described in Defendants' Form-483 Response; and

(3) Prior to initiating production pursuant to paragraph 8, 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);

C. If Defendants choose to restrict Specialty Operations to specified equipment and processing environments, then Defendants shall ensure that any cleaning, sanitizing, dry-out, and/or environmental testing during the pendency of Specialty Operations of equipment and processing environments that are not part of Specialty Operations is accomplished in a manner that protects against contamination of the specified equipment and processing environments (and utensils therein) that are part of Specialty Operations;

D. Defendants shall, as and when feasible, prioritize production in a manner that minimizes the risk of market disruption;

E. Prior to distribution of each product lot produced during Specialty Operations, Defendants shall ensure that a qualified individual in Defendants' quality unit reviews the batch record, the test results for in-process and finished product, and the environmental monitoring results that pertain to the product lot, and certifies in writing to FDA that such lot meets all specifications;

F. Defendants shall ensure that environmental monitoring during Specialty Operations consists of routine sampling and, when appropriate, investigative sampling, and that a qualified individual in Defendants' quality unit conducts trending analyses of environmental monitoring results from both routine and investigative sampling;

G. Defendants shall collect in-process and finished product samples during Specialty Operations and shall analyze the powdered infant formula samples for *Cronobacter* spp. and *Salmonella* spp., in the manner specified in 21 C.F.R. § 106.55, and shall analyze the powdered non-infant product samples for *Salmonella* spp. If any test of in-process or finished product detects the presence of *Cronobacter* spp. and/or *Salmonella* spp., Defendants shall:

(1) Cease production at the earliest time practicable and, in any event, no later than the completion of any batch then in progress, dispose of the affected in-process and/or finished product batch, conduct a thorough contamination-source determination (i.e., root-cause analysis), and adequately remediate the processing equipment and environment. Defendants shall maintain records of all the steps taken pursuant to this paragraph and shall make the records available to FDA immediately upon request. After a cessation of production pursuant to this paragraph, Defendants shall not resume production unless and until they receive

written notice from FDA that Defendants may resume production. Within fifteen days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 8(G)(1) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification;

(2) Forward the test results detecting the presence of *Cronobacter* spp. and/or *Salmonella* spp. in in-process and/or finished product to FDA within twenty-four hours after receipt by Defendants (along with a written statement confirming that Defendants have ceased production in accordance with paragraph 8(G)(1)), speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(3) Retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or *Salmonella* spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of a written request;

H. Defendants shall maintain a record of all sales and distribution of products, including shipping documents and the following information for the product distributed: the product name; the product size and configuration if variations exist; the batch, lot, and manufacturing codes; and the names of customers to whom the product is shipped, along with quantities shipped to each such customer. Defendants shall make the records described in this paragraph available to FDA immediately upon request; and

I. Defendants shall, in accordance with the procedures in paragraph 10, destroy all Inventory Products defined in paragraph 7(E) that have not been distributed within fifteen days after Defendants initiate production under Specialty Operations. The parties may mutually agree in writing to modify this fifteen-day time frame, which modification may be granted without seeking leave of Court. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of the Inventory Products, Defendants shall be permitted to segregate and retain such Inventory Products for the duration of such preservation obligation.

Other Operations

9. Upon entry of this Decree, Defendants and each and all of their Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from conducting Other Operations, unless all the following conditions are met:

A. Defendants shall have continuously complied with paragraph 8 since entry of this Decree;

B. Defendants shall ensure that the Sturgis Facility and equipment therein: (1) are cleaned and sanitized to render them suitable for manufacturing, processing, preparing, packing, labeling, holding, and distributing articles of food in accordance with this Decree, the

Act, and its implementing regulations; and (2) will be continuously maintained in a sanitary condition;

C. Defendants shall ensure that the Expert retained under paragraph 8(A):

(1) Reviews all FDA inspectional observations of deficiencies at the Sturgis Facility identified in the FDA Form-483 issued on March 18, 2022, and all records related to the detection of *Cronobacter* spp. and/or *Salmonella* spp. in the environment or in-process or finished product at the Sturgis Facility from September 2019 to the present;

(2) Reviews, and modifies as necessary, Defendants' written sanitation procedures including, but not limited to, sanitation standard operating procedures for receiving, manufacturing, processing, preparing, packing, holding, and distributing articles of food ("Sanitation Plan") to verify that the Sanitation Plan complies with the CGMP Regulations for Human Food and the Infant Formula CGMP Regulations and adequately: (a) establishes sanitation controls, monitoring procedures, and corrective actions for: *(i)* manufacturing processes; *(ii)* cleaning (including, but not limited to, cleaning in place), sanitizing, and dry-out operations (including, but not limited to, verified dry-out procedures and validated test methods for dry-out of production equipment and processing environments); and *(iii)* facilities (including, but not limited to, building construction and maintenance to ensure, among other things, adequate water management) and equipment and utensils contained therein; (b) addresses the risks of microbiological contamination from contaminants including, but not limited to, pathogens such as *Cronobacter sakazakii* and *Salmonella* spp.; and (c) protects against the contamination of food and food-contact surfaces and prevents insanitary conditions at the Sturgis Facility;

(3) Reviews, and modifies as necessary, Defendants' written environmental monitoring and testing program ("Environmental Monitoring Plan") to verify that the Environmental Monitoring Plan complies with the requirements in paragraph 11(G);

(4) Reviews, and modifies as necessary, Defendants' written product sampling and testing program ("Product Monitoring Plan") to verify that the Product Monitoring Plan complies with the requirements in paragraph 11(H);

(5) Reviews, and modifies as necessary, Defendants' written employee training program ("Employee Training Program") (in English and any other language necessary to effectively convey the substance of the training) that addresses: (a) maintaining sanitation, conducting adequate sampling and analysis, avoiding bacterial contamination, and controlling pathogens; and (b) the CGMP Regulations for Human Food and the Infant Formula CGMP Regulations, and the requirements in the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan. The Employee Training Program shall include training for new employees and ongoing training programs for existing employees;

(6) Conducts a comprehensive inspection at the Sturgis Facility (including, but not limited to, buildings and equipment and utensils contained therein) and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food, and certifies in writing to FDA that:

(a) He or she has evaluated the results of environmental monitoring tests, and inspected the Sturgis Facility (including, but not limited to, buildings and equipment and utensils contained therein) and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food;

(b) Defendants have corrected all deficiencies at the Sturgis Facility identified in the FDA Form-483 issued on March 18, 2022, and any deficiencies identified during the Expert's record review of the detection of *Cronobacter* spp. and/or *Salmonella* spp. in the environment or in any article of food at the Sturgis Facility (including samples collected during production under Specialty Operations), from September 2019 to the present, specifying each deficiency and Defendants' corrections thereof. Where applicable, the Expert may refer to any completed or ongoing action described in Defendants' Form FDA-483 Response; and

(c) Based on the Expert's review and inspection, Defendants' facilities, methods, processes, and controls (including the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan) are: (*i*) in compliance with this Decree, the Act, and its implementing regulations; and (*ii*) adequate to ensure that Defendants' products are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, the CGMP Regulations for Human Food, and the Infant Formula CGMP Regulations; and

(7) Prepares and submits in writing to FDA a detailed report of all findings, with supporting documentation, and submits the certification, detailed report, and supporting documentation to Defendants and FDA concurrently, within fifteen days after completing the inspection; and

D. Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of paragraphs 9(A) and 9(B). Defendants shall also submit the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training

Program certified by the Expert pursuant to this paragraph to FDA for review and concurrence, and receive written notification of concurrence from FDA. Within twenty days after receipt of the Expert-certified plans (the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training Program), unless FDA determines that a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional twenty days to complete its review, FDA will review the Expert-certified plans and provide written notification to Defendants either concurring with the plans or explaining the basis for FDA's decision not to concur with any plan(s), including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to concur, Defendants shall submit a revised plan to FDA for review and concurrence. Within fifteen days after receipt of a revised plan, unless FDA determines that a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review the revised plan and provide written notification to Defendants either concurring with the revised plan or explaining the basis for FDA's decision not to concur with the revised plan, including the concerns with Defendants' submission. This process shall be repeated until Defendants receive written notification of concurrence from FDA. In no circumstance shall FDA's silence be construed as a substitute for written notification.

General Provisions

10. Subject to the exception described in this paragraph, within twenty-five days after entry of this Decree, Defendants shall destroy all articles of food that Defendants recalled prior to the date of entry of this Decree ("recalled articles"). Defendants shall give notice to FDA that, under FDA's supervision, Defendants are prepared to destroy the recalled articles and shall

specify the proposed time, place, and method of destruction. Defendants shall not commence, or permit any other person to commence, destruction until they have received written authorization from FDA to commence destruction. In no circumstance shall FDA's silence be construed as a substitute for written notification. Within fifteen days after receiving authorization from FDA to commence destruction, Defendants shall, under FDA supervision, complete destruction in compliance with this provision. Defendants shall not dispose of any recalled article in a manner contrary to the provisions of the Act, any other federal law, any court order, or the laws of any state or Territory, as defined in the Act, in which the recalled articles are disposed. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 17. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of the recalled products, Defendants shall be permitted to segregate and retain such recalled products for the duration of such preservation obligation.

11. After receiving written concurrence from FDA under paragraph 9(D), Defendants shall continuously and effectively comply with the following requirements:

A. Defendants shall immediately implement and follow the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan approved by FDA under paragraph 9(D) and shall ensure that all powdered products at the Sturgis Facility are produced under conditions and practices that comply with these plans and the remaining provisions of this Decree;

B. Prior to distribution of each product lot, Defendants shall ensure that a qualified individual in Defendants' quality unit reviews the batch record, the test results for in-process and finished product, and the environmental monitoring results that pertain to the product lot, and certifies in writing that such lot meets all specifications. Defendants shall

maintain copies of all certifications required by this paragraph at the Sturgis Facility, in a location where the certifications are readily available for reference and inspection by FDA;

C. Within two days after receiving FDA's written notification under paragraph 9(D), Defendants shall assign continuing responsibility for implementing and monitoring the FDA-approved Sanitation, Environmental Monitoring, and Product Monitoring Plans to a person(s) who, by reason of education, training, or experience, is qualified to maintain the Sturgis Facility in a sanitary condition and implement appropriate corrective actions, and Defendants provide such person(s) with the authority and resources to achieve any necessary corrective action. Defendants shall provide to FDA, in writing, the identities, titles, and qualifications of the individual(s) assigned responsibility under this paragraph within ten days after assigning responsibility to such individuals;

D. Within ten days after receiving FDA's written notification under paragraph 9(D), Defendants shall ensure that the FDA-approved Sanitation, Environmental Monitoring, and Product Monitoring Plans are available and accessible (in English and any other language necessary to effectively convey the substance of these documents) to their officers, employees, and all other persons who perform duties at the Sturgis Facility;

E. Within twenty days after receiving FDA's written notification under paragraph 9(D), Defendants shall train their employees, and all other persons who perform duties at the Sturgis Facility, in accordance with the FDA-approved Employee Training Program, to ensure that the individuals who receive, manufacture, process, prepare, pack, label, hold, or distribute articles of food are qualified to perform their assigned duties. Defendants shall submit documentation to FDA demonstrating that they have adequately trained all persons who perform duties at the Sturgis Facility in accordance with the Employee Training Program;

F. Defendants shall provide training to each new employee within five days after the new employee commences duties at the Sturgis Facility, and provide ongoing training programs for existing employees, in accordance with the FDA-approved Employee Training Program;

G. Defendants shall conduct environmental monitoring and testing in accordance with the Environmental Monitoring Plan to demonstrate that the Sanitation Plan is consistently followed to provide systematic control over pathogens, including *Cronobacter* spp. and *Salmonella* spp., to prevent contamination of finished products. Defendants' Environmental Monitoring Plan shall conform to the following requirements:

(1) Environmental monitoring shall include, but not be limited to: (a) collecting samples from equipment and production areas that may pose a high risk of contamination; other environmental sites where food is received, manufactured, processed, prepared, packed, labeled, held, or distributed; and additional areas that may be reservoirs for cross-contamination; (b) analyzing samples in an industry-recognized method that is acceptable to FDA; (c) implementing remedial action, should any pathogen be detected in the environment, including, but not limited to, intensified sanitation measures, intensified sampling and testing measures, comprehensive investigations, and a contamination-source determination (i.e., a root-cause analysis); and (d) conducting trend analyses by a qualified analyst and reviewed by a qualified manager;

(2) A majority of swabs shall be collected from Zone 2 areas (i.e., areas in the vicinity of food contact surfaces) during both routine environmental monitoring and, when appropriate, investigative environmental monitoring. When the Sanitation Plan and/or Environmental Monitoring Plan requires or recommends equipment tear-down, Defendants shall

ensure that swabs are collected from Zone 1 (i.e., food-contact surfaces): (a) after such equipment is disassembled, before being cleaned and sanitized; and (b) after the equipment is cleaned and sanitized. Defendants shall also ensure that, if any *Cronobacter* spp. or *Salmonella* spp. is detected in a Zone 3 environment (i.e., areas surrounding Zone 2 areas), additional swabs are collected from surrounding Zone 2 areas;

(3) If any *Cronobacter* spp. is detected in the environment, Defendants shall speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(4) Defendants shall retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or *Salmonella* spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of written request;

H. Defendants shall conduct product monitoring and testing in accordance with the Product Monitoring Plan, to ensure that controls are adequate to prevent contamination by pathogens, including *Cronobacter* spp. and *Salmonella* spp. Defendants' Product Monitoring Plan shall conform to the following requirements:

(1) At a minimum, Defendants shall test representative samples from the beginning, middle, and end (i.e., three separate sampling periods) of each lot of each batch of finished product; and

(2) The Product Monitoring Plan shall include remedial action to be implemented should any *Cronobacter* spp. or *Salmonella* spp. be detected in any article of food (including raw ingredients and in-process and finished product batches). As part of the Product

Monitoring Plan's remedial action, if any test of in-process or finished product detects the presence of *Cronobacter* spp. and/or *Salmonella* spp., Defendants shall:

(a) Cease production at the earliest time practicable and, in any event, no later than the completion of any batch then in progress, dispose of the affected in-process and/or finished product batch, conduct a thorough contamination-source determination (i.e., root-cause analysis), adequately remediate the processing equipment and environment, and conduct intensified sanitation measures and intensified sampling and testing measures. Defendants shall maintain records of all these steps and shall make those records available to FDA immediately upon request. After a cessation of production pursuant to this paragraph, Defendants shall not resume production unless and until they receive written notice from FDA that Defendants may resume production. Within fifteen days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 11(H)(2)(a) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification;

(b) Forward the test results detecting the presence of *Cronobacter* spp. and/or *Salmonella* spp. in in-process and/or finished product to FDA within

twenty-four hours after receipt by Defendants (along with a written statement confirming that Defendants have ceased production in accordance with paragraph 11(H)(2)(a)), speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(c) Retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or Salmonella spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of written request;

I. Defendants shall prepare a plan that assesses the need for any repair of buildings (such as roofs) and/or equipment (such as spray dryers), including a determination whether to continue repairing or replace that equipment. Defendants shall submit the plan to FDA within four months after receiving written notification from FDA under paragraph 9(D). If applicable, Defendants may refer to any completed or ongoing action described in Defendants' Form FDA-483 Response;

J. In the event that Defendants decide to transfer any of their equipment that is used for production of powdered products from the Sturgis Facility to any other manufacturing site, Defendants shall notify FDA in writing at least forty-five days prior to the planned transfer. Defendants' notification shall include, but not be limited to, a plan for cleaning and sanitizing, and refurbishing if necessary, the equipment, followed by environmental testing for pathogens, prior to the transfer of equipment to any other manufacturing site. Defendants shall not transfer any such equipment unless and until they: (a) receive written concurrence from FDA on the plan to clean, sanitize, and refurbish the equipment; (b) clean, sanitize, and refurbish the equipment in

accordance with the FDA-concurred plan; (c) submit to FDA a detailed written report, with supporting documentation, describing the actions taken to comply with paragraph 11(J); and (d) receive written notification from FDA that Defendants appear to be in compliance with paragraph 11(J);

K. Defendants shall retain an independent person or persons (the "Auditor") who shall meet the criteria for and may be the same person as the Expert described in paragraph 8(A), to conduct audit inspections at the Sturgis Facility of the facilities, methods, processes, and controls used to receive, prepare, process, pack, label, hold, or distribute articles of food. Defendants shall notify FDA in writing of the identity and qualifications of the Auditor within two days after retaining the Auditor. Defendants shall ensure that the audit inspections are conducted as follows:

(1) Defendants shall ensure that, within six months after Defendants resume operations after receiving FDA's written notification pursuant to paragraph 9(D), the Auditor shall conduct an audit at the Sturgis Facility of the facilities, methods, processes, and controls used to receive, manufacture, process, prepare, pack, label, hold, and distribute articles of food to determine whether Defendants are operating in compliance with this Decree, the Act, and its implementing regulations, and to identify any deviations from such requirements. Defendants shall also ensure that the Auditor submits an Audit Report documenting all findings to Defendants and FDA concurrently, within seven days after completing the audit;

(2) Thereafter, Defendants shall ensure that the Auditor conducts audits no less frequently than once every six months for a period of one year, and then annually for the next three years, unless FDA informs Defendants in writing that more frequent audit

inspections and reporting are required. If any Audit Report identifies any deviation from this Decree, the Act, or its implementing regulations, FDA may require the audit cycle be extended;

(3) Defendants shall ensure that, as part of every Audit Report (except the first one), the Auditor assesses the adequacy of actions taken by Defendants to correct all previous audit observations, if any, indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall make all necessary corrections within ten days after receipt of the Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary or, upon written request by Defendants and/or based on the nature of the correction to be made, that a longer time period is permitted; and

(4) Defendants shall ensure that, within twenty days after the required completion date for any corrective action under this paragraph, the Auditor reviews each and all corrective action(s) taken by Defendants and reports in writing to FDA whether each deviation listed in the Audit Report has been corrected;

L. In the event that the Expert or the Auditor determines that the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, or the Employee Training Program needs to be revised, Defendants shall:

(1) Ensure that the Expert or Auditor reviews the proposed changes and certifies in writing that the proposed changes establish methods, processes, and controls at the Sturgis Facility that are adequate to ensure that articles of food are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, and implementing regulations ("paragraph L certification");

(2) Ensure that the Expert's or Auditor's paragraph L certification with supporting documentation is submitted to Defendants and FDA concurrently, within five days after completing the review; and

(3) Provide to FDA the revised Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and/or the Employee Training Program, within twenty-four hours of the submission to FDA of the Expert's or Auditor's paragraph L certification. Any change to the Sanitation Plan, the Environmental Monitoring Plan, and/or the Product Monitoring Plan shall ensure that pathogens, including *Cronobacter* spp. and *Salmonella* spp., are systematically controlled to prevent contamination of finished products; and

M. In the event that Defendants terminate their agreement with:

(1) The Expert retained pursuant to paragraph 8(A), Defendants shall notify FDA within five days after such termination and immediately retain another expert who meets the qualifications of the Expert described in paragraph 8(A). Defendants shall notify FDA in writing of the identity and qualifications of the new Expert within five days after retaining the new Expert; and

(2) The Auditor retained pursuant to paragraph 11(K), Defendants shall notify FDA within five days after such termination and immediately retain another expert who meets the qualifications of the Auditor described in paragraph 11(K). Defendants shall notify FDA in writing of the identity and qualifications of the new Auditor within five days after retaining the new Auditor.

12. Defendants and all Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act at or from the Sturgis Facility that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3);

C. Violates 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4);

D. Violates 21 U.S.C. § 331(k) by causing articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 350a(a)(3); and/or

E. Results in the failure to implement and continuously maintain the requirements of this Decree, the Act, and its implementing regulations.

13. If, at any time after this entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, report or data prepared or submitted by Defendants, the Expert(s), or the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action,

including, but not limited to, ordering Defendants to immediately take one or more of the following actions, which remedies shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, and/or distributing any and all powdered products;

B. Recall, at Defendants' expense, any and all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers that, in FDA's judgment, are adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations. Defendants shall initiate the recall(s) within twenty-four hours after receiving notice from FDA that a recall is necessary;

C. Destroy, under FDA supervision, all articles of food (including raw ingredients and in-process and finished products) that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 18. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of such articles of food, Defendants shall be permitted to segregate and retain such articles of food for the duration of such preservation obligation;

D. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

E. Submit additional reports or information to FDA as requested;

F. Submit samples to a qualified laboratory for analysis;

G. Institute or re-implement any of the requirements set forth in this Decree;

H. Issue a safety alert; and/or

I. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

Any cessation of operations or other action described in this paragraph shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. Within twenty days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional twenty days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 13(I) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification. The cost of FDA inspections, investigations, supervision, examinations, sampling, testing, travel time, and subsistence expenses to implement and monitor the remedies set forth in this paragraph shall be

borne by Defendants at the rates specified in paragraph 17. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

14. If FDA issues a directive pursuant to paragraph 13, the following process and procedures shall apply:

A. Unless a different time frame is specified by FDA in its directive, within ten days after receiving such directive, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's directive. If Defendants notify FDA that they do not agree with FDA's directive, Defendants shall explain in writing the basis for their disagreement and, in doing so, may provide specific alternative actions and time frames for achieving FDA's objectives. After receipt of Defendants' notification and explanation, FDA will review Defendants' notification and explanation and, in writing, affirm, modify, or withdraw its directive, as FDA deems appropriate. If FDA affirms or modifies its directive, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action. If FDA affirms or modifies its directive, Defendants shall, upon receipt of FDA's affirmed or modified directive, immediately implement it, and may, if Defendants so choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to implement and fully comply with FDA's directive, unless and until the Court stays, reverses, or modifies FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 25; and

B. The process and procedures in paragraph 14(A) shall not apply to any directive issued pursuant to paragraph 13 if such directive states that, in FDA's judgment, the

matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such directive, immediately and fully comply with the terms of that directive, and the directive shall be a final agency decision. Should Defendants seek to challenge any such directive, they may petition the Court for relief while they implement FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 25.

15. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect the Sturgis Facility, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to the Sturgis Facility and/or other place(s) of business including, but not limited to, all buildings or other structures, equipment, raw ingredients, in-process materials, unfinished and finished materials and products, containers, and labeling; take photographs and make video recordings; take samples, without charge to FDA, of raw ingredients, in-process materials, unfinished and finished materials and products, containers, and labeling; and examine and copy all records relating to the receipt, holding, and distribution of any and all articles of food and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate and apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

16. Defendants shall promptly provide any information or records to FDA upon request regarding the receipt, manufacture, processing, preparing, packing, labeling, holding, and/or distributing of articles of food. Defendants shall maintain copies of the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training

Program, along with copies of all records required by such plans and this Decree, at the Sturgis Facility, in a location where the records are readily available for reference and inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three years after the date the records are prepared.

17. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $105.46 per hour or fraction thereof per representative for inspection and investigative work; $126.24 per hour or fraction thereof per representative for analytical or review work; $0.59 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

18. Within five days after the entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Sturgis Facility, and publish the Decree on an internal website and a publicly-available website maintained and/or controlled by Defendants. Defendants shall ensure that this Decree remains posted as described herein for as long as this Decree remains in effect. Within ten days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph.

19. Within ten days after the entry of this Decree, Defendants shall provide a copy of this Decree by electronic mail to each and all Associated Persons. Within twenty days after the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph. Within seven days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

20. Within fifteen days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree. Within twenty days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

21. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree by electronic mail to such Associated Person(s). On a quarterly basis, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of the additional Associated Person(s) who have received a copy of this Decree pursuant to this paragraph. Within seven

days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

22. Defendants shall notify FDA in writing at least thirty days before any change in ownership, name, or character of their business at the Sturgis Facility that occurs after entry of this Decree including, but not limited to, any of the following, if they may affect obligations arising out of this Decree: (1) an incorporation, reorganization, relocation, dissolution, bankruptcy, assignment or sale resulting in the emergence of a successor corporation; the creation or dissolution of subsidiaries; the creation of any additional entities that engage in the manufacture and distribution of articles of food; the discontinuation of any line of powdered product; and any other change in the structure or identity of Abbott Nutrition or change in the responsibility of any individual defendant that affects the Sturgis Facility; and (2) the sale or assignment of any business assets, such as buildings, equipment, or inventory. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten days before any such assignment or change in ownership.

23. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America thirty thousand dollars ($30,000) in liquidated damages for each day such violation continues. The total amount of such liquidated damages shall not exceed five million dollars ($5,000,000) annually. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

24. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, expert witness fees, administrative and court costs, and any other costs or fees incurred by the United States in bringing such an action.

25. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

26. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence," shall reference this civil action by case name and civil action number, and shall be submitted electronically to the Program Division Director, Office of Human and Animal Food Operations, Human and Animal Food Division East 6, at ORAHAFEAST6FIRMRESPONSES@fda.hhs.gov. If electronic submission is not possible, communications shall be addressed to the attention of OHAFO East 6 Program Division Director, FDA, 550 West Jackson Boulevard, Chicago, Illinois 60661.

27. This Decree shall apply only to Defendants and Associated Persons, as defined in paragraph 7(A), involved with the manufacture, processing, preparing, packing, labeling, holding, or distribution of powdered products at or from the Sturgis Facility.

28. No sooner than sixty months after resuming production after receipt of written notification from FDA under paragraph 9(D), Defendants may provide written notice to FDA that they seek relief from this Decree. If, at the time of such notice, in FDA's judgment Defendants have maintained a state of continuous compliance with the terms of this Decree, the Act, and all applicable laws and regulations for at least sixty months after resuming production after receipt of written notification from FDA under paragraph 9(D), the Defendants may petition the Court to grant such relief and the United States will not oppose Defendants' petition.

29. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this 16th day of May, 2022.

/s/ Hala Y. Jarbou
HALA Y. JARBOU
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendants

LORI J. RANDALL,
Individually and on behalf of
ABBOTT LABORATORIES DBA
ABBOTT NUTRITION

TJ HATHAWAY,
Individually

KEENAN S. GALE,
Individually

Mark R. Filip, P.C.
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Attorney for Defendants

For Plaintiff

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Principal Deputy Assistant Attorney
General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director
Consumer Protection Branch

ALLAN GORDUS
Assistant Director

By: s/ Donald Lorenzen
DONALD LORENZEN
CHRISTINA PARASCANDOLA
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PERHAM GORJI
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CLAUDIA J. ZUCKERMAN
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10903 New Hampshire Avenue
Bldg. 31, Rm 4550
Silver Spring, MD 20993-0002

From: Trzeciak, Kimberlee [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B24F98D119FA4FA1B04704E9A3A0B3F3-KIMBERL.TRZ]
Sent: 5/17/2022 12:04:25 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]; 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]
CC: 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]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: RESPONSE NEEDED: E&C Witness Request

Okay, thank you all.

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, May 17, 2022 11:58 AM
To: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@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>; Flahive, James <James.Flahive@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Re: RESPONSE NEEDED: E&C Witness Request

Janet felt it was best that I be responsive and show up and that 4 would be too many. So be it.

rmc

From: Kimberlee Trzeciak <Kimberlee.Trzeciak@fda.hhs.gov>
Date: Tuesday, May 17, 2022 at 11:13 AM
To: Robert Califf <(b) (6) @fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Andi Fristedt <Andi.Fristedt@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>
Cc: Andrew Tantillo <Andrew.Tantillo@fda.hhs.gov>, "Flahive, James" <James.Flahive@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Subject: RESPONSE NEEDED: E&C Witness Request

Dr. Califf and Dr. Woodcock –

As you know E&C Republicans are calling on Dr. Califf to testify at the E&C hearing on infant formula shortages and supply scheduled for May 25. We have not received formal invitations yet, but originally the E&C Majority intended to invite Dr. Woodcock, Dr. Mayne, and Frank Yiannas as we discussed.

On the Hill call this afternoon, Rep. Griffith, Ranking on the O&I Subcommittee, asked Dr. Califf directly to come testify. Up until now, E&C Majority was not formally asking for Dr. Califf. However, I just received a call that the Speaker is doing a press conference this afternoon on IF and **Pallone wants to announce in the next hour who the witnesses are for the May 25 hearing**.

E&C Majority is now thinking having Dr. Califf come testify on May 25 would show how important this is to the agency.

Dr. Califf, if you would be amenable to testifying on May 25, we would propose that the E&C announce/formally invite Dr. Califf, Dr. Mayne, and Frank Yiannas.

Please let us know how you would like to proceed.

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
U.S. FOOD & DRUG ADMINISTRATION

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/17/2022 8:21:00 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; 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]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: 05/18, Agenda: Weekly Check-In: Legislative Forecast
Attachments: 1030-Legislative Forecast Agenda_05.18.22.docx

Good evening,

Attached please find the agenda for reference at tomorrow's "**10:30am - Weekly Check-In: Legislative Forecast**". This agenda has been shared with Dr. Califf.

Thank you,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

Weekly Check-In: Legislative Forecast
Wednesday, May 18, 2022 – 10:30-10:55am
Virtual/Zoom
Materials: none

AGENDA

1. OCA updates
    a. Infant Formula Supplemental Update
    b. Update on DeLauro Infant Formula Concerns
    c. Budget Hearing Updates

2. OL Updates
    a. Update on E&C Hearing
    b. HELP UFA Discussion Draft

3. Open Discussion

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 5/17/2022 5:07:46 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; 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]; 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]; 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]; Roosen, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67e5a1139af248699616f7f8c44f46bd-Suzanne.Roo]; Staton, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa0c184a115047a6ba76a2c614026426-Anna.Staton]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]
Subject: Re: Sharing: Latest Infant Formula "in stock" graphics

Very nice; this will help a lot. The one thing I'd like to add is an estimate of sales in a corner of the map so that people could compare serial changes in % but have the context of sales.

Also hope we can go to more freauent than weekly.

Thanks again.

rmc

From: Erica Jefferson <Erica.Jefferson@fda.hhs.gov>
Date: Tuesday, May 17, 2022 at 4:59 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Cc: Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Andi Fristedt <Andi.Fristedt@fda.hhs.gov>, Frank Yiannas <Frank.Yiannas@fda.hhs.gov>, Caitlin Boon <Caitlin.Boon@fda.hhs.gov>, "Roosen, Suzanne" <Suzanne.Roosen@fda.hhs.gov>, "Staton, Anna" <Anna.Staton@fda.hhs.gov>, "Walsh, Sandy" <Sandy.Walsh@fda.hhs.gov>
Subject: Sharing: Latest Infant Formula "in stock" graphics

Here is where the team has landed so far. Awaiting feedback from the WH, but the plan would be to push out on social.

Thanks to Frank and his team for collaboration on this. Definitely a labor of love. A huge thanks to my team for bringing this to life.

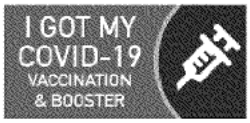
We can look at building into our work plan a weekly update of this.

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



From: McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]
Sent: 5/17/2022 3:40:50 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]; 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]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]
CC: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bdaa04f42f0afb9dd6abf39793a-Daniel.Hatt]; Roosen, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67e5a1139af248699616f7f8c44f46bd-Suzanne.Roo]; Baker, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38ef2177c11646b4b89a048f4f66be5e-Matthew.Bak]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Barfell, Glenda F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33b220e98ac9456eb32888261156f400-GBARFELL]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Wade, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbc3da04754040b6bd8107a700959e17-Jennifer.Wa]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]
Subject: RE: IF supp info/update

Update from Rules earlier below.

Commissioner, I'll also note that I was told the supp will likely be on the House floor during your hearing on Thursday so it's possible there will be members hopping in and out or some delays related to the floor action.

Further, I'm getting the sense the Senate Rs will not support a supplemental at this point.

Hi everyone,

The House Rules Committee has concluded its House Rules Committee meeting on H.R. 7790, the FY 2022 Infant Formula Supplemental Appropriations Act, and provided a closed rule for the bill. The legislation will likely come to the House floor this week, but a specific day has yet to be announced.

As you know, H.R. 7790 would provide $28 million to FDA, available through the end of FY 2023, to address the current shortage of FDA-regulated infant formula and certain medical foods in the U.S., as well as to prevent future shortages of these products and to prevent fraudulent products from entering the U.S. The legislation would also require FDA to provide congressional appropriators with weekly status updates on obligations of this funding. The bill as currently written does not provide more specifics on how the funding should be spent.

During the House Rule Committee meeting, however, Chair DeLauro stated that of the $28 million total, funding should be used by the FDA in the following ways:

- $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.

It is unclear why these greater specifics are not contained in the current bill text, whether these greater specifics would be provided to FDA as part of a funding crosswalk or other separate appropriations communication, or whether changes will still occur to Chair DeLauro's stated funding details.

Rep. Cole and Ranking Member Granger, along with other Republicans, stated that they do not support the bill as currently written, do not have faith in FDA to properly spend these new funds or address the current problems, and questioned why the greater specifics on use of the funding was not placed in the bill to begin with. Chair DeLauro could not give an explanation on the funding details situation during the meeting, and also could not address what would happen if the bill passes in its current form and reaches the Senate.

For your awareness, during the meeting Chair DeLauro also expressed her concern at FDA's role in the current infant formula situation, said she still does not know why it took FDA so long to act after the initial reporting, and said she will address these questions at the Thursday appropriations hearing. She also stated that she has called on Abbott to testify before the House Appropriations Committee. Finally, Chair DeLauro stated that she was shocked to learn how understaffed FDA is on infant formula work, she believes we need to address this, and restated her belief that there should be a single, separate food safety agency.

For Ranking Member Granger, she questioned why FDA could not use existing infant formula funds to address the current situation, questioned why USDA could not use similar existing funds, and questioned why purported infant formula stockpiles couldn't be used to address shortages (Chair DeLauro stated FEMA told her there are not large stockpiles of infant formula).

From: McBride, Maren
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>; Frank Yiannas (Frank.Yiannas@fda.hhs.gov) <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>; Daniel Hattis (Daniel.Hattis@fda.hhs.gov) <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.

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON RULES
James P. McGovern, Chairman
NEWS

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: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 5/23/2022 11:29:40 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]; 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]; 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]; 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]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: FYI: Baby Formula Shortage Reveals Gaps in Regulation and Reporting - The New York Times

Sharing the NYT story that posted this evening. Discusses why this situation is especially challenging because of reporting and testing requirements, notes the history at the facility and the industry pushback over regulations related to testing.

https://www.nytimes.com/2022/05/23/us/abbott-baby-formula-sturgis-regulation.html

Baby Formula Shortage Reveals Gaps in Regulation and Reporting

The government has ordered more safeguards at an Abbott Nutrition plant. But the lack of reporting requirements and limited testing make it hard to monitor the deadly bacterium that led to a recall.

Riley San Miguel said her son, Kru, was barely a month old when he started crying all the time, not wanting to eat. When he developed a fever, he was quickly admitted to an intensive care unit. His spinal fluid was infected with bacteria, and it was spreading to his brain. The doctors believed it had probably come from his infant formula.

“Initially, doctors were worried Kru wasn’t going to make it,” said Ms. San Miguel, 23, who lives in Sonora, Texas. The baby underwent the first of several operations on his brain to control escalating seizures and swelling, and when he could no longer breathe on his own,

From: Colonius, Tristan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2B3590C046734A2E928858BD579ED852-TRISTAN.COL]
Sent: 5/22/2022 7:59:30 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]
Subject: NYT on 2018 French Formula Scandal

HI y'all – if you need more interesting formula reading this eve, the French confronted a lot of similar issues just a few years back in 2018. NYT article linked and below.

'My Baby Almost Died': Formula Scandal Sends Shudders Through France

By Liz Alderman

- Feb. 1, 2018

An officer standing guard near the Lactalis factory in Craon, France, last month while investigators were on the premises.Credit...Damien Meyer/Agence France-Presse — Getty Images

From: Ramos, Melissa * [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F30D58CC38D04AA3894A8DE1D0113EFB-MELISSA.RAM]
Sent: 5/25/2022 10:36:39 AM
To: Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]; 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]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; 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]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; 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]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Byerts, Kirsten [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3d165c657f04e43bd053efb83e96459-Kirsten.Bye]
CC: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: RE: New comms/potential hearing issue

Hi Teresa,

Caitlin is staffing a hill briefing this morning and may be a bit delayed in her response.

Very Respectfully,

Melissa

From: Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Sent: Wednesday, May 25, 2022 10:30 AM
To: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; 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>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>
Cc: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: New comms/potential hearing issue

Hi Caitlin – I circled with IGA and they dealt with a similar request last week where IGA sent the request through their HHS IGA contacts for ASPR to handle. From the description you provided it sounds like this should be routed the same way.

Do you want to put either the Denver District or the UT Governor's office contact IGA directly?

Adding Kirsten for IGA to this thread.

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

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