From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 3/6/2022 7:40:46 AM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Subject: Re: Confidential - Powdered Infant Formula Discussion

Thx; my personal cell is (b) (6) Call on that one as its configured for my car.

FDA # is 240

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Date: Saturday, March 5, 2022 at 5:11 PM
To: Califf, Robert <(b) (6)@fda.hhs.gov>
Subject: RE: Confidential - Powdered Infant Formula Discussion

That would be great!

If you can share a number where I can reach you, I can call you, so you can stay hands free while driving.

Here are my mobile numbers too, which will be good for you to have.

FDA 240-478-1688
Personal (b) (6)

Thanks,

Frank

From: Califf, Robert <(b) (6)@fda.hhs.gov>
Sent: Saturday, March 5, 2022 12:52 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: Re: Confidential - Powdered Infant Formula Discussion

How about 5 pm tomorrow. I'll be on the road and its good to talk to stay awake. I look forward to getting your viewpoint. Politico is certainly not being nice to us.

rmc

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Date: Friday, March 4, 2022 at 5:29 PM
To: Califf, Robert <(b) (6)@fda.hhs.gov>
Subject: RE: Confidential - Powdered Infant Formula Discussion

Thanks Rob. I don't want to interrupt your weekend, and I know you have your plate full, but if you want to talk, just name a time and I'll make myself available.

Frank

PS. I'll be watching for you on TV ☺

From: Califf, Robert (b) (6)@fda.hhs.gov>
Sent: Friday, March 4, 2022 7:04 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: Re: Confidential - Powdered Infant Formula Discussion

Frank,

Lets talk over the weekend. Agree that this we should be proactive here. The question is how to go about it.

rmc

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Date: Thursday, March 3, 2022 at 5:03 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>
Subject: Confidential - Powdered Infant Formula Discussion

Internal, Privileged, and Confidentia
Rob:

I know how busy you are, so I thought I'd drop you a quick note for you to review when you have time. Below are quick few points I want to share with you.

1. **Infant Formula Timeline**

- While there is a more detailed, after-action timeline being developed through OCC, I've attached a high level one that I think will help you better understand it for now, as we're starting to receive numerous questions.
- I've already shared this timeline with Janet, but if you have the time, I'd like to personally walk you through it too, maybe one-on-one, so you can hear my unvarnished perspective
- See attached timeline

  Timeline_initial 4 Cases.pptx

2. **Media Clips**

- I've shared a few of the more concerning coverage that I've come across. The Consumer Reports article below was just published yesterday.
- How the FDA Bungled the Powdered Infant Formula Recall **(Consumer Reports)**
- FDA learned of suspected infant formula illness four months before recall **(Politico)**
- After a massive baby formula recall, 2 senators want answers from maker Abbott **(Fortune)**

3. **Comms**

- I continue to advocate for a more forward leaning posture on comms, rather than appearing to avoid the questions about the timeline.
- Thus, we've worked through Erica and her team in OMA to fine-tune the message, which I've attached, in case they're useful as you navigate your day-to-day and should you get questions.
- As you will see, we go as far to say we acknowledge that people have questions about the timeline, and we'll get to that. But our priority right now is infant safety.

DRAFT Message Points_Infant Formula.docx

4. **FDA's Outbreak Improvement Plan – Independent Review**

- The next time we talk, I want to share this outbreak investigation improvement plan that we just published in Dec of 2021.
- After arriving, I saw there were serious shortfalls and opportunities to strengthen and accelerate FDA's response to foodborne outbreak investigations.
- Thus, I chartered an independent review through the University of Minnesota, which also included experts from other federal and State agencies.
- (b) (5) [redacted]
(b) (5) [redacted]
- Nevertheless, the review is done know, but I'd like to explain it to you – and why it's needed.

5. Lastly, I think we'll start hearing calls for an **independent review of how FDA handled the infant formula incident** (see attached request by Delauro to the Inspector General).

- On our last call, Janet said she will run it.
- I agree that no one in foods should run it (not me, nor anyone in CFSAN, nor ORA). However, I have a different perspective on who should run it and why I feel this way.
- Our internal review must uncover anything an external review by the Inspect General will uncover.

DeLauro OIG Request Infant Formula Recall 3.1.2022.pdf

In summary, I would love to spend 30 minutes with you on this topic. It's a hot item that is only likely to grow if not managed well. Happy to make myself available around your availability.

Frank

From: Hermsen, Catherine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=64A671332F224DEEA657D04B505EEDF6-CATHERINE.H]
Sent: 3/7/2022 5:58:30 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: Automatic reply: Infant Formula Update

I will be out of the office 3/4/22-3/7/22. Please contact Deputy Director Justin Green, if you need immediate assistance at 301-250-6675. I am available via cell phone at (b) (6) if needed.

Support and engage people directly impacted by foodborne illness and mobilize them to help prevent illness and death by driving change through advocacy, collaboration and innovation.

Stop Foodborne Illness

March 7, 2022

Dr. Rochelle P. Walensky
Director
U.S. Centers for Disease
Control and Prevention

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration

Drs. Walensky and Califf,

Stop Foodborne Illness (STOP), the "Voice for Safe Food," represents all consumers and works to prevent foodborne disease. I am writing to call for *Cronobacter sakazakii* to be added to the Nationally Notifiable Disease List.

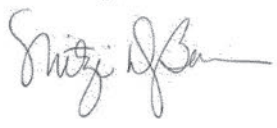
The current international infant formula recall, which has been linked to illnesses in at least five children and has been linked to the tragic deaths of two infants, calls for an urgent and expedited response. Although rare, *Cronobacter sakazakii* is extremely deadly to infants younger than three months of age, yet it is *not* included in CDC's important pathogens that local and state health partners must report identifying.

The lack of inclusion of this devastating pathogen on the Nationally Notifiable Disease List only adds to the potential of underreporting of illnesses, making it difficult for epidemiologists to do their important job of identifying clusters of illnesses to better understand sources and root causes of outbreaks. Lack of reporting also reduces the chances that FDA will become aware of incidents that need swift response and corrective action to protect infants.

Federal agencies have focused their efforts on infant and maternal health for detection of *Listeria monocytogenes;* STOP appeals to both agencies to institute the same standards for *Cronobacter sakazakii*. There must be equivalent surveillance for both deadly bacteria.

Now is the time to act. How can parents have trust in a system that does not protect the most vulnerable?

Sincerely,



Mitzi D. Baum
CEO

stopfoodborneillness.org | 4809 N. Ravenswood Ave, #214 Chicago, IL 60640 | 773.883.3098 fax | 773.269.6555

From: McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]
Sent: 3/8/2022 2:30:11 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: RE: infant formula

Get it scheduled! That was a really good call. And chatting with him offline will be a good thing to do. I'll fill you in on my thoughts at our next check-in.

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Tuesday, March 8, 2022 2:28 PM
To: McBride, Maren <Maren.McBride@fda.hhs.gov>
Subject: Re: infant formula

Ok, where does a golf match fit in the agenda?

rmc

From: McBride, Maren <Maren.McBride@fda.hhs.gov>
Date: Tuesday, March 8, 2022 at 2:18 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>
Subject: infant formula

We had money in 22 budget request to beef up program

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/9/2022 2:29:42 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 2:45pm: Infant Formula Update

Hi there,

FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: +16692545252,(b) (6)
+16692161590(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 +1 669 216 1590 or +1 646 828 7666 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: 161.199.138.10 (US West)
161.199.136.10 (US East)

Meeting ID: (b) (6)

Passcode (b) (6)

SIP: (b) (6)

Passcode (b) (6)

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/16/2022 7:44:54 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 8:00am: Commissioner Touch Base: Infant Formula Work

Hi there,

FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

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+16692161590,,(b) (6)
Meeting URL: https://fda.zoomgov.com/j(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 +1 669 216 1590 or +1 646 828 7666 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: 161.199.138.10 (US West)
161.199.136.10 (US East)

Meeting ID: (b) (6)

Passcode (b) (6)

SIP: (b) (6)

Passcode (b) (6)

From: Sigg, Jim [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=37695069DC214F5CB20E6056DD4D7CF7-SIGG]
Sent: 3/16/2022 9:00:58 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: infant Formula IMG

Hi Dr. Califf. We had a good call with Frank, Susan, Judy, and our Emergency Management folks this evening. We are going to provide them a draft structure of what the IMG could look like tomorrow.

Not all on the call thought an IMG was needed but most did. Naming a "lead" going forward will be helpful.

We will keep you updated as we establish the structure and let me know when you decide who will serve as the lead.

Thanks,
Jim

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/17/2022 11:14:15 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 11:30am: Commissioner Touch Base: Communications Strategy for Abbott
Attachments: 1130-Infant Formula Comms Plan Tick Tock 03.17.22.docx

Hi there,

FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: +16692545252,(b) (6) +16692161590,,(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 +1 669 216 1590 or +1 551 285 1373 or +1 646 828 7666 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: 161.199.138.10 (US West)
161.199.136.10 (US East)

Meeting ID: (b) (6)

Passcode (b) (6)

SIP: (b) (6)

Passcode (b) (6)

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: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 3/17/2022 5:12:07 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: Re: Schedule for Thursday, March 17,2022

B v v v v v . Cm

Get Outlook for iOS

From: Califf, Robert (b) (6) @fda.hhs.gov>
Sent: Thursday, March 17, 2022 5:11:23 PM
To: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Re: Schedule for Thursday, March 17,2022

Thx

Get Outlook for iOS

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Sent: Thursday, March 17, 2022 5:11:02 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>
Subject: RE: Schedule for Thursday, March 17,2022

Good to know, thank you. Frank is working on rescheduling the 8am to later in the day.

Jakea

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Thursday, March 17, 2022 5:10 PM
To: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Re: Schedule for Thursday, March 17,2022

Yes. But need to move that 8 am meeting. That's 5 am in SF!

Get Outlook for iOS

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Sent: Thursday, March 17, 2022 4:13:34 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>
Subject: RE: Schedule for Thursday, March 17,2022

Hi Dr. Califf,

I wanted to know if the SharePoint links are working/helpful for you to access documents. If not, I will no longer include them in your nightly email.

Jakea

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Sent: Wednesday, March 16, 2022 8:45 PM
To: Califf, Robert <(b) (6) @fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; 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: Schedule for Thursday, March 17,2022

Your first meeting is scheduled for *8 AM [Weekly CTP Meeting with the Commissioner]*. Your final meeting is scheduled for *1:30 PM [FDA Inspectional Affairs Council*.

8:00-8:30am Weekly CTP Meeting with the Commissioner

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

9:00-10:00am Commissioner Informational Briefing - Innovation in Evidence Generation (Real World Evidence) CDER/CBER
Materials: Attached; 2 documents
SP Links:
0900-1-RWE Briefing Memo.docx
0900-2-Commissioner Briefing - RWD-RWE - 3.17.2022.pptx

10:00-10:30am BHCC Update
Materials: Attached; 2 documents
SP Links:
1000-1-BHCC OPS 3.21.22 agenda.docx
1000-2-BHCC Summary Slides March 2022.pptx

10:30-10:50am DESK TIME

10:50-11:00am Internal FDA Prep for telecon with Congresswoman Chellie Pingree
Materials: Attached; 1 document
SP Link: 1050+1100-Califf - Pingree Introductory Call.docx

11:00-11:15am Telecon: Congresswoman Chellie Pingree / Commissioner Califf
Materials: Same memo referenced during 10:50am prep telecon

11:15-11:30am Weekly CDER Meeting with the Commissioner
Materials: Agenda attached
SP Link: 1115-CDER Weekly Meeting Agenda_03.17.2022.docx

11:30am-12:00pm Commissioner Touch Base: Communications Strategy for Abbott

12:00-12:30pm LUNCH

12:30-1:00pm Commissioner Briefing: Inspections (ORA)

Materials: Attached; 2 documents
SP Links:
1230-1-Commissioner Briefing Memo - ORA 3.14.2022.final.docx
1230-2-ORA Inspections FINAL 03.16.22.pdf

1:30-2:30pm FDA Inspectional Affairs Council
***Note**: You can join for informational purposes, only to listen in. You cannot yet weigh in on deliberations or decisional matters.*
Materials: Attached; 2 documents
SP Links:
1330-1-FDA Inspectional Affairs Council Agenda.docx
1330-2-FIAC_March17_Slides2.pptx

2:30-3:00pm DESK TIME

3:00-8:00pm TRAVEL (Personal - DNS)

OEA/OMA READING:
None

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/23/2022 10:37:18 PM
To: 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]; 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]; 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]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: WEDNESDAY HOMEWORK 03.23.2022 - INTERNAL CONFIDENTIAL
Attachments: Politico Foods Program Interview Talking Points FINAL 03.23.22.docx; Politico QA Foods Program FINAL 03.23.22.docx; Reactive Comment+QA Abbott 483s_FINAL_03.22.22.docx

Good evening Dr. Califf,

For your action (three items), below. Items 2 & 3 were not updated from last night's homework, though item #1 is updated to reflect Dr. Woodcock's feedback.

ITEM(S) FOR YOUR REVIEW (INTERNAL/CONFIDENTIAL)	
Action: Commissioner review, feedback, edits, or Commissioner clearance, requested by ASAP (prep session is at 9:00 AM):  Politico Foods Program Intervie...	**ITEM #1: UPDATED Background & Talking Points:** *Politico Interview on FDA Foods Program* • **Interview Date:** Thursday, 3/24 10 AM • **Note:** Preparation material for Politico interview on FDA's foods program, including discussion on infant formula. UPDATE NOTE: Updated talking points for Politico interview on FDA's foods program, including discussion on infant formula. Incorporates Dr. Woodcock's feedback highlighted in yellow. • **HW POC**: Tara Rabin (OEA/OMA)
Action: Commissioner review, feedback, edits, or Commissioner clearance requested:  Politico QA Foods Program FINAL ...	**ITEM #2: Technical Written QAs:** *Politico FDA Foods Program Story* • **Anticipated Release Date:** Wednesday, 3/23 • **Note:** Written responses to reporter questions to be provided to Politico in advance of interview • **HW POC**: Tara Rabin (OEA/OMA)
Action: Commissioner review, feedback, edits, or Commissioner clearance requested:	**ITEM #3: Media Comment & Responsive QAs:** *Abbott Nutrition FDA Form 483s* • **Anticipated Release Date:** Thursday, 3/24 • **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. • **HW POC**: Tara Rabin (OEA/OMA)

Reactive Comment+QA A...	

Thank you,
Frank

Frank A. Olivarria
Management and Program Analyst
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Tel: 240-402-9882
Frank.Olivarria@fda.hhs.gov

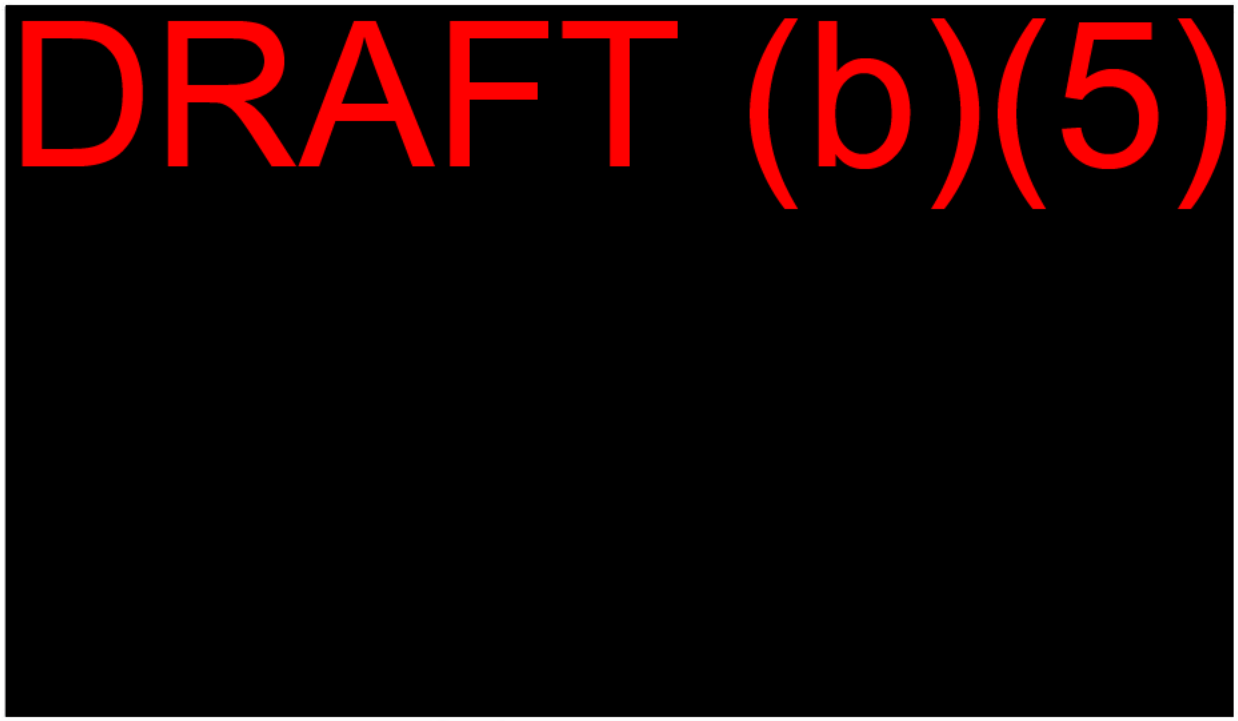
Background & Talking Points:
Politico Interview on FDA Foods Program

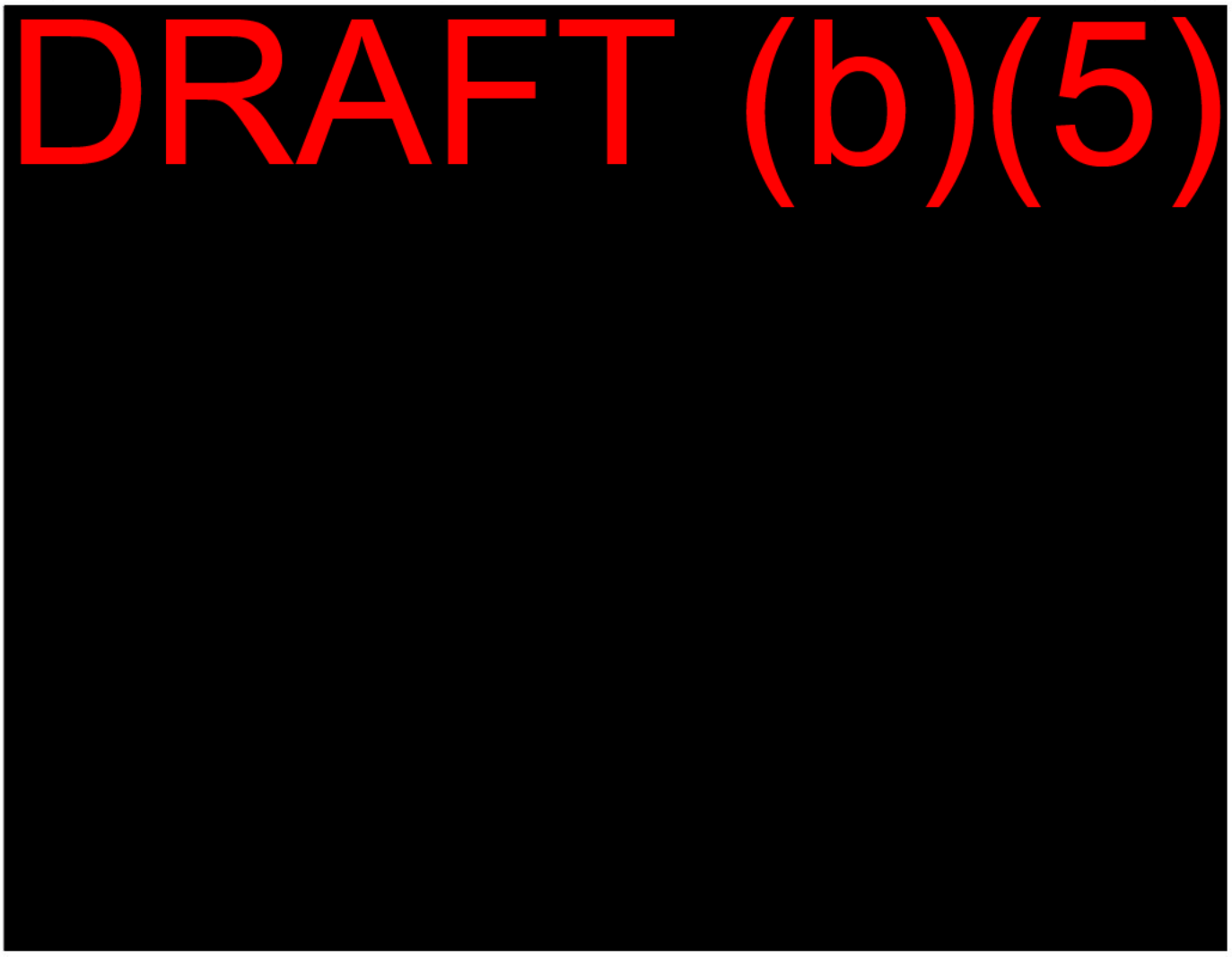
Overview

- **Outlet/Reporter:** Politico/Helena Bottemiller Evich
- **FDA Spokespeople:** Commissioner Robert M. Califf, M.D., MACC and Principal Deputy Commissioner Janet Woodcock, M.D.
- **Interview Date:** Thurs., March 24, 10:00 – 10:45 AM ET
- **Expected Date of Publication:** Sat., April 2
- **Subject:** FDA's Foods Program
- **Response Approach:** An interview to discuss the current infant formula investigation, as well as high-level themes designed to address narratives in the reporter's story (agency priorities, prioritization of urgent public health responses, timeliness of regulations/guidances, and internal organization). Foods program informed written responses to topic-specific reporter questions (see addendum).
- **Story Background:** Deep dive story about food issues at the FDA, based on more than 50 interviews with current and former FDA officials, including former Commissioners, consumer advocates and industry leaders, etc. Broad strokes as provided by the reporter:
    - Regulating food is not a high priority at the agency – a longstanding dynamic that's only been exacerbated during the pandemic. This is due to some structural reasons: the FDA is buried within HHS; Commissioners almost always do not come in with interest or background in food issues.
    - CFSAN has repeatedly failed to take timely action on a number of safety and health issues the agency has been aware of or even working on for several years. The three main examples in the story are: agricultural water, heavy metals in baby food and sodium reduction. Other issues that may be mentioned briefly include: PFAS, phthalates, arsenic and lead juice guidances not finalized, and allergen labeling (sesame in particular).
    - The story also notes there are unique problems within CFSAN, which has way less resources compared to other parts of the agency. There is also a deep-seated culture of avoiding hard decisions and a near paralyzing fear of picking any serious fights with the food industry. A Trump-era change in leadership structure set up a power struggle between the two top officials, deputy commissioner for food policy and response and CFSAN director. Turf battles are rampant. No one person is in charge of food at the FDA. This dysfunction only further hampers decision making.
    - The result is that the agency fails to come anywhere close to meeting most American consumers' basic expectations of government oversight on food safety and nutrition, even as Congress has directed more and more money to tackle food safety problems.

Interview Talking Points

DRAFT (b)(5)


DRAFT (b)(5)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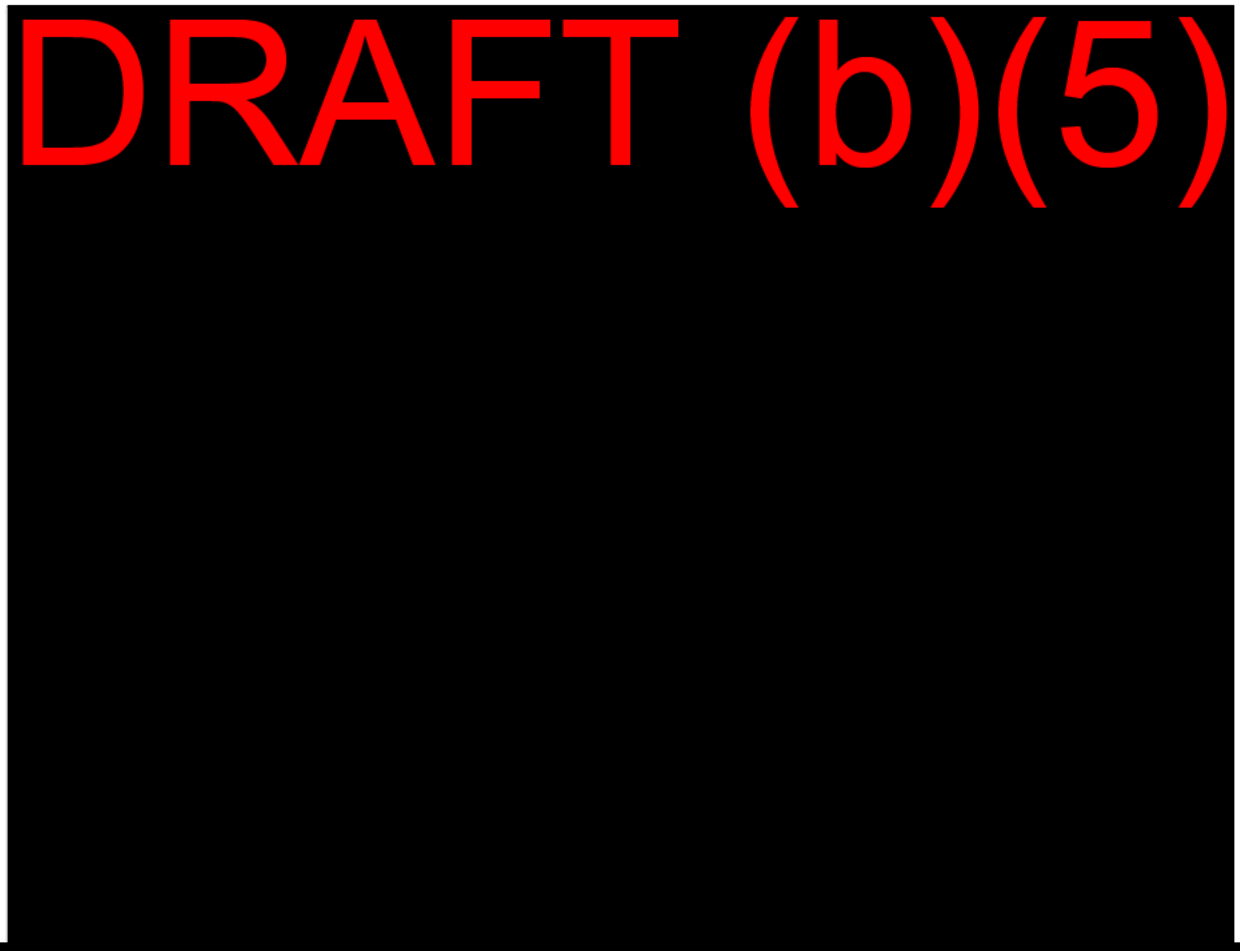
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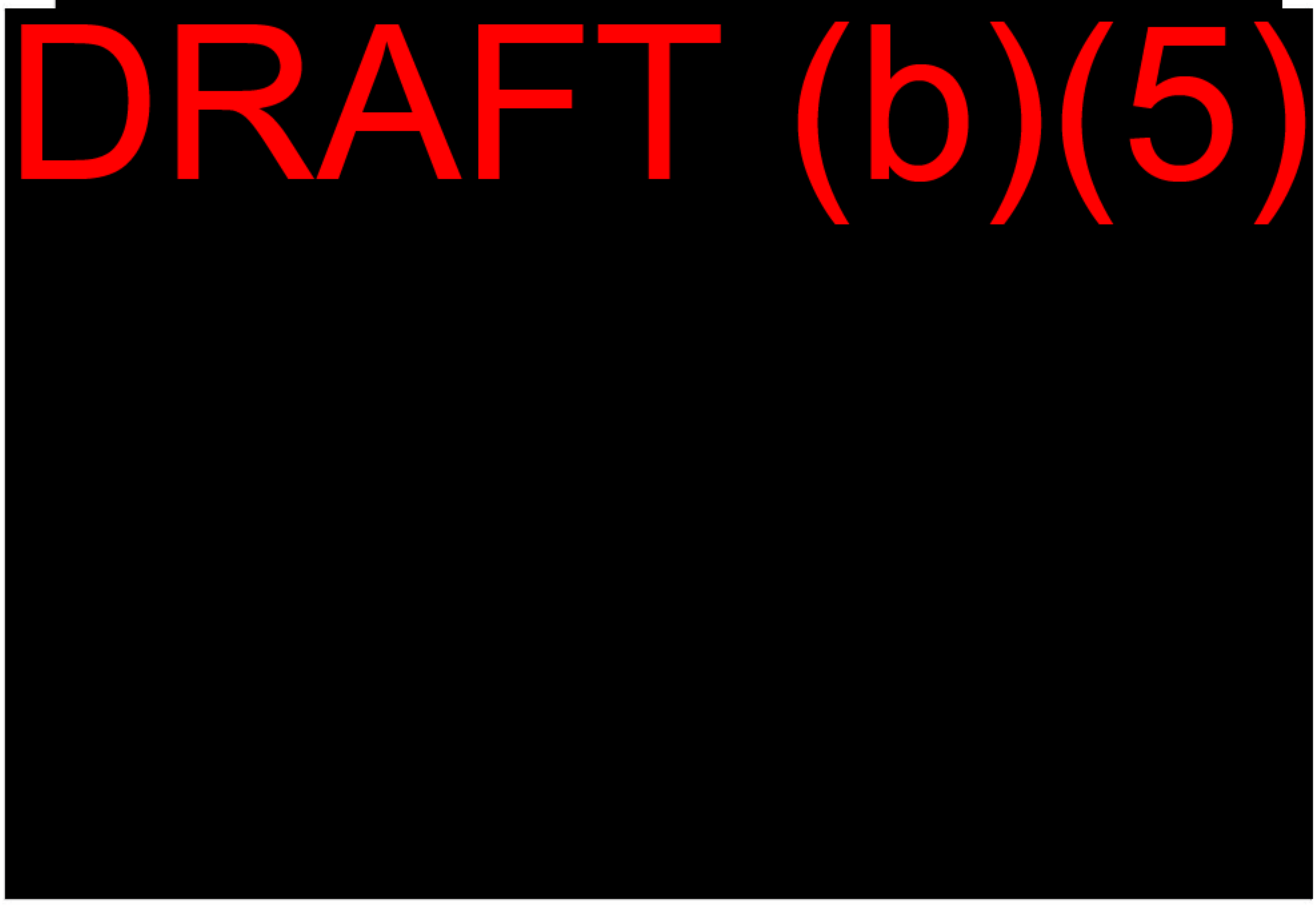
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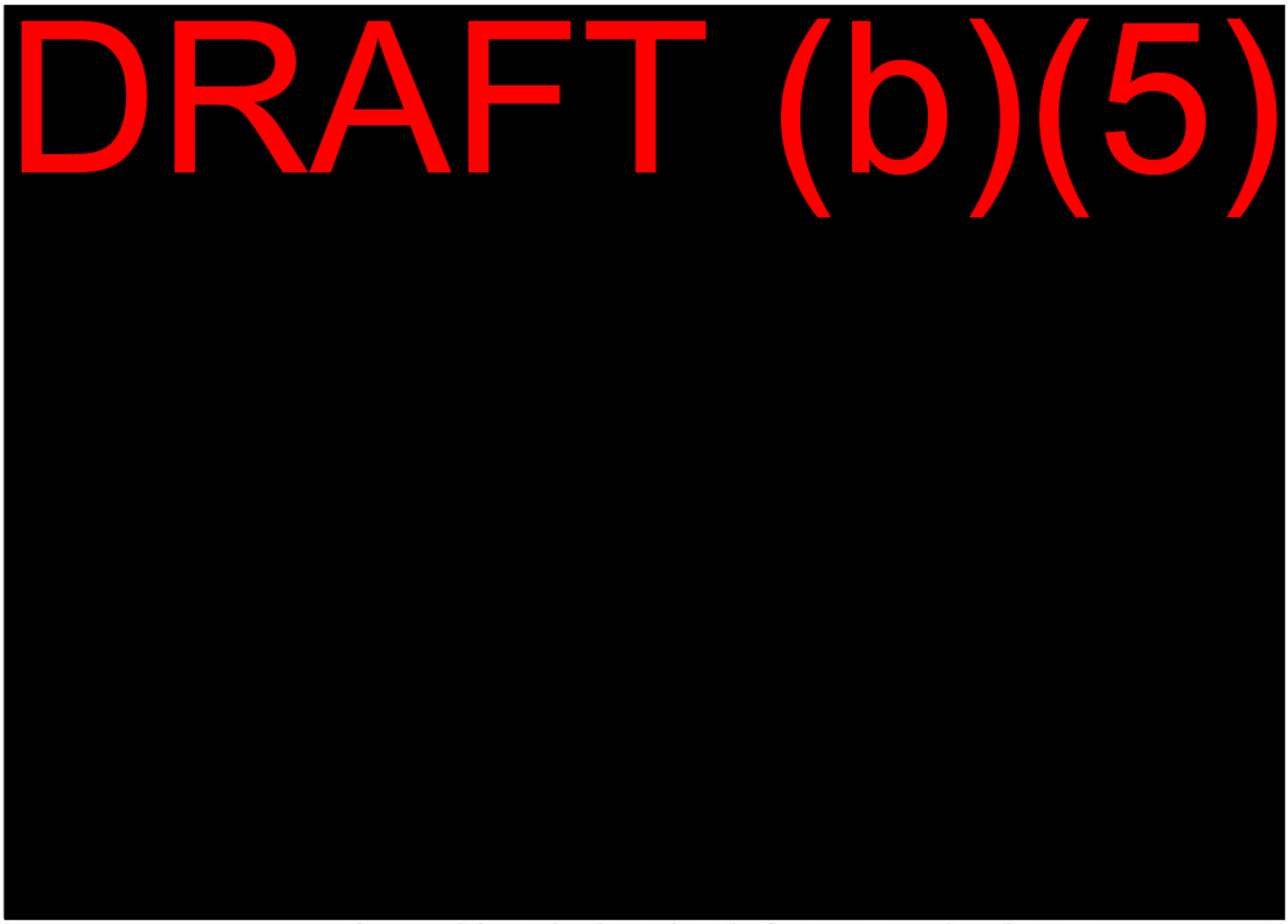
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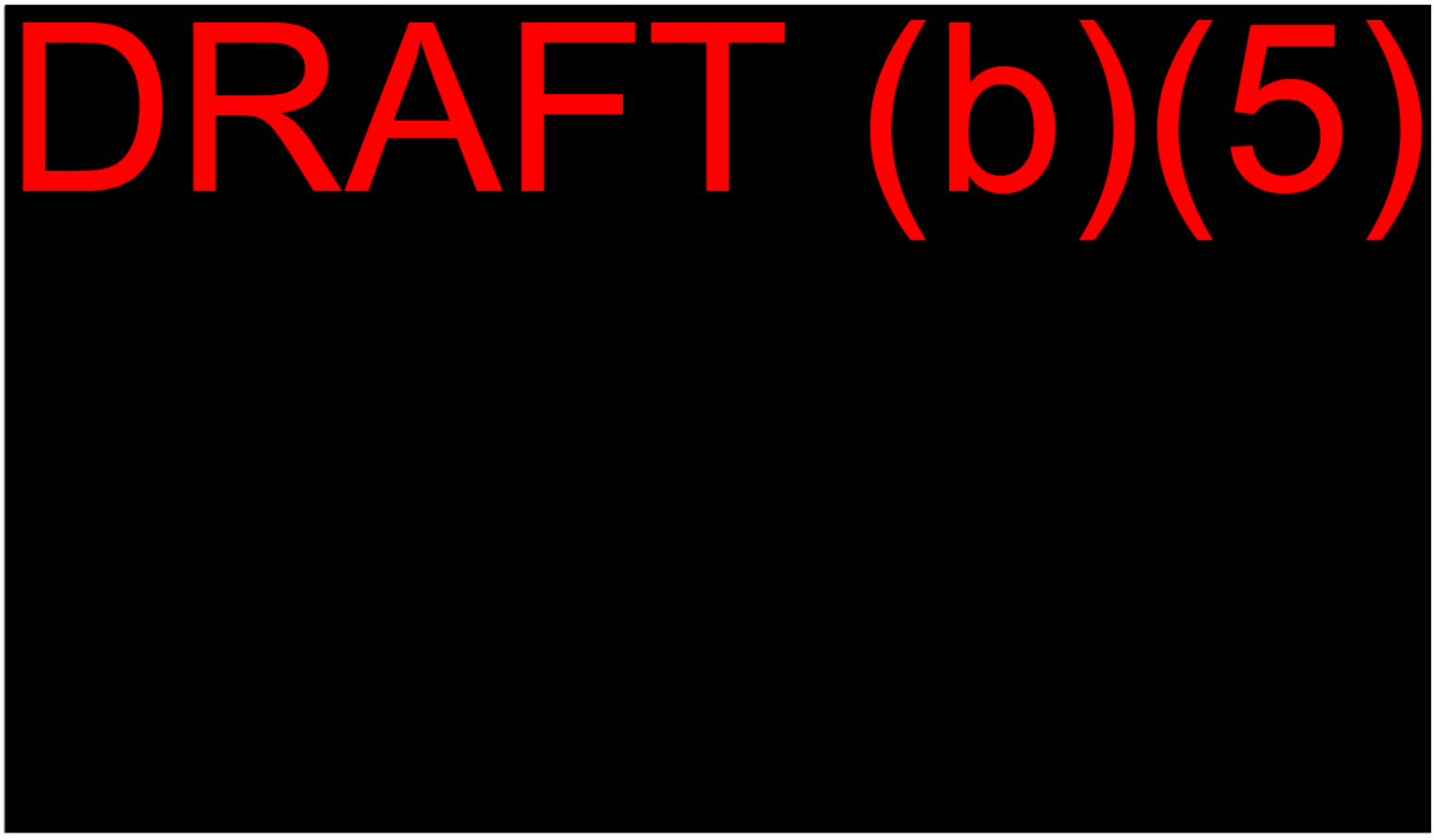
DRAFT (b)(5)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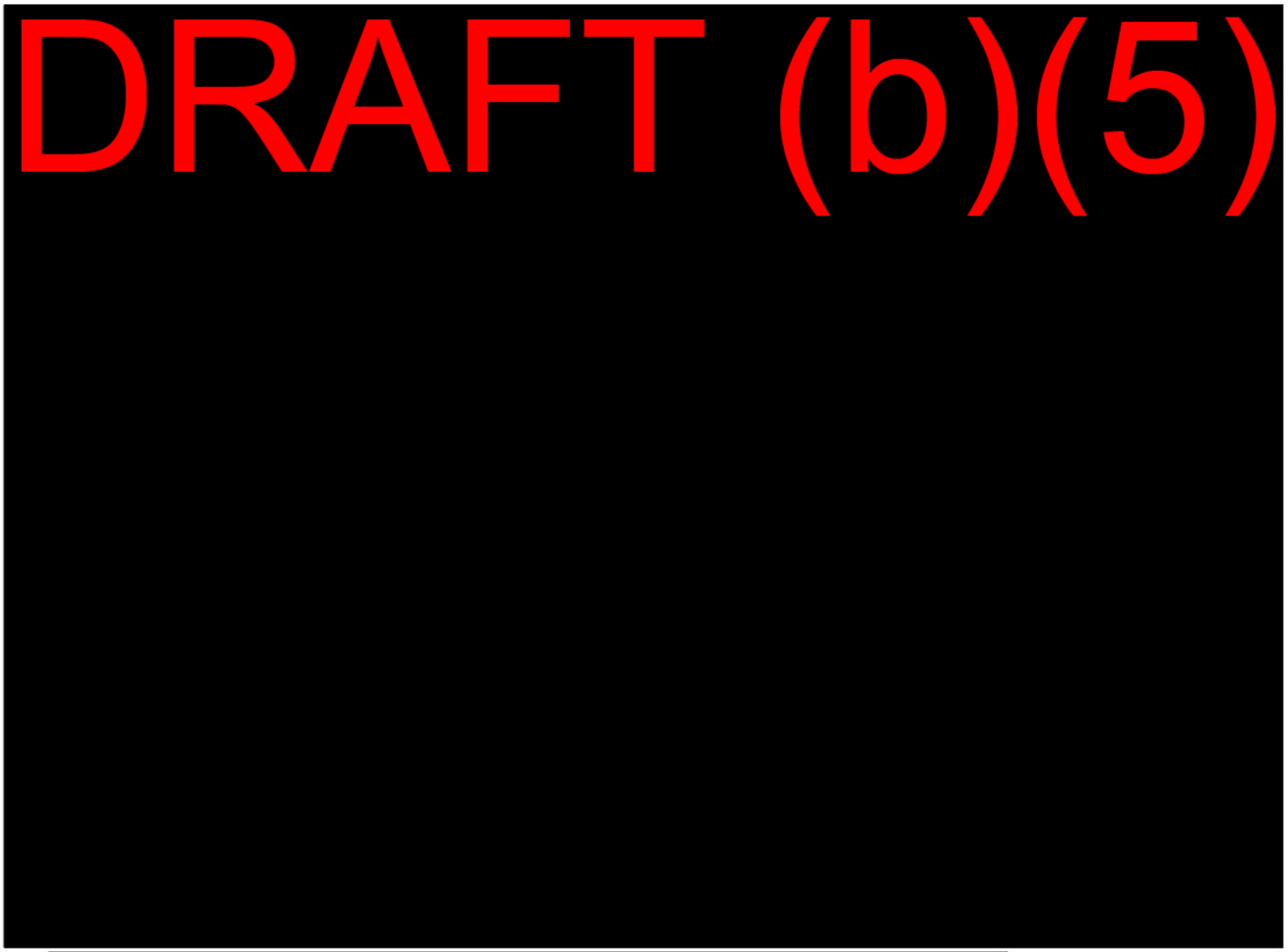
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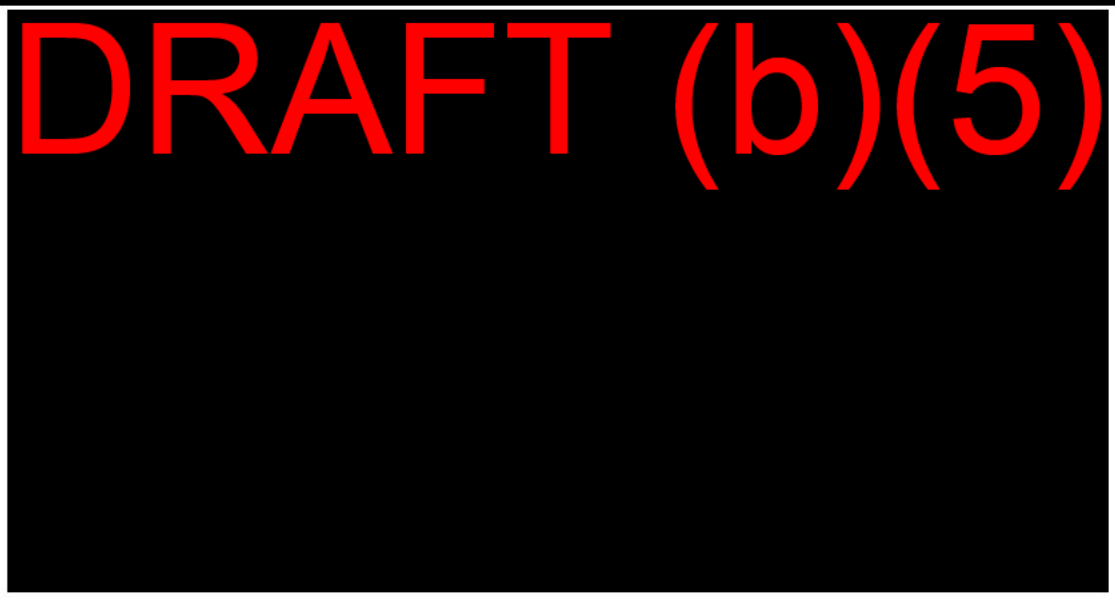

DRAFT (b)(5)

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/25/2022 10:24:06 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: 10:30 AM: Biweekly OFPR Check-In with the Commissioner
Attachments: 1030-Biweekly OFPR Meeting_3.25.2022.pdf

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: 161.199.138.10 (US West)
161.199.136.10 (US East)

Meeting ID: (b) (6)

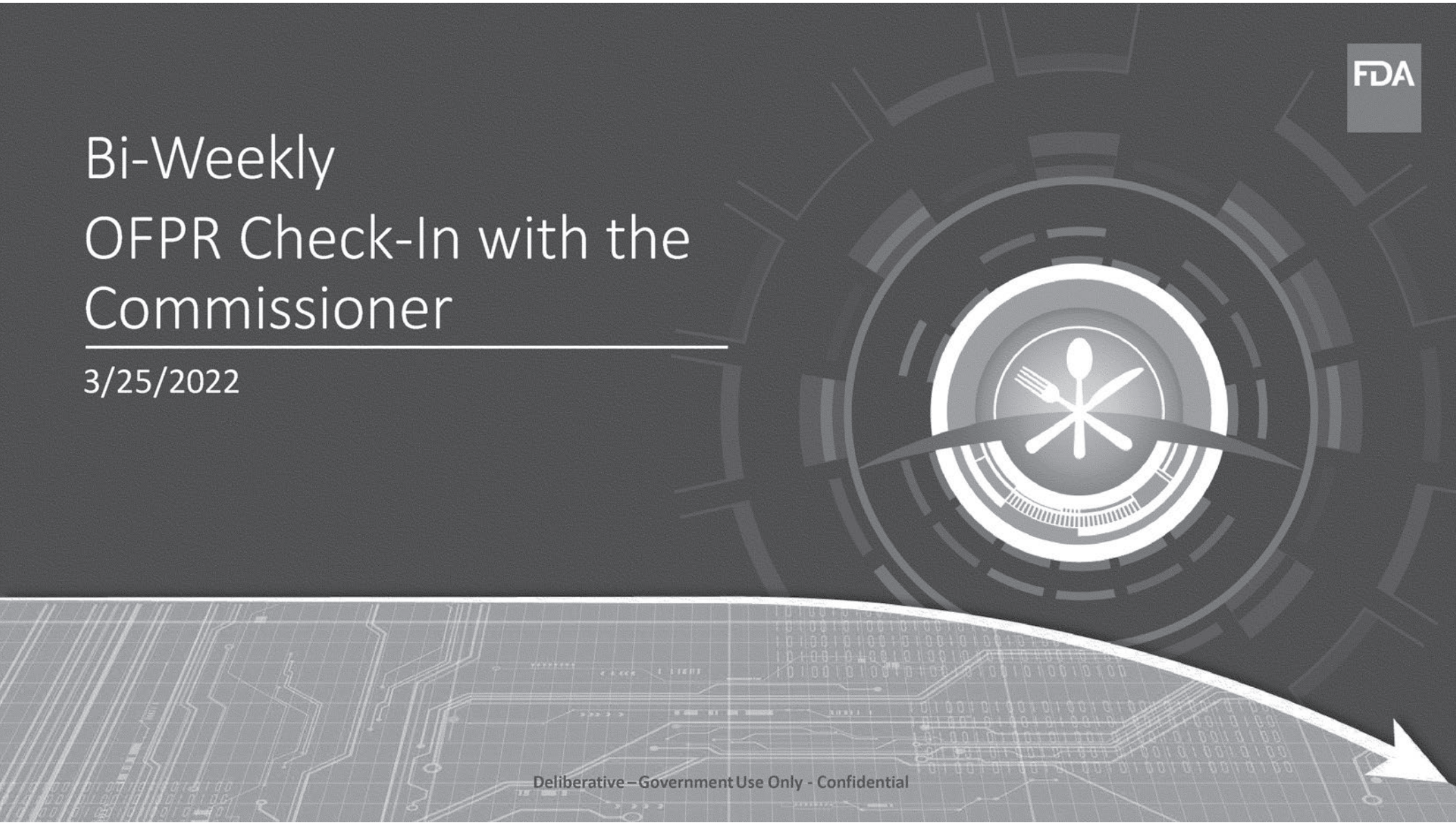
Passcode (b) (6)

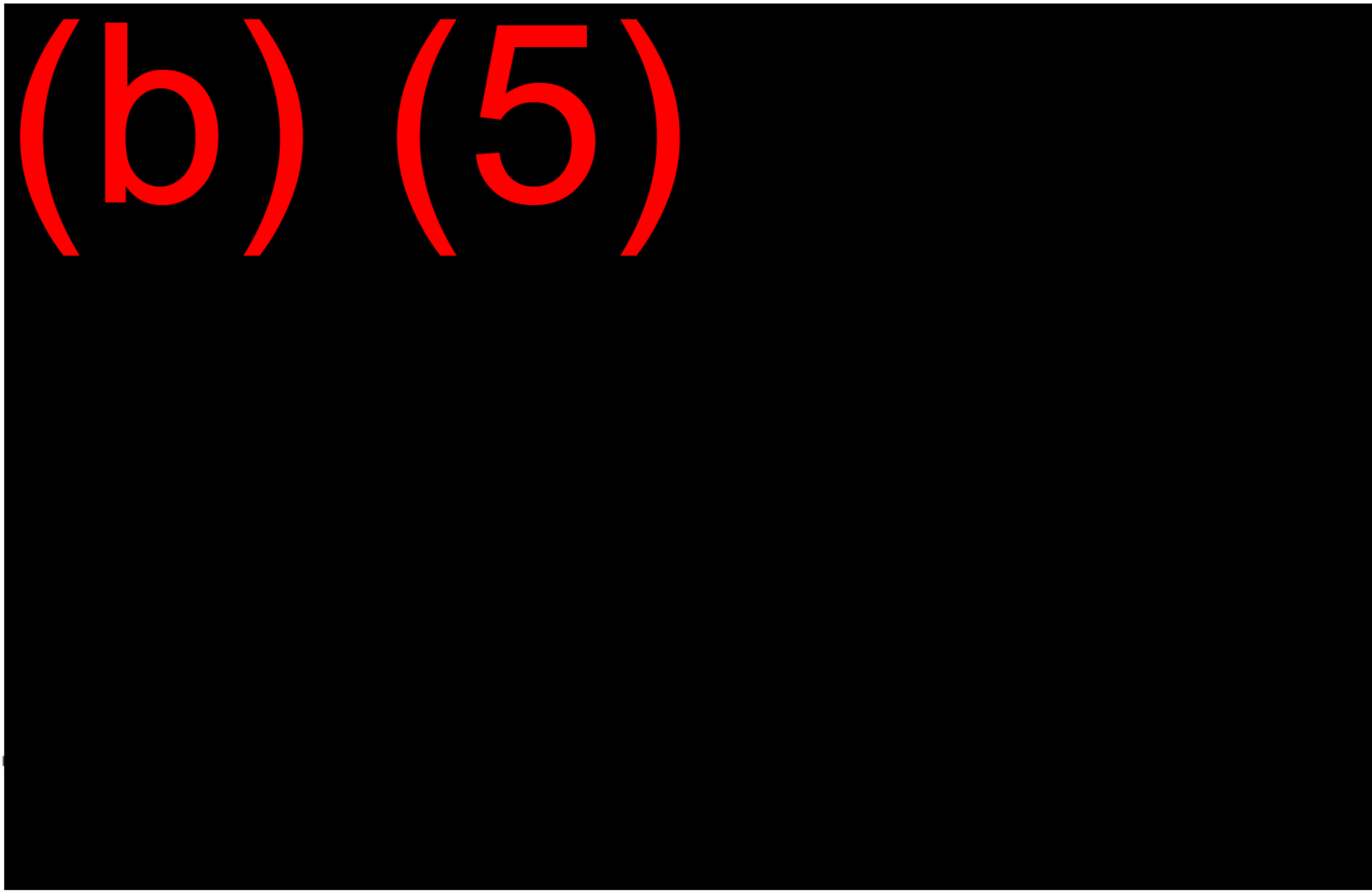
SIP: (b) (6)

Passcode (b) (6)

Bi-Weekly OFPR Check-In with the Commissioner

3/25/2022

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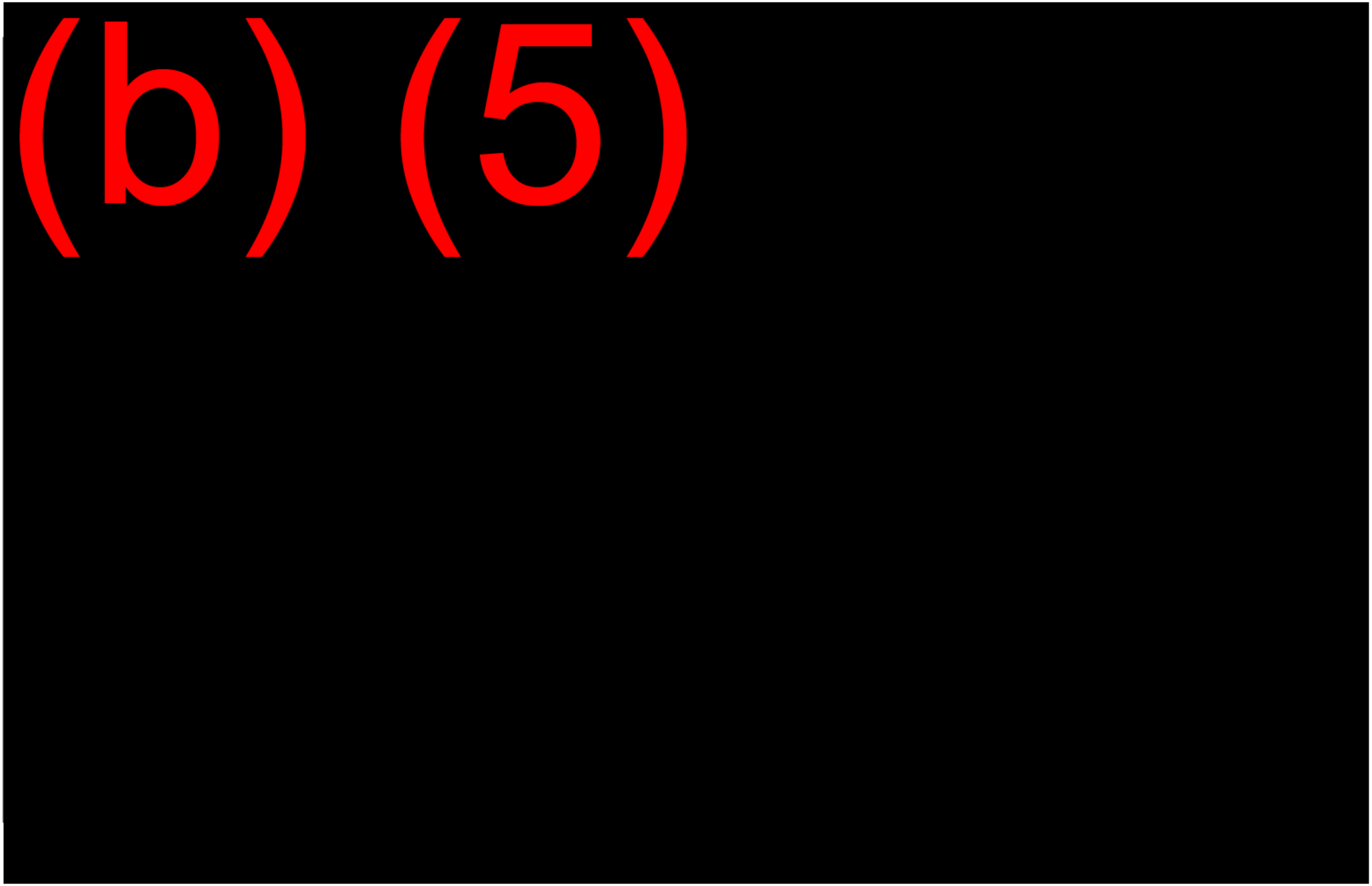
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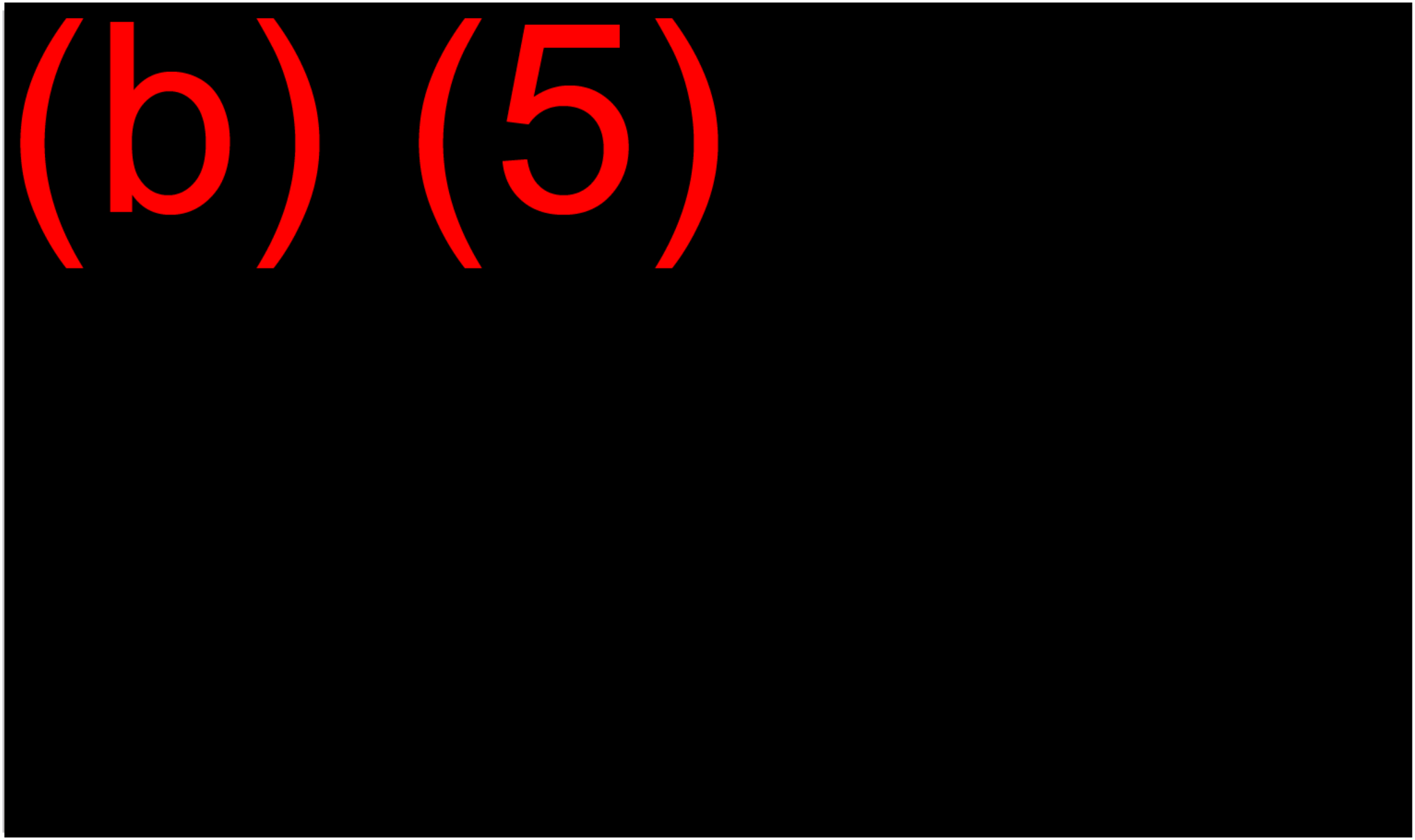
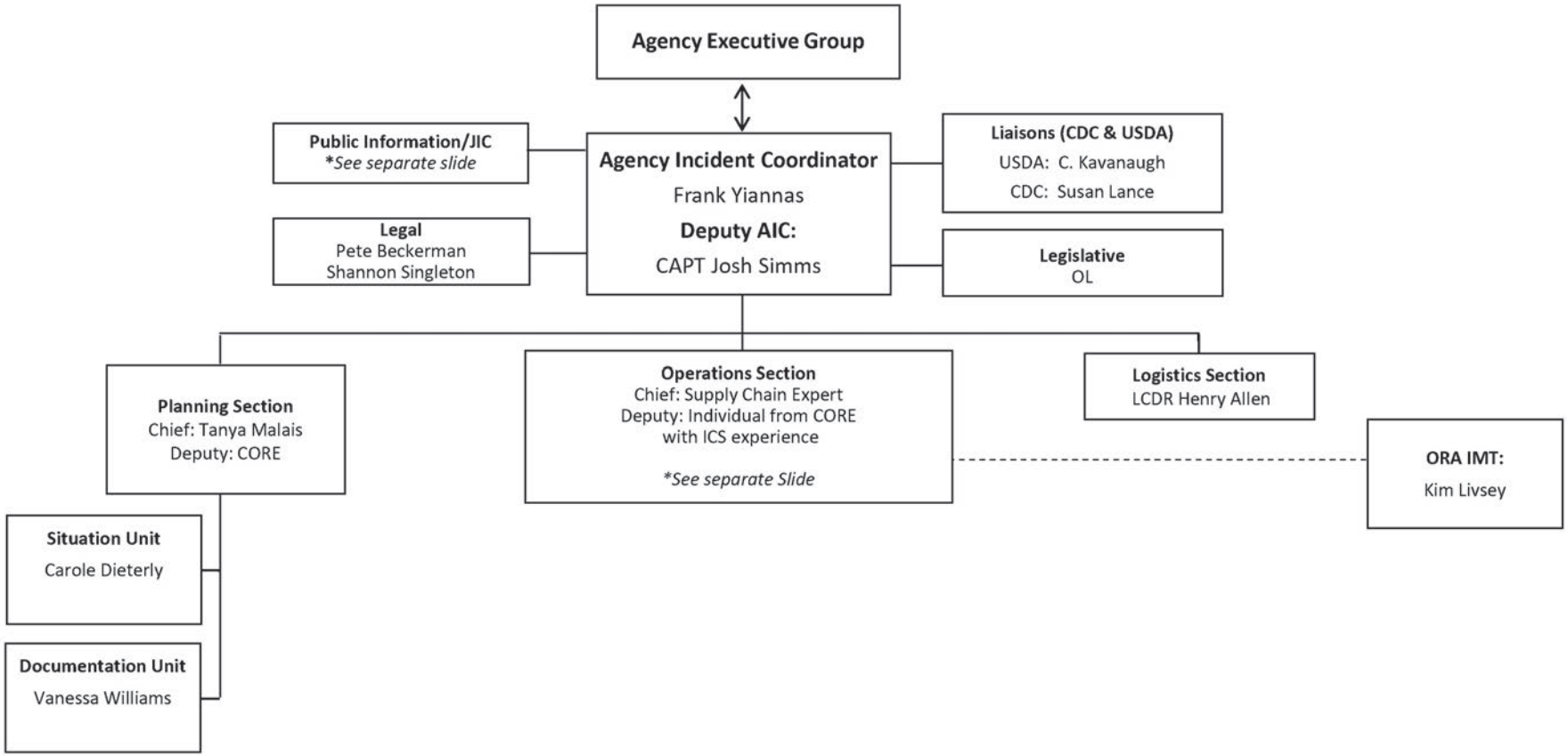
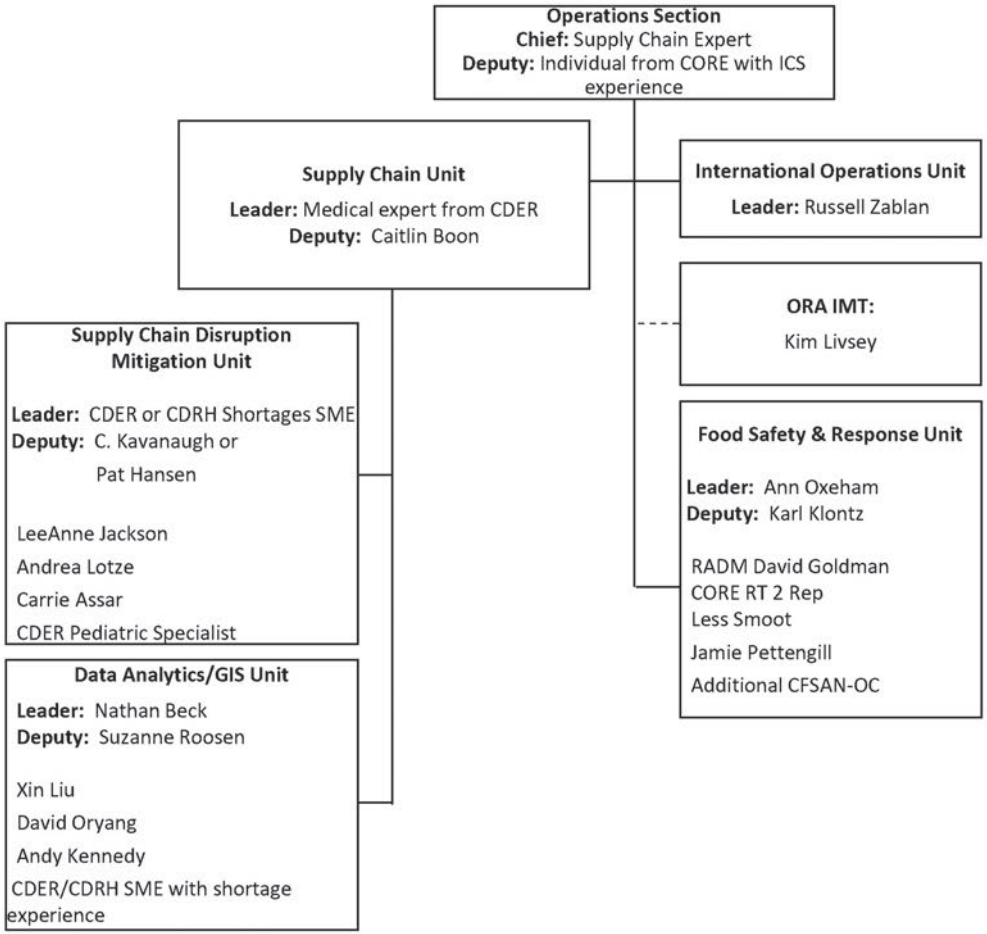

(b) (5)

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: Condillac, Ryan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8D1346DFEC5B4C84B92AC6614F018788-RYAN.CONDIL]
Sent: 4/4/2022 11:10:41 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FW: Schedule & Read Ahead for Wednesday, March 9, 2022
Attachments: 00-03.09.2022-Calendar.pdf; 1020+1030-Califf_Call Memo_Eshoo_030922.docx; 1200-1-OFFICE OF THE COMMISSIONER.BriefingMemo_IGA_USDA_FINAL (update).docx; 1200-2-Tab A-Commissioner Briefing Animal Biotech_InformationalOnly_Final(update.pptx; 1200-3-Tab B-Heritable Intentional Genomic Alterations inAnimalsRisk Based InfoOnly.pdf; 1200-4-Tab C-Heritable Intentional Genomic Alterations in Animals The Approval Process.InfoOnly.pdf; 1200-5-Tab D BIO OMB Animal Letter.Informational Only.pdf; 1445-FDA Abbott infant formula timeline final.pptx; 1600-OEA Comms Forecast Agenda_03.09.2022.docx; READING-FDA Press Release - Philips 518(a).CLEARED.docx

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From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Wednesday, March 9, 2022 10:42 AM
To: Condillac, Ryan <Ryan.Condillac@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: FW: Schedule & Read Ahead for Wednesday, March 9, 2022

Hi Ryan, here is the email/attachments to test when you get the Mac. Thanks! -j

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From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Sent: Tuesday, March 8, 2022 8:02 PM
To: Califf, Robert (b) (6) @fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; 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: Schedule & Read Ahead for Wednesday, March 9, 2022

Your first meeting is scheduled for *8:45 AM [Small OC Executive Team]*. Your final meeting is scheduled for *4 PM [Weekly Check-In: Upcoming Communications Forecast]*.

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

9:00-9:30am DESK TIME

9:30-10:00am RMC to join CTP Leadership Team Meeting (POC: Lindsay Tobias)

10:20-10:30am Internal FDA Prep for telecon with Chairwoman Anna Eshoo
Materials: Memo attached

10:30-10:45am Telecon: Chairwoman Anna Eshoo and Commissioner Califf
Materials: Same memo referenced during prep

10:45-11:00am Weekly Check-In: Legislative Forecast

11:00-11:30am Smaller Group Check-In

11:30am-12:00pm LUNCH

12:00-1:00pm Commissioner Informational Briefing - Intentional Genomic Alteration + USDA
Materials: Attached; 5 documents

1:00-1:30pm Biweekly Check-In: JO'Shaughnessy/Woodcock/Califf

1:30-2:45pm DESK TIME

2:45-3:30pm Infant Formula Update
Materials: Attached; 1 document

3:30-4:00pm DESK TIME

4:00-4:30pm Weekly Check-In: Upcoming Communications Forecast
Materials: Agenda attached

4:30-5:00pm DESK TIME

OEA/OMA READING:

1. **FYI Only, Press Release, Philips 518(a) Recall Order**
- Quotes Jeff Shuren
- Planned release: tomorrow or Thursday
- OEA POC: Stephanie Caccomo

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 9, 2022

Wednesday

March 2022

SuMo	TuWe	Th	Fr	Sa
	1 2	3	4	5
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April 2022

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17 18	19 20	21	22	23
24 25	26 27	28	29	30

	WEDNESDAY
	9
7 AM	**DESK TIME**
8	**Small OC Executive Team;** Zoom details below; FDA Commissioner
9	**DESK TIME** **RMC to join CTP Leadership Team Meeting (POC: Lindsay Tobias)**
10	**Internal FDA Prep for telecon with Chairwoman Anna Eshoo;** +16468287666, (b) (6) one tap mobile; Califf, Robert **Telecon: Chairwoman Anna Eshoo and Commissioner Califf;** +16 **Weekly Check-In: Legislative Forecast;** Zoom details below.; FD
11	**Smaller Group Check-In;** Microsoft Teams meeting ; Califf, Robert **LUNCH**
12 PM	**Commissioner Informational Briefing - Intentional Genomic Alteration + USDA** https://fda.zoomgov.com (b) (6) FDA Commissioner
1	**Biweekly Check-In: JO'Shaughnessy/Woodcock/Califf;** Zoom, details below; FDA Commissioner **DESK TIME**
2	
3	**Infant Formula Update** Zoom, details below; Califf, Robert **DESK TIME**
4	**Weekly Check-In: Upcoming Communications Forecast;** Zoom details below; FDA Commissioner **DESK TIME**
5	
6	
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8	

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 4/10/2022 2:58:49 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FW: Schedule & Read Ahead for Monday, April 11, 2022
Attachments: 00-04.11.2022-Calendar.pdf; 1100-1-Meeting Memo for Asst Sec. Pace - Commissioner Califf.docx; 1100-2-Bio-Loyce Pace, MPH _ HHS.pdf; 1400-1-Commissioner Briefing Memo (Import Operations) 4.7.2022.docx; 1400-2-Commissioner briefing - FDA Imports 101 FINAL 4.5.2022.pdf; 1500-1-2022.04.11_CFSAN Agenda.doc; 1500-2-Dairy Standards of Identity.pptx; READING-1A-Email from Tara Rabin OEA OMA RE Foods Program Story - Politico.pdf; READING-1B-Politico Foods Program Interview Talking Points FINAL 03.23.22.docx; READING-1C-Politico QA Foods Program FINAL 03.23.22.docx; READING-2-OPLIA-OGPS Misinformation Proposal 4-8-22.docx; READING-3-FDA Forecast 4-11 to 4-22-2022.docx

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From: Califf, Robert <RMC001@fda.hhs.gov>
Date: Saturday, April 9, 2022 at 10:02 AM
To: Califf, Robert (b) (6) @fda.hhs.gov>
Subject: FW: Schedule & Read Ahead for Monday, April 11, 2022

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Date: Friday, April 8, 2022 at 8:55 PM
To: Califf, Robert (b) (6) @fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Helms Williams, Emily <Emily.HelmsWilliams@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: Schedule & Read Ahead for Monday, April 11, 2022

Your first meeting is scheduled for *8 AM [Califf/Woodcock/Marks/Tierney]*. Your final meeting is scheduled for *5:30 PM [National Academy of Medicine Evening of Fellowships]*.

8:00-8:30am Califf/Woodcock/Marks/Tierney

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

9:00-9:30am TELECON ONLY: Commissioner's Weekly Check-In

9:30-10:00am Smaller Group Check-In

10:00-10:30am DESK TIME

10:30-11:00am RMC Opioid Speech Prep

11:11:45am Meeting with Dr. Califf - A/S Loyce Pace
Materials: Attached; 2 documents

SP Links:
1100-1-Meeting Memo for Asst Sec. Pace - Commissioner Califf.docx
1100-2-Bio-Loyce Pace, MPH _ HHS.pdf

12:00-1:00pm LUNCH

1:00-1:30pm Staff/Op Div Check In

1:30-2:00pm WEEKLY SENIOR COVID ADVISORS / SECRETARY BECERRA

2:00-3:00pm Commissioner Informational Briefing - Import Operations
Materials: Attached; 2 documents
SP Links:
1400-1-Commissioner Briefing Memo (Import Operations) 4.7.2022.docx
1400-2-Commissioner briefing - FDA Imports 101 FINAL 4.5.2022.pdf

3:00-3:25pm Weekly CFSAN Meeting with the Commissioner
Materials: Attached; 2 documents
SP Links:
1500-1-2022.04.11 CFSAN Agenda.doc
1500-2-Dairy Standards of Identity.pptx

3:30-4:20pm DNS

4:20pm Travel to National Academy of Sciences Building
Notes: National Academy of Medicines, 2101 Constitution Ave, NW, Washington, D.C.

5:30-7:00pm National Academy of Medicine Evening of Fellowships (5:30pm Introduction, 5:35pm Keynote in Kavli Auditorium, 6:00pm Reception in Great Hall)

OEA/OMA READING:

1. **Politico Foods Program Story - Sat., 4/9**

SP Links:
READING-1A-Email from Tara Rabin OEA OMA RE Foods Program Story - Politico.pdf
READING-1B-Politico Foods Program Interview Talking Points FINAL 03.23.22.docx
READING-1C-Politico QA Foods Program FINAL 03.23.22.docx

2. **OPLIA-OGPS Misinformation Proposal**

SP Link: READING-2-OPLIA-OGPS Misinformation Proposal 4-8-22.docx

3. **FDA Communications Forecast (Mon., April 11 - Fri., April 22)**

SP Link: READING-3-FDA Forecast 4-11 to 4-22-2022.docx

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

April 11, 2022

Monday

April 2022

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May 2022

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29	30	31				

MONDAY

11

National Academy of Medicines Evening of Fellowships [National Academy of Sciences Building, 2101 Constitution Ave, NW, Washington, D.C. 21418)

7 AM — **DESK TIME**

8 — **TRAVEL (POV): White Oak**

Califf/Woodcock/Marks/Tierney
Microsoft Teams meeting; Califf, Robert

Small OC Executive Team
Zoom details below; FDA Commissioner

9 — **TELECON ONLY: Commissioner's Weekly Check-In**
Zoom details below.; FDA Commissioner

Smaller Group Check-In
Microsoft Teams meeting ; Califf, Robert

10 — **DESK TIME**

RMC Opioid Speech Prep
Please see Zoom below; Califf, Robert

11 — **Meeting with Dr. Califf - A/S Loyce Pace**
Microsoft Teams Meeting
Pace, Loyce (HHS/OS/OGA)

12 PM — **LUNCH**

1 — **Staff/Op Div Check In**
HYBRID - IN PERSON 607G -ZOOM: https://hhsgov.zoomgov.com/[(b) (6) [redacted] Palm, Andrea (OS/IOS)

WEEKLY SENIOR COVID ADVISORS / SECRETARY BECERRA
Zoom ; OS Scheduling (HHS/OS)

2 — **Commissioner Informational Briefing - Import Operations**
https://fda.zoomgov.com/(b) (6) [redacted]
FDA Commissioner

3 — **Weekly CFSAN Meeting with the Commissioner**
Zoom details below; FDA Commissioner

DNS

4 — **TRAVEL (POV): National Academy of Sciences Building (Parking spot will be reserved in visitor parking lot and security will have RMC on guest list)**
National Academy of Medicines, 2101 Constitution Ave, NW, Washington, D.C.

5 — **National Academy of Medicine Evening of Fellowships (5:30pm Introduction, 5:35pm Keynote in Kavli Auditorium, 6:00pm Reception in Great Hall)**
National Academy of Sciences Building, 2101 Constitution Ave, NW, Washington, D.C. 21418

6

7 — **TRAVEL (POV)** (b) (6) [redacted]

8

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

Olivarria, Frank

From: Rabin, Tara G.
Sent: Friday, April 8, 2022 5:34 PM
To: Tierney, Julia; Colonius, Tristan; Tobias, Lindsay; Olivarria, Frank; Thomas, Jacqueline; Jefferson, Erica; Felberbaum, Michael; Hetlage, Daniel; DiFonzo, Kimberly; Pfaeffle, Veronika; Yiannas, Frank; Mayne, Susan; McMeekin, Judith; Fristedt, Andi; Flahive, James; Tantillo, Andrew; Croce, Teresa; Rogers, Michael; Cave, Carol; Boon, Caitlin; Buckner, Rebecca J; Prater, Donald; Kux, Leslie; Stearn, Douglas; Musser, Steven M; Choiniere, Conrad; Moorman, Mark; Kavanaugh, Claudine; McKinnon, Robin; Smith-Dulley, Jasmine *; Ramos, Melissa *; Morris, Larry; Kelly, Susan; Sjursen, Taryn; Dooren, Jennifer; Butler, Kristine; Naum, Marianna; Barrett, Kari; Davis, Elisabeth; Haake, Lindsay; Turney, Amanda; Pillsbury, Laura; Velez, Megan; Saben, Alyson L; ORA Press; Newhart, Corinne; Mangia, Julia
Subject: Politico Foods Program Story - Sat., 4/9
Attachments: Politico Foods Program Interview Talking Points FINAL 03.23.22.docx; Politico QA Foods Program FINAL 03.23.22.docx

All,

Flagging that tomorrow morning, April 9, Politico will be running their in-depth story on the FDA's overall foods program. It will explore why food issues take so long to address with the three main examples being agricultural water, heavy metals in baby food, and sodium reduction. Other issues that may be mentioned briefly include: PFAS, phthalates, arsenic and lead juice guidances not finalized, and allergen labeling.

The story is based on more than 50 interviews with current and former FDA officials, including former Commissioners, consumer advocates, industry leaders and others. In addition, the reporter interviewed Commissioner Califf and Principal Deputy Commissioner Woodcock for this piece. CFSAN, OFPR and ORA provided extensive written responses. I've attached all the final materials again here for central access/records.

The article will be featured in the Politico Playbook over the weekend and then in various other newsletters on Monday. Story will not run on Politico Pro, but will be on Politico.com – meaning it will not be behind a paywall. I will send over a link as soon as available tomorrow morning.

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: Helms Williams, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=873BE46F1B1A4D2B8DF3FE67137CBDC8-HELMSWILLIA]
Sent: 5/6/2022 3:39:08 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FW: Abbott Nutrition - litigation hold

Heads up that you should have received a "litigation hold" email related to Abbott Nutrition earlier this week, I believe on Tuesday evening. Please make sure to retain all emails and other documents related to that matter. If you haven't done so already, you'll need to acknowledge receipt of the email via a voting button at the top of the email (I'm happy to connect via Teams to walk through it if needed, although maybe it's self explanatory enough).

Thanks!
Emily

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Tuesday, May 3, 2022 9:54 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Dickinson, Elizabeth (FDA) <Elizabeth.Dickinson@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>
Subject: FW: Abbott Nutrition - litigation hold

Hi - FYI

From: Gorji, Perham <Perham.Gorji@fda.hhs.gov>
Sent: Tuesday, May 3, 2022 9:52 AM
To: Zuckerman, Claudia <Claudia.Zuckerman@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Dickinson, Elizabeth (FDA) <Elizabeth.Dickinson@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: FW: Abbott Nutrition - litigation hold

Thanks, Claudia. I'm cc'ing Mark and Liz so they are aware Dr. Califf will be getting the hold request, as they might want Julie Tierney to get a heads up.

From: Zuckerman, Claudia <Claudia.Zuckerman@fda.hhs.gov>
Sent: Tuesday, May 3, 2022 9:45 AM
To: Gorji, Perham <Perham.Gorji@fda.hhs.gov>
Cc: Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: Abbott Nutrition - litigation hold

Perham,

A heads-up—we're going to issue a litigation hold today in the Abbott Nutrition matter. Among the 410+ recipients will be Dr. Califf.

Claudia

Claudia J. Zuckerman
Senior Counsel
Food & Drug Division, OGC
FDA Office of the Chief Counsel
Tel: 301-796-8609

Claudia.Zuckerman@fda.hhs.gov

From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 5/12/2022 10:27:30 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: Re: [EXTERNAL] Re: IRi Data - Powdered Infant Formula Availability

Yes. Sorry. Just seeing this!

Get Outlook for iOS

From: Califf, Robert <(b) (6)@fda.hhs.gov>
Sent: Thursday, May 12, 2022 9:06:37 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: IRi Data - Powdered Infant Formula Availability

Frank—do you have time for a quick call?

rmc

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

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

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

Frank, happy to help.

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

Krishnakumar (KK) S. Davey
President, Client Engagement

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

IRIworldwide.com

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

KK

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

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

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

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

Thanks

Frank

IRi

Krishnakumar (KK) S. Davey
President, Client Engagement

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

IRIworldwide.com

From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 5/13/2022 10:05:02 AM
Subject: <no subject>

1. We appreciate the concern of parents about the well-being of their children. Nothing is more precious or important than the well-being of our youngest children.
2. We are working night and day to:
a. Get Abbott back in compliance
b. Increase production from other manufacturers
3. Our measures indicate that the overall supply of general infant formula is not the problem.
a. People have bought more formula in the last month than in the month before the recall
b. Our sources do not report a 43% in stock number. Our estimates look much better than that.
c. However, because Abbott had 43% of the market consumers will find bare areas on the shelves and a different mix of formula products

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/15/2022 3:14:18 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 3:30pm: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Hi there,

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Meeting ID: (b) (6)

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Meeting ID:

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: 5/15/2022 3:44:20 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 4:00pm: Infant Formula (IF) Daily Update Kickoff Meeting (30 mins)

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FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

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Meeting ID: (b) (6)

Passcode(b) (6)

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Meeting ID: (b) (6)

Passcode(b) (6)

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Meeting ID:

Passcode (b) (6)

SIP: (b) (6)

Passcode (b) (6)

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 5/15/2022 10:13:58 PM
To: 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]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; 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]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: RE: Follow up: Broadcast TV hits tomorrow am

Great – good luck!

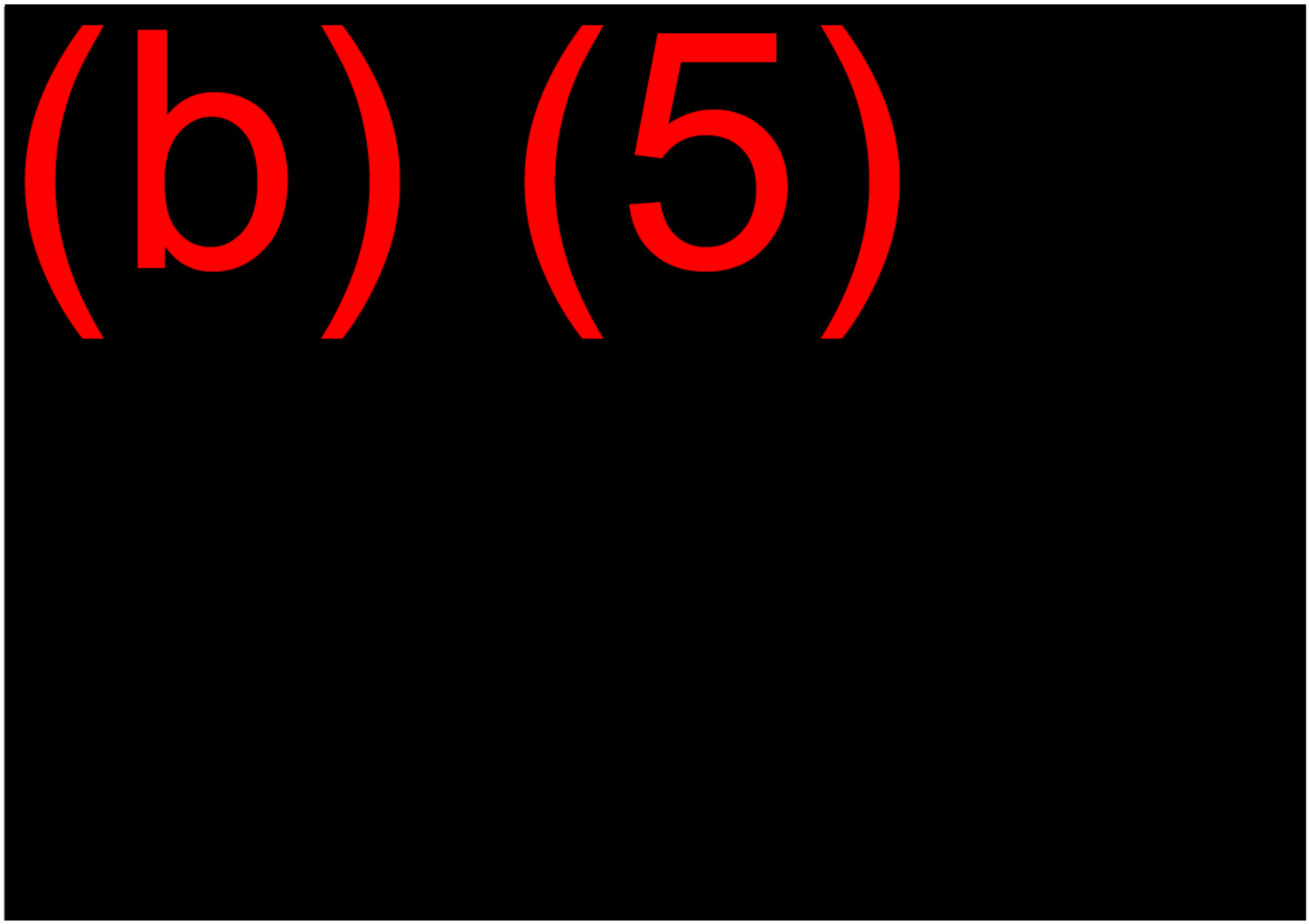
From: Califf, Robert <(b) (6)@fda.hhs.gov>
Sent: Sunday, May 15, 2022 10:10 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>;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

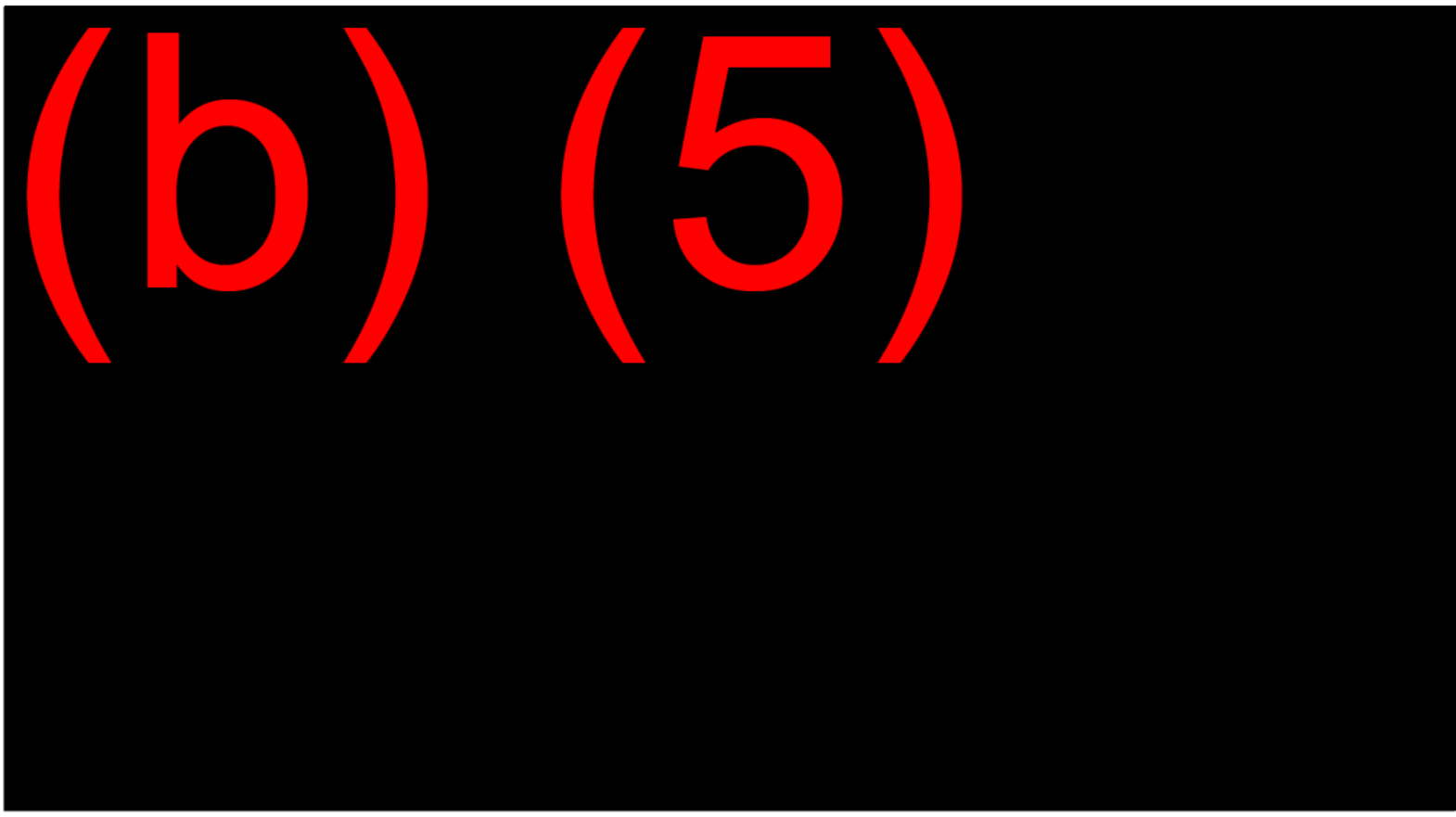
Just read them. Looks good. Onward and upward.

rmc

From: Michael Felberbaum <Michael.Felberbaum@fda.hhs.gov>
Date: Sunday, May 15, 2022 at 10:02 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, Erica Jefferson <Erica.Jefferson@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>, "Rabin, Tara G." <Tara.Rabin@fda.hhs.gov>
Subject: RE: Follow up: Broadcast TV hits tomorrow am

(b) (5)


(b) (5)


(b) (5)

(b) (5)

(b) (5)

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: (b) (5)

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:

(b) (5)

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 (b) (5) I've attached the final version that was provided to us.
Toplines:

(b) (5)

(b) (5)

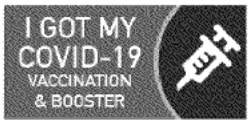
non-responsive

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: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/16/2022 8:59:57 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 9:15am: Infant Formula (IF) Daily Update

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Sent: 5/16/2022 9:14:39 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 9:30am: Internal FDA Media Prep: Infant Formula Supply Rollout

Monday, May 16
Subject: Internal FDA Media Prep: Infant Formula Supply Rollout
Time: 9:30-10:00am
Note: FDA's plans to exercise flexibilities regarding the importation of certain infant formula products from abroad in an effort to increase powdered infant formula supply in the U.S.

The purpose of this meeting is to conduct a media prep in anticipation of media call on this announcement.

Rollout Target: Wednesday, May 18

POCs: Michael Felberbaum (Cell: (b) (6) Tara Rabin (Cell: (b) (6)

[redacted]

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Passcode:

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/16/2022 6:45:52 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: RE: 6:55pm: Media Call: Actions to Increase Infant Formula Supply
Attachments: Media Call Script_Infant Formula_FINAL 05.16.22_630pm.docx

Updated media script attached.

Note: noting that language reflects that the consent decree was just entered.

Jakea

From: Copeland, Jakea
Sent: Monday, May 16, 2022 6:39 PM
To: Califf, Robert (b) (6) @fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: 6:55pm: Media Call: Actions to Increase Infant Formula Supply

Reference materials attached.

1-800-857-9826,,(b) (6)

1-800-857-9826; Speaker Code: (b) (6)

Subject: TENTATIVE Media Call: Actions to Increase Infant Formula Supply

WHAT:
A media briefing to discuss the FDA's plans to exercise flexibilities regarding the importation of certain infant formula products from abroad in an effort to increase powdered infant formula supply in the U.S.

HOW:
- Speaker dial in: 800-857-9826
- Speaker passcode: (b) (6)

This call is voice-only; there is no video component. Please remember to use a fully-charged mobile phone with a strong signal or use a land line.

WHEN:
Monday May 16 at 7:00 p.m. ET
Speakers must dial-in 5 minutes before the scheduled call at 6:55 p.m. call for a sound check.

WHO:
- Robert Califf, M.D., FDA Commissioner

- Susan T. Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition
- Frank Yiannas, Deputy Commissioner for Food Policy and Response

POCs: Michael Felberbaum (Cell: (b) (6) Tara Rabin (Cell: (b) (6)

Please do not forward this invite

Invitees
Michael Felberbaum
Susan Mayne
Robert Califf
Frank Yiannas
Tara Rabin
Julia Tierney
Erica Jefferson

Script: FDA Provides New Updates on Activities to Mitigate Infant Formula Supply Challenges
May 16, 2022

1) FDA Encourages Importation of Safe Infant Formula and Other Flexibilities to Further Increase Availability
2) Abbott Nutrition Agrees to Take Corrective Actions at Facility to Produce Safe Infant Formula

I. Moderator

Good afternoon and welcome to today's U.S. Food and Drug Administration media briefing on new updates that the agency is taking to mitigate infant formula supply challenges. Today we're announcing two significant updates focused on increasing the supply and availability of infant formula in the U.S.

I'm Michael Felberbaum with the FDA's Office of Media Affairs.

In a moment, I will turn it over to FDA Commissioner Dr. Robert Califf, Dr. Susan Mayne, Director of the FDA's Center for Food Safety and Applied Nutrition, and Frank Yiannas, FDA's Deputy Commissioner for Food Policy and Response, to provide brief remarks.

After the remarks, we will move to the question-and-answer portion of the call, where Dr. Califf, Dr. Mayne, and Mr. Yiannas will be available to answer questions.

Reporters on the phone will be in a listen-only mode until we open the call up for questions. As a reminder, this call is being recorded and livestreamed on the FDA's YouTube channel.

With that, I will now turn the call over to FDA Commissioner Dr. Robert Califf.

II. FDA Commissioner Robert Califf, M.D.

Thank you, Michael, and good evening everyone.

Today we announced two updates regarding our efforts to respond to infant formula supply challenges that parents and caregivers in the U.S. are currently facing: First, we've set-up a mechanism that streamlines the ability for companies that do not normally sell infant formula in this country to do so and provides other flexibilities to domestic distributors who can help increase availability. Second, a consent decree of permanent injunction was entered by the U.S. District Court for the Western District between the FDA and Abbott Nutrition. Under the consent decree, Abbott has agreed to take actions that would be expected to ultimately result in an increase of infant formula products and ensure safe powdered infant formula is produced at the facility.

We know many parents and caregivers are feeling frustrated by their inability to access needed or desired infant formula and critical medical foods. Please know that we at the FDA are doing everything in our power to address these challenges as quickly as possible.

Our new guidance streamlines the ability for companies – including those that do not normally sell infant formula in this country – to make products available to the U.S. market while also ensuring nutrition and safety standards are being met. It also provides flexibilities to those who do distribute infant formula products in the U.S. and may be able to increase available product volume even further than they have already.

I strongly encourage all those who are or could manufacture infant formula products quickly and safely, including those that do not currently sell in the U.S., to help us increase the supply of

products, which may serve as the only source of nutrition for many infants.

With these additional flexibilities in place, we anticipate that additional products can quickly hit U.S. stores.

Today, we're also pleased that under a consent decree Abbott Nutrition has agreed to address certain issues that the agency identified at their infant formula production facility in Sturgis, Michigan. During our inspection, we identified multiple samples positive for *Cronobacter sakazakii*, a bacterium that can potentially cause severe foodborne illness primarily in infants, and observed significant operational deficiencies.

While the agency's inspection was ongoing earlier this year, Abbott Nutrition *voluntarily* shut down its facility to implement corrective actions to address issues raised by the FDA and also *voluntarily* recalled certain products. Under the consent decree, when they restart production at this facility, they must follow specific provisions focused on ensuring safe powdered infant formula is produced at the facility and meet FDA food safety standards.

If contamination is identified in the future, the company must notify the FDA, identify the source of the problem, and conduct a root-cause investigation before resuming production.

We are also taking a look at the supply of infant formulas developed by manufacturers across the country and around the world to determine if a reallocation of their distribution can be made to help get the right product to the right place, at the right time.

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. In fact, our data – which we'll discuss in more detail later on – tell us that in-stock rates in retail stores are already improving.

With increased production by other manufacturers, the many actions we've been taking and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, the FDA expects supply to continue to improve over the next couple of months.

I am now going to turn it over to the director of the FDA's Center for Food Safety and Applied Nutrition, Dr. Susan Mayne, to further discuss the new guidance issued today.

III. Director of the FDA's Center for Food Safety and Applied Nutrition Susan Mayne, Ph.D.

Thank you, Dr. Califf.

As the director of the FDA's Center for Food Safety and Applied Nutrition, I know just how important it is to protect the health of infants, for whom infant formula is often the sole source of nutrition during a critical period of growth and development.

Getting our most vulnerable populations the infant formula products needed remains an utmost priority for me and my colleagues here at the FDA.

That's why today, I'm happy to announce a new FDA guidance focused on increasing infant formula supplies in the U.S. The guidance lays out the agency's intention to exercise flexibility, on a case-by-case basis, for certain requirements that apply to infant formula.

The guidance is related to both the importation of infant formula produced in other countries and infant formula that is produced in the U.S. It explains to infant formula manufacturers what information the FDA needs to show that their product is safe and nutritionally adequate, and the extent to which they may be able to assist in mitigating the current supply challenges.

The FDA will review the infant formula's nutritional composition, ingredients, current or anticipated inventory of the formula, microbiological testing results and facility inspection history. In addition, we'll make sure any ingredient used in the infant formula is safe and suitable.

We'll also make sure that any new product introduced to the U.S. marketplace follows specific requirements for labeling of infant formulas. This includes directions for preparation and use and appropriate allergen labeling.

The agency intends to prioritize submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest.

The FDA is already in discussions with some manufacturers regarding additional imports and increased production at domestic facilities.

We know that U.S. consumers are weathering challenges related to the current supply of infant formulas and we care deeply. I want you to know that we are making progress and will continue to make progress on your behalf.

With that, I'd like to turn it over to our Deputy Commissioner for Food Policy and Response Frank Yiannas to talk more about the FDA's efforts and infant formula data trends we're seeing.

IV. Deputy Commissioner for Food Policy and Response Frank Yiannas

Thank you, Dr. Mayne.

Thank you for joining us today. First, I want to express my deep empathy for parents and caregivers who are experiencing anxiety related to the current infant formula situation. Dr. Califf, Dr. Mayne and I are all parents and understand how much everyone cares about the safety and nutrition of products they feed their children.

We recognize the hardships that infant formula consumers may have faced in obtaining their desired infant formula products. We're focused on getting as much product as possible on store shelves including getting the right product to the right place and won't rest until the infant formula market gets back to normal with the hundreds of products American families are used to.

We know that all infant formula manufacturers who supply to the U.S. have already stepped to the challenge and are producing at an expanded capacity. Gerber increased the amount of their infant formula available to consumers by approximately 50% in March and April and Reckitt is supplying more than 30% more product so far this year.

With this increased production, we're now seeing increased infant formula sales. I'm encouraged to share with you the data the FDA is seeing from Information Resources Inc. (or IRI) – a widely cited company – which shows that national infant formula sales by volume for the month of April were up more than 13% compared to the month prior to the recall. It also shows that national infant formula sales by unit for the month of April are up by more than 5% compared to the month prior to the recall.

Now we know some data suppliers have reported lower in-stock rates, but we've also seen the most complete data sets from IRI that are showing nearly 80% in-stock rates at the week ending May 8. To illustrate a bit further, what this means is – let's say a local supermarket normally carries 50 different infant formula products, an 80% in-stock rate would mean that 40 of those 50 product types are available. What these data tell us is that while there is more product being sold, it may be of less variety than prior to the recall.

You may be wondering why, if these data are true, are you seeing photos of empty shelves and parents and caregivers struggling to find their infant formula? We do know that there is variation in availability throughout the country, and we are working with other government partners to try to address these regional and localized shortages. We also believe that there may have been additional panic buying over the last week given the extensive coverage of this issue.

Parents and caregivers deserve access to the brands and options they're used to, so please know that we're doing everything possible to rectify this situation and replenish the typical supply of infant formula products that American consumers expect.

Looking at increased sales are a good indicator of standard formula available to the general population of infants, but the agency understands that availability of specialty and metabolic products continues to be of concern. For those who fall into this category, we've 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 all efforts to make these products even more readily available. If you are in dire need of specialty and metabolic products from Abbott Nutrition, please call their hotline – which is listed on the FDA's website as well – for assistance.

With increased production by other manufacturers, forthcoming flexibilities for imported and domestically produced products import and along with the potential for Abbott Nutrition's Sturgis facility to resume production of these specialty formulations in the near-term, the FDA expects supply to continue to improve over the next couple of months.

As you can see, the FDA is leaving no stone unturned to further increase the availability of infant formula and we are doing everything possible as part of the all-of-government efforts to ensure there's adequate product available wherever and whenever parents and caregivers need it.

Thank you. And now I will turn back to the moderator to begin questions and answers.

IV. Moderator

Thank you, Deputy Commissioner Yiannas.

At this time, we will begin the question-and-answer portion of the briefing.

As a reminder, this call is being recorded.

When asking a question, please state your name and media outlet.

Also, please ensure questions pertain to today's announcement and limit yourself to one question and one follow-up so we can get to as many questions as possible.

Operator, we'll take the first question.

****

[*After response to each question, moderator says, "Operator, we'll take the next question, please."*]

[*Before the final question, moderator will note, "Operator, we have time for one more question."*

[And then following the response to the final question, continue with the script below]

****

This concludes today's media briefing.

A replay will be available on the FDA's YouTube page.

The FDA's press release has been posted on the agency's website.

If you have follow-up questions, please don't hesitate to contact the FDA press office at fdaoma@fda.hhs.gov.

Thank you and goodbye.

Clearance chain:

(b) (5)

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/17/2022 8:29:51 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 8:45am: Infant Formula (IF) Daily Update

Hi there,

FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: +16692545252,(b) (6)
+16692161590,(b) (6)

Meeting URL: https://fda.zoomgov.com(b) (6)

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For higher quality, dial a number based on your current location.
Dial:

US: +1 669 254 5252 or +1 669 216 1590 or +1 646 828 7666 or +1 551 285 1373 or 833 568 8864 (Toll Free)

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International numbers

Join from an H.323/SIP room system

H.323: [redacted]

Meeting ID:

Passcode

SIP:

Passcode

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/17/2022 8:45:33 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 9:00am: Hill Call on Infant Formula Importation Guidance / Consent Decree

800-369-2057,(b) (6)

Ph: 800-369-2057
Leader passcode: (b) (6)(for FDA)
Participant passcode: (b) (6)

Thanks,
Mahlet

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/17/2022 11:19:15 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: Materials Attached: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input
Attachments: NGA Infant Formula Briefing.051722.FINAL SCRIPT.docx; State-Local Clippings-Infant Formula Recall&Shortage.051622.docx

Dr. Califf,

Attached are the reference documents for today's 12pm – Governor's call. These materials were also included in last nights schedule email.

Jakea

From: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 11:12 AM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input

Sent last night – attached here, along with state document.

-- Nick

Nick Alexander, J.D.
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Office of Policy, Legislation, and International Affairs
Office of the Commissioner
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nicholas.alexander@fda.hhs.gov

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 11:04 AM
To: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input

Good morning, Nick!

RMC is asking if we have updated scripts for this call please?

Thank you!

-j

From: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 10:48 AM
To: Morris, Larry <Larry.Morris@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: RE: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input

Yes. I believe so. Will double check, but I would prepare as if cameras are to be used.

Also – JUST received confirmation that Secretary will be on to do the call "topper"

-- Nick

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From: Morris, Larry <Larry.Morris@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 10:46 AM
To: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: RE: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input

Hi Nick and team, sorry if I missed this, are leaders expected to have camera's on for this next call?

Thank you,
Larry

Larry G Morris Jr
Special Assistant to the Deputy Commissioner
Office of Food Policy and Response
Office of the Commissioner
Office: (301) 796-6903 / Mobile: (b) (6)

Larry.morris@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>
Sent: Monday, May 16, 2022 7:34 PM
To: Morris, Larry <Larry.Morris@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: RE: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input
Importance: High

Thank you all!

Update re: materials that are attached:

1. Updated Agenda from HHS that was provided to NGA
2. NGA briefing script for Dr. Califf, Dr. Mayne and DepCom Yiannas. This was crafted from the final media script (minor edits re: tense of actions).
3. A very quick scan of state/local policymaker clippings (big thanks to Kirsten and Jessica from IGA team!)

Other than the reactive QA doc that was being used for the media and Hill calls, I don't anticipate any additional materials.

More info as I have it. Happy to answer any questions or provide additional/different info.

Thanks!!

-- Nick

Nick Alexander, J.D.
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Office of the Commissioner
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Direct: 301-796-8893 Mobile: (b) (6) [redacted]
nicholas.alexander@fda.hhs.gov

From: Morris, Larry <Larry.Morris@fda.hhs.gov>
Sent: Monday, May 16, 2022 7:06 PM
To: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Byerts, Kirsten

<Kirsten.Byerts@fda.hhs.gov>; Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input

Confirming DC Yiannas has been registered.

From: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>
Sent: Monday, May 16, 2022 6:45 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; Morris, Larry <Larry.Morris@fda.hhs.gov>; Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Cc: Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input
Importance: High

Hi everyone. Please note that the following registration link must be completed for Dr. C, Frank and Dr. Mayne (Kirsten – you and I should register for IGA):

Meeting Registration - Zoom

They will get an INDIVIDUALIZED log-in confirmations after registration is complete and that is the one that must be used to log in.

I am waiting to hear about the possible involvement of the Secretary (doing a "topper" on the call).

Also – I have not seen any materials – including a media script or QA. Once I do, I can certainly pass along to this chain.

-- Nick

Nick Alexander, J.D.
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From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Sent: Monday, May 16, 2022 5:10 PM
To: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Cc: Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Morris, Larry

<Larry.Morris@fda.hhs.gov>; Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input

Thanks, Nick, +Jakea as she provides background material to Dr. Califf. -j

---

From: Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>
Sent: Monday, May 16, 2022 4:47 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Cc: Byerts, Kirsten <Kirsten.Byerts@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Morris, Larry <Larry.Morris@fda.hhs.gov>; Hageman, Natalie <Natalie.Hageman@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>
Subject: UPDATE: Call with Governors and/or Staff Tomorrow; Need Input
Importance: High

Hi there. Wanted to provide everyone all the info I have in one place. I will reply to this group with any additional information (including final script, received QA ahead of call, etc.). Also see end for one item than needs SLT input:

Context/Logistics:
The White House asked HHS to set up a call with Governors and/or staff to discuss the upcoming action on infant formula and to take questions. HHS has worked with the National Association of Governors (NGA) to arrange this briefing from FDA at **12:00p ET tomorrow, May 17**. Dr. Califf, Frank Yiannas, and Dr. Mayne will represent FDA. IGA will be on the call to manage follow-up. The call will be co-moderated by NGA and HHS IEA Director Marvin Figueroa. As soon as I get the Zoom/conference call info, I will pass it along.

Background/TPs:

(b) (5)

NEED INPUT RE: USDA PARTICIPATION:
NGA has asked us to have a rep from USDA on the call for WIC related questions. HHS has asked if we (specifically Dr. Califf) would object to that. Please let me know.

Happy to answer questions.

-- Nick

Nick Alexander, J.D.
Director of Intergovernmental Affairs
Office of Policy, Legislation, and International Affairs

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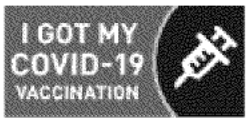

Script: FDA Infant Formula Briefing for the National Governors Association
May 17, 2022

1) FDA Encourages Importation of Safe Infant Formula and Other Flexibilities to Further Increase Availability
2) Abbott Nutrition Agrees to Take Corrective Actions at Facility to Produce Safe Infant Formula

[Lack of clarity as of this writing re: who will turn it over to Dr. Califf. Secretary may do a "topper" on the call]

Robert Califf, M.D., FDA Commissioner

Thank you, and good afternoon everyone.

Yesterday, we announced two updates regarding our efforts to respond to infant formula supply challenges that parents and caregivers in the U.S. are currently facing: First, we've set-up a mechanism that streamlines the ability for companies that do not normally sell infant formula in this country to do so and provides other flexibilities to domestic distributors who can help increase availability. Second, a consent decree of permanent injunction was entered by the U.S. District Court for the Western District between the FDA and Abbott Nutrition. Under the consent decree, Abbott has agreed to take actions that would be expected to ultimately result in an increase of infant formula products and ensure safe powdered infant formula is produced at the facility.

We know many parents and caregivers are feeling frustrated by their inability to access needed or desired infant formula and critical medical foods. Please know that we at the FDA are doing everything in our power to address these challenges as quickly as possible.

Our new guidance streamlines the ability for companies – including those that do not normally sell infant formula in this country – to make products available to the U.S. market while also ensuring nutrition and safety standards are being met. It also provides flexibilities to those who do distribute infant formula products in the U.S. and may be able to increase available product volume even further than they have already.

I strongly encourage all those who are or could manufacture infant formula products quickly and safely, including those that do not currently sell in the U.S., to help us increase the supply of products, which may serve as the only source of nutrition for many infants.

With these additional flexibilities in place, we anticipate that additional products can quickly hit U.S. stores.

We're also pleased that under yesterday's consent decree Abbott Nutrition has agreed to address certain issues that the agency identified at their infant formula production facility in Sturgis, Michigan. During our inspection, we identified multiple samples positive for *Cronobacter sakazakii*, a bacterium that can potentially cause severe foodborne illness primarily in infants, and observed significant operational deficiencies.

While the agency's inspection was ongoing earlier this year, Abbott Nutrition *voluntarily* shut down its facility to implement corrective actions to address issues raised by the FDA and also *voluntarily* recalled certain products. Under the consent decree, when they restart production at this facility, they must follow specific provisions focused on ensuring safe powdered infant formula is produced at the facility and meet FDA food safety standards.

If contamination is identified in the future, the company must notify the FDA, identify the source of the problem, and conduct a root-cause investigation before resuming production.

We are also taking a look at the supply of infant formulas developed by manufacturers across the country and around the world to determine if a reallocation of their distribution can be made to help get the right product to the right place, at the right time.

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. In fact, our data – which we'll discuss in more detail later on – tell us that in-stock rates in retail stores are already improving.

With increased production by other manufacturers, the many actions we've been taking and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, the FDA expects supply to continue to improve over the next couple of months.

I am now going to turn it over to the director of the FDA's Center for Food Safety and Applied Nutrition, Dr. Susan Mayne, to further discuss the new guidance issued yesterday.

Susan Mayne, Ph.D., Director of the FDA's Center for Food Safety and Applied Nutrition

Thank you, Dr. Califf.

As the director of the FDA's Center for Food Safety and Applied Nutrition, I know just how important it is to protect the health of infants, for whom infant formula is often the sole source of nutrition during a critical period of growth and development.

Getting our most vulnerable populations the infant formula products needed remains an utmost priority for me and my colleagues here at the FDA.

That's why I was happy to announce yesterday a new FDA guidance focused on increasing infant formula supplies in the U.S. The guidance lays out the agency's intention to exercise flexibility, on a case-by-case basis, for certain requirements that apply to infant formula.

The guidance is related to both the importation of infant formula produced in other countries and infant formula that is produced in the U.S. It explains to infant formula manufacturers what information the FDA needs to show that their product is safe and nutritionally adequate, and the extent to which they may be able to assist in mitigating the current supply challenges.

The FDA will review the infant formula's nutritional composition, ingredients, current or anticipated inventory of the formula, microbiological testing results and facility inspection history. In addition, we'll make sure any ingredient used in the infant formula is safe and suitable.

We'll also make sure that any new product introduced to the U.S. marketplace follows specific requirements for labeling of infant formulas. This includes directions for preparation and use and appropriate allergen labeling.

The agency intends to prioritize submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest.

The FDA is already in discussions with some manufacturers regarding additional imports and increased production at domestic facilities.

We know that U.S. consumers are weathering challenges related to the current supply of infant formulas and we care deeply. I want you to know that we are making progress and will continue to make progress on your behalf.

With that, I'd like to turn it over to our Deputy Commissioner for Food Policy and Response Frank Yiannas to talk more about the FDA's efforts and infant formula data trends we're seeing.

Frank Yiannas, Deputy Commissioner for Food Policy and Response

Thank you, Dr. Mayne.

Thank you for joining us today. First, I want to express my deep empathy for parents and caregivers who are experiencing anxiety related to the current infant formula situation. Dr. Califf, Dr. Mayne and I are all parents and understand how much everyone cares about the safety and nutrition of products they feed their children.

We recognize the hardships that infant formula consumers may have faced in obtaining their desired infant formula products. We're focused on getting as much product as possible on store shelves including getting the right product to the right place and won't rest until the infant formula market gets back to normal with the hundreds of products American families are used to.

We know that all infant formula manufacturers who supply to the U.S. have already stepped to the challenge and are producing at an expanded capacity. Gerber increased the amount of their infant formula available to consumers by approximately 50% in March and April and Reckitt is supplying more than 30% more product so far this year.

With this increased production, we're now seeing increased infant formula sales. I'm encouraged to share with you the data the FDA is seeing from Information Resources Inc. (or IRI) – a widely cited company – which shows that national infant formula sales by volume for the month of April were up more than 13% compared to the month prior to the recall. It also shows that national infant formula sales by unit for the month of April are up by more than 5% compared to the month prior to the recall.

Now we know some data suppliers have reported lower in-stock rates, but we've also seen the most complete data sets from IRI that are showing nearly 80% in-stock rates at the week ending May 8. To illustrate a bit further, what this means is – let's say a local supermarket normally carries 50 different infant formula products, an 80% in-stock rate would mean that 40 of those 50 product types are available. What these data tell us is that while there is more product being sold, it may be of less variety than prior to the recall.

You may be wondering why, if these data are true, are you seeing photos of empty shelves and parents and caregivers struggling to find their infant formula? We do know that there is variation in availability throughout the country, and we are working with other government partners to try to address these regional and localized shortages. We also believe that there may have been additional panic buying over the last week given the extensive coverage of this issue.

Parents and caregivers deserve access to the brands and options they're used to, so please know that we're doing everything possible to rectify this situation and replenish the typical supply of infant formula products that American consumers expect.

Looking at increased sales are a good indicator of standard formula available to the general population of infants, but the

agency understands that availability of specialty and metabolic products continues to be of concern. For those who fall into this category, we've 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 all efforts to make these products even more readily available. If you are in dire need of specialty and metabolic products from Abbott Nutrition, please call their hotline – which is listed on the FDA's website as well – for assistance.

With increased production by other manufacturers, forthcoming flexibilities for imported and domestically produced products import and along with the potential for Abbott Nutrition's Sturgis facility to resume production of these specialty formulations in the near-term, the FDA expects supply to continue to improve over the next couple of months.

As you can see, the FDA is leaving no stone unturned to further increase the availability of infant formula and we are doing everything possible as part of the all-of-government efforts to ensure there's adequate product available wherever and whenever parents and caregivers need it.

Thank you. And now I will turn back to the moderator to begin questions and answers.

LOCAL AND STATE INFORMATION ON INFANT FORMULA (AS OF COB 5/16/22)

ALASKA

- Governor Mike Dunleavy (5/13/22): "I'm concerned that our most vulnerable are now bearing the brunt of supply chain issues. As families now struggle to get the proper formula for their babies, please consult your doctor to ensure the little ones get the proper nutrients they need. Here is some information on the situation we have received from [HYPERLINK "https://www.facebook.com/alaska.dhss?__cft__%5b0%5d=AZWrPNxgqaa7FmJypMj0IZD3Kd19CjIejtLhRjsxlzeWG5GF-yl94ObV71Lh_zGC-4rcAi4I8mX3TqTEgfucS9327YY62HZkh2oU83OO3aIh3fSRJcTf5q5dFnzi18eeUDviRjO62nYhcznHezE1_eLae6UDRQZBSQAn7a1Y2cy92Q&__tn__=-%5dK-R"]: A Nationwide formula shortage affecting Alaska started in mid-February due to a voluntary recall by Abbott. Since then, the supply chain issues have impacted the matter further. Formula-fed infants are dependent on formula availability for their well-being, growth, and development. Unfortunately, there are no recommended substitutes for infant formula. The Women, Infants, and Children (WIC) program has monitored the situation since the beginning of the recall. We have a contract with Abbott providing a substantial rebate for participation that is paid back to the state to offset the overall costs of the formula. It reduces the federal spending to the program. Approximately 95% of formula-fed WIC infants have been prescribed Abbott products. During the recall, we were allowed the flexibility for participants to purchase a wide variety of formulas. However, we are unclear how long we will be given this flexibility," Dunleavy said. [[HYPERLINK "https://mustreadalaska.com/baby-formula-crisis-over-33-percent-shortage-in-alaska/"]]

ARIZONA

- Arizona Supplemental Nutrition Program for Women, Infants, and Children (5/13/22): "WIC families normally receive products made by Abbott Nutrition, maker of Similac brand infant formulas; at this time our staff and [HYPERLINK "https://clinicsearch.azbnp.gov/" \t "_blank"] are helping connect clients to alternatives until supplies return to normal. To provide families with more flexibility, we have since the beginning of the infant formula shortage made available additional can sizes of Similac and certain other brands for WIC families, and this will continue," the department said in a statement. "About half of WIC families receiving formula use Similac Advance Infant Formula, and supplies of that product are now fairly stable. About a third receive Similac Sensitive, for which store supplies have markedly increased in the past week. There also are increasing supplies of Similac Soy Isomil, used by a smaller number of WIC families." [[HYPERLINK "https://www.kvoa.com/news/adhs-reminds-families-that-wic-program-can-help-them-through-infant-formula-crisis/article_e288a252-d310-11ec-96ca-733534f4ce16.html"]]

CALIFORNIA

- California Department of Public Health (5/13/22): The California Department of Public Health/Women, Infants and Children Division (CDPH/WIC) is monitoring reports of widespread low-stock situations, outages, and rationing of powdered infant formula in California. CDPH/WIC

is also working closely with federal partners at the United States Department of Agriculture (USDA) to monitor participant access to WIC-provided formulas. [[HYPERLINK "https://www.cdph.ca.gov/Programs/CFH/DWICSN/Pages/Information-for-WIC-Families-on-Infant-Formula-Availability.aspx"]]

CONNECTICUT

- Connecticut State Department of Public Health (5/11/22): Please note that due to availability concerns we have added larger container sizes than what is typically WIC approved. If you are purchasing a larger container size, you will notice that your WIC benefits will appear to remove more formula than may be expected. This is due to the container size. You will still receive a similar quantity of formula. We understand that this is a challenging situation and is affecting many families across the country. We are working hard to find solutions that work for our Connecticut families. [[HYPERLINK "https://portal.ct.gov/dph/WIC/WIC"]]

DC

- **Mayor Muriel Bowser** (5/15/22): "We discourage hoarding, because sometimes the scarcity of products makes people buy more than they need right now," Bowser said, adding that it can exacerbate the problem." [[HYPERLINK "https://wtop.com/dc/2022/05/bowser-asks-dc-residents-not-to-hoard-baby-formula-amid-shortage/"]]

IOWA

- Iowa Department of Public Health advises against homemade baby formulas in wake of shortage (5/13/22): [[HYPERLINK "https://www.kcrg.com/2022/05/13/iowa-department-public-health-fda-advise-against-homemade-baby-formulas-wake-shortage/"]]

ILLINOIS

- **Illinois Department of Human Services** (5/12/22): "The Department is aware that Infant formula supply chain challenges that arose from the Covid-19 pandemic continue to be a challenge for some specialty and medically prescribed infant formulas." [[HYPERLINK "https://www.dhs.state.il.us/page.aspx?item=144296"]]

LOUISIANA

- **Jennifer Nicklas, the Director of LDH's Bureau of Nutrition Services** (5/10/22): "We understand the frustration families are feeling if they're not able to find a brand their baby has become accustomed to, but it is very important that we focus during this shortage on keeping babies well-fed with appropriate substitutes," Nicklas said. "Families should not substitute cow's milk, goat's milk or plant-based milk for infant formula, or water their formula down. Families with questions about other substitutes should contact their pediatrician." [[HYPERLINK "https://ldh.la.gov/news/baby-formula-shortage"]]

MARYLAND

- **MDH Secretary Dennis R. Schrader** (5/16/22): "MDH is working with federal, state, local, and community partners to ensure Maryland families with newborns and infants have the information they need regarding options during this national formula shortage and recent recalls," said MDH Secretary Dennis R. Schrader. "We will continue to monitor all aspects of the formula shortage and encourage families to access the numerous resources available to stay up to date." [[HYPERLINK "https://health.maryland.gov/newsroom/Pages/Maryland-Department-of-Health-releases-guidance-for-families-seeking-baby-formula-during-national-shortage-.aspx"]]

MICHIGAN

- **Governor Gretchen Whitmer** (5/13/22): "Today I spoke with Abbott leadership and offered support to help get production back on track," said Governor Whitmer. "I will do everything I can as governor to boost baby formula production, getting it from factories to store shelves and into people's homes. I know how anxious parents must feel right now, and it's crucial that they have confidence that a product is safe for their babies. I urge federal leaders to use every tool at their disposal to boost formula production. We're tackling the shortage head-on in Michigan and working with our federal and private sector partners to fix supply logistics and ensure every baby has what they need."
    - "Additionally at the state-level, I've taken action to lower costs and put money in people's pockets. We've sent out $400 auto refund checks per vehicle to every Michigan driver and I proposed tripling the Earned Income Tax Credit in my budget to deliver a $3,000 tax refund for over 730,000 Michiganders, directly benefiting half the kids in Michigan," Governor Whitmer added. "I will continue staying focused on lowering costs on essentials like formula, groceries, and gas for families by putting more money in their pockets and work with anyone to tackle supply chain challenges impacting Michiganders." [[HYPERLINK "https://www.michigan.gov/whitmer/news/press-releases/2022/05/13/whitmer-coordinates-statewide-response-to-baby-formula-shortage"]]

- **Michigan Attorney General Dana Nessel** (5/10/22): "While we have not seen a significant influx of complaints thus far, my team will remain vigilant in ensuring this shortage isn't compounded by illegal business practices that will only inflict additional harm on parents of infants right now," Michigan Attorney General Dana Nessel said. "If you suspect instances of price gouging, please report it to our office so we can take appropriate action." [[HYPERLINK "https://www.michigan.gov/whitmer/news/press-releases/2022/05/13/whitmer-coordinates-statewide-response-to-baby-formula-shortage"]]

- (5/10/22): In response to the Abbott recall, Michigan has temporarily expanded access to alternate formula options that qualify for WIC assistance, to ensure families can use their benefits on formulas readily available. Approximately 85% of formula-fed WIC participants are **affected. [**[HYPERLINK "https://www.michigan.gov/whitmer/news/press-releases/2022/05/13/whitmer-coordinates-statewide-response-to-baby-formula-shortage"]]

NORTH CAROLINA

- (5/13/22): Some families in North Carolina are facing challenges accessing infant formulas. These challenges are related to the February recall of certain Abbott infant formulas, the resulting increased demand for other brands of formula, and the lingering effects of supply issues during the pandemic. [[HYPERLINK "https://www.nutritionnc.com/docs/2022.05.13FormulaFactSheet.pdf%20"]]

NORTH DAKOTA

- **Marie Moe, Chief Communications Officer for the North Dakota Department of Health** (5/16/22): "It really is ok for most babies to easily switch from one formula to another brand, including store brands. Some babies do have sensitive diets so it's important to work with a pediatrician before choosing an alternative brand if that's the case. Definitely talk with healthcare providers, they may have resources, they may even have samples on hand. One thing that many people may not realize is that this recall is only affecting the powdered formula and so a lot of the times there are the ready to feed infant concentrates and those may be more available as well."
    - "It's really important for people to talk to their own pediatricians about what their babies need. There is great information out there that is available, including on the Department of Health's website, about things to do and things not to do, but one of the things is to not make homemade formula. Homemade formula does not have the necessary nutrients that an infant needs and it could possibly be risky to give it to them. So if a family is in need of formula, definitely reach out. If it's an immediate need, you can call 211 and let them know that you have an immediate need. Otherwise we would encourage them to contact a local WIC office or their pediatrician." [[HYPERLINK "https://news.prairiepublic.org/local-news/2022-05-16/nd-department-of-health-has-recommendations-for-formula-shortage"]]

NEBRASKA

- Nebraska Department of Health and Human Services (5/13/22): The Nebraska Department of Health and Human Services (DHHS) is urging all parents and caregivers to contact their pediatrician or other healthcare provider during the nationwide baby formula shortage before pursuing alternatives. [[HYPERLINK "https://dhhs.ne.gov/Pages/Safety-Notifications-and-Tips-for-Parents-and-Caregivers-During-Nationwide-Baby-Formula-Shortage.aspx"]]

NEW MEXICO

- **David R. Scrase, M.D. acting cabinet secretary for the New Mexico Department of the Health** (5/13/22): ""Some New Mexico families may be facing challenges locating infant formula, and we are working diligently to assist families in our Women, Infants, and Children program to make sure babies are getting the food they need." [[HYPERLINK "https://www.nmhealth.org/news/awareness/2022/5/?view=1859"]]
- **Early Childhood Education & Care Department Cabinet Secretary Elizabeth Groginsky** (5/13/22): "ECECD continues to fund the purchase of high quality, nutritious infant formula for

hundreds of child care homes and centers throughout the state," said ECECD Cabinet Secretary Elizabeth Groginsky. "Although child care providers have not reported difficulty maintaining adequate supplies of formula for babies in their care, we are monitoring the situation closely to ensure that infants in child care throughout the state continue to receive the formula they need at no cost to their families." [[HYPERLINK "https://www.nmhealth.org/news/awareness/2022/5/?view=1859"]]

NEW YORK

- **Governor Kathy Hochul** (5/12/22): "In close coordination with our federal partners, New York State will continue to do everything possible to support New York families in need of formula for their infants," **Governor Hochul said.** "My administration is committed to ensuring every newborn and child has access to the nutritional support they need to stay healthy. I urge every parent and guardian to take advantage of these resources and keep up to date with important information to take care of their families." [[HYPERLINK "https://www.governor.ny.gov/news/governor-hochul-announces-resources-new-york-families-amid-infant-formula-shortages"]]
- **State Health Commissioner Dr. Mary T. Bassett** (5/12/22): "Reports of infant formula supply shortages are concerning, and we urge New York families to follow the Department's recommendations as we continue to monitor the situation in New York. New York families should work with their infant's medical provider if a new formula suggestion is needed to meet their infant's needs, and all New Yorkers should visit their local New York State Women, Infants and Children Office or prescreen with Wanda, the Department's chatbot, to see if their infant is eligible for WIC benefits. The Department remains committed to ensuring families have the nutritional support and resources needed to best care for our youngest New Yorkers." [[HYPERLINK "https://www.governor.ny.gov/news/governor-hochul-announces-resources-new-york-families-amid-infant-formula-shortages"]]

OREGON

- **Oregon Gov. Kate Brown** (5/13/22): Oregon Gov. Kate Brown declared an "abnormal market disruption" Friday as prices for baby formula continue to rise amid the nationwide shortage. [[HYPERLINK "https://www.koin.com/news/oregon/brown-declares-abnormal-market-disruption-amid-baby-formula-shortage/"]]
    - "Many Oregon families across the state rely on baby formula to nourish their newborns and children, and it is critical that they can easily access this nutrition without abnormally increased prices," said Governor Brown. [[HYPERLINK "https://www.koin.com/news/oregon/brown-declares-abnormal-market-disruption-amid-baby-formula-shortage/"]]
    - The announcement comes a day after **Oregon Attorney General Ellen Rosenblum** sent a letter to Brown asking the governor to make the declaration. Along with calling on Brown, Rosenblum urged Oregonians to **report baby formula price gouging.** [[

HYPERLINK "https://www.koin.com/news/oregon/brown-declares-abnormal-market-disruption-amid-baby-formula-shortage/"]]

TENNESSEE

- (5/11/22): Tennessee ranks #1 in baby formula shortage [[HYPERLINK "https://www.wvlt.tv/2022/05/11/tennessee-ranks-1-baby-formula-shortage-fda-lists-solutions/"]]

TEXAS

- **Texas Gov. Greg Abbott** and **National Border Patrol Council President Brandon Judd** (5/12/22): "Children are our most vulnerable, precious Texans and deserve to be put first. Yet, President Biden has turned a blind eye to parents across America who are facing the nightmare of a nationwide baby formula shortage. While mothers and fathers stare at empty grocery store shelves in a panic, the Biden Administration is happy to provide baby formula to illegal immigrants coming across our southern border. This is yet another one in a long line of reckless, out-of-touch priorities from the Biden Administration when it comes to securing our border and protecting Americans. Our children deserve a president who puts their needs and survival first – not one who gives critical supplies to illegal immigrants before the very people he took an oath to serve." [[HYPERLINK "https://gov.texas.gov/news/post/governor-abbott-national-border-patrol-council-release-joint-statement-on-biden-administration-providing-baby-formula-to-illegal-immigrants-amid-national-shortage"]]

VIRGINA

- **Governor Glenn Youngkin** (5/13/22): "My administration remains engaged with industry leaders on their production capabilities, and the Virginia Department of Heath is working to ensure that there are adequate supplies of baby formula state-wide. Additionally, my administration has asked the FDA to utilize all resources to get the U.S. plant back into production as quickly as possible. Simply put, acquiring baby formula shouldn't be a challenge in the United States," said Gov. Youngkin. [[HYPERLINK "https://www.altavistajournal.com/news/article_88293e74-d339-11ec-93bb-dfc227fde576.html"]]
- **Richmond Mayor Levar Stoney** (5/16/22): Richmond's mayor is asking Virginia's governor for a State of Emergency, among other requests, to deal with rising concerns over a baby formula shortage. "Yes we've laid out a series of requests to them but it's our hope that they are willing to partner and do everything they can to make sure infants don't go hungry in the Commonwealth of Virginia." [[HYPERLINK "https://www.nbc29.com/2022/05/16/richmonds-mayor-calls-state-emergency-deal-with-baby-formula-shortage/"]]
- **Eva Colen of the City of Richmond Office of Children and Families** (5/16/22): "Do what you can to buy those options that are not WIC restrictive. So when you go to that shopping center take the extra step to look and see if there is a purple sticker on the price label that says WIC on it. Because that means somebody has no other options. You might be able to," said Eva Colen of the City of Richmond Office of Children and Families. [[HYPERLINK "https://www.nbc29.com/2022/05/16/richmonds-mayor-calls-state-emergency-deal-with-baby-formula-shortage/"]]

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Sent: 5/18/2022 8:29:52 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 8:40am: Infant Formula (IF) Daily Update

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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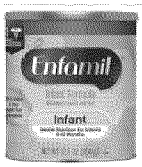
Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

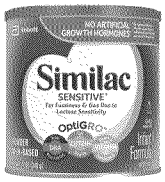
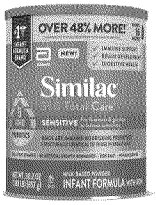
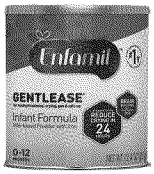
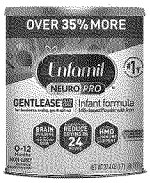
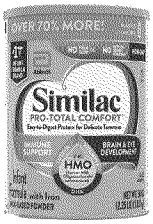
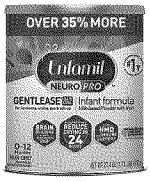
Appendix A. MARYLAND WIC FORMULA SUBSTITUTES

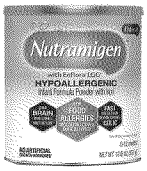
Maryland WIC staff are offering participants with affected products an alternate form (e.g., concentrate or ready to feed) of the current product they have on hand. If the caregiver prefers a product from another manufacturer, USDA has granted a waiver to allow for the provision of an alternate product

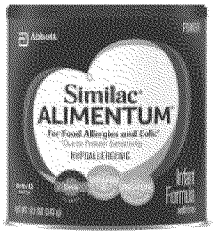
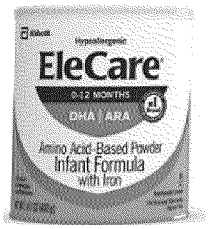
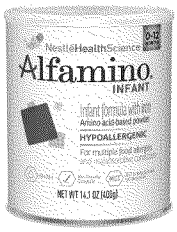
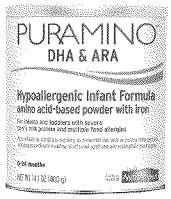
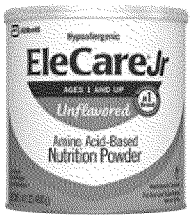
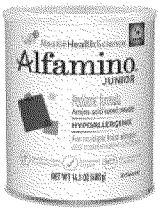
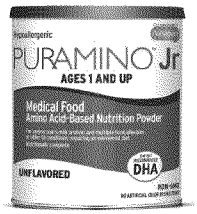
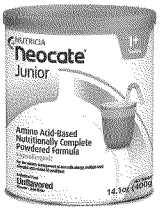
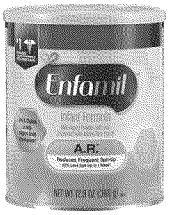
If Maryland WIC participants cannot find their usual formula, local WIC staff can change food benefits to offer options[1]:
1) Participants can purchase different container sizes of the same formula
2) Participants can switch to a different form of the formula (e.g. concentrate or ready-to-feed)
3) Participants can switch to a different manufacturer (available switches are listed below)

Formulas that family can change by calling WIC			
Your Baby's Formula	**Alternate Abbott Formulas**	**Alternate Gerber Formulas**	**Alternate Mead Johnson Formulas**
 Similac Advance	 1. Similac Pro-Advance  2. Similac 360 Total Care	 1. Gerber Good Start Gentle  2. Gerber Good Start GentlePro	 1. Enfamil Infant  2. Enfamil NeuroPro Infant

[1] This flexibility is due to a USDA waiver as a result of the nation-wide infant formula shortage.

 Similac Sensitive	 1. Similac Pro-Sensitive  2. Similac 360 Total Care Sensitive	 1. Gerber Good Start SoothePro	 1. Enfamil Gentlease  2. Enfamil NeuroPro Gentlease  3. Enfamil NeuroPro Sensitive
 Similac Total Comfort	 1. Similac Pro-Total Comfort	 1. Gerber Good Start SoothePro	 1. Enfamil Gentlease  2. Enfamil NeuroPro Gentlease

Formulas that require a healthcare provider's verbal order or medical documentation form to change			
Your Baby's Formula	**Alternate Gerber Formulas**	**Alternate Mead Johnson Formulas**	**Alternate Nutricia Formulas**
			

 Similac Alimentum	 1. Gerber Extensive HA	1. Nutramigen  2. Enfamil Pregestimil	
 Similac EleCare	 1. Alfamino Infant	 1. PurAmino	 1. Neocate Infant  2. Neocate Syneo
 Similac Elecare Jr.	 1. Alfamino Junior	 1. PurAmino Jr.	 1. Neocate Jr.
 Similac for Spit Up		 1. Enfamil AR (12.9oz or 27.4oz size only)	

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/18/2022 3:14:22 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 3:30pm: ADM Levine / Dr. Califf (specialty infant formula and healthcare professional engagement)

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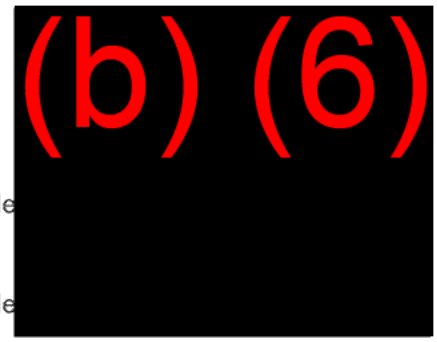


From: 2022 Infant Formula IMG [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F57E96E5B1744559B186D367018DF1D7-OC-OO-OSEM-]
Sent: 5/18/2022 6:06:16 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: You've joined the 2022 Infant Formula IMG group

Welcome Email

Microsoft 365

Work Brilliantly Together

FDA

Welcome to the 2022 Infant Formula IMG Group

OEO's Infant Formula IMG Response Page

Private group with 72 members

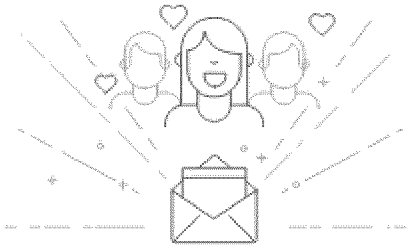
View group in Outlook

Get started

You're set to receive only replies and events in your inbox. Change this setting below, or anywhere you see the group in Outlook, to see all of this group's conversations.

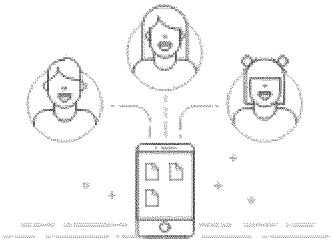
Follow in inbox

Follow in inbox



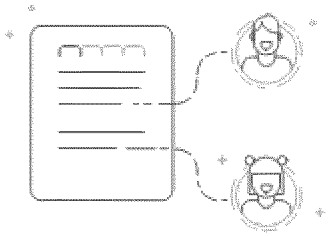
Get the conversation rolling

Start your own. Or just catch up. All in the group inbox.



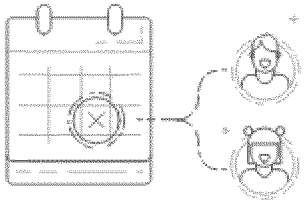
Keep things together

Now, your documents and attachments in one place.



Stay on the same page

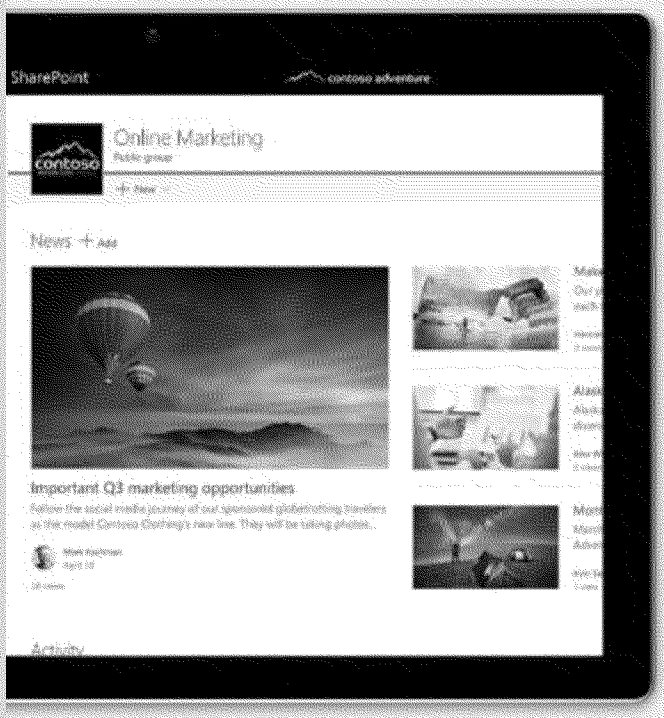
Groups that take notes together, stay together. In the group notebook.



Don't miss a thing

Track milestones (and everything in between) in the group calendar.

Collaborate with your group across Microsoft 365



Create content seamlessly

The group's SharePoint team site is the place to share news, work on and organize content, manage rich data within lists, and track all site activities across all members.

Check it out

Check it out

Organize group work with Planner

Planner makes it easy for your team to create new plans, organize and assign tasks, share files, chat about what you're working on, and get updates on progress.

Check it out

Check it out

Go further. Do more. Look here.

Follow your Twitter feeds.

Track your Salesforce updates.

All your Trello cards, lists and boards.

Team notifications from Jira.

Microsoft

Microsoft Corporation
One Microsoft Way
Redmond, WA 98052 USA

From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 5/18/2022 6:26:22 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FW: DRAFT Question - Will FDA be inspecting plants approved through the newly announced enforcement discretion process?

You'll get more polished version, but here are some thoughts

From: Yiannas, Frank
Sent: Wednesday, May 18, 2022 6:26 PM
To: Hattis, Daniel <Daniel.Hattis@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>
Cc: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: DRAFT Question - Will FDA be inspecting plants approved through the newly announced enforcement discretion process?

Dan/Susan

Here's a start

Will FDA be inspecting plants approved through the newly announced enforcement discretion process?

This is a dire situation. As you know, we've recently announced an enforcement discretion process to accelerate getting safe infant formula to store shelves.

As we've announced, FDA will be pre-approving any infant formulas that are allowed into the U.S. The review and approval process will include:

(b) (5)

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/19/2022 8:24:34 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 8:40am: Infant Formula (IF) Daily Update

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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SIP: (b) (6)

Passcode

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/20/2022 12:15:04 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 12:30pm: Abbott / FDA

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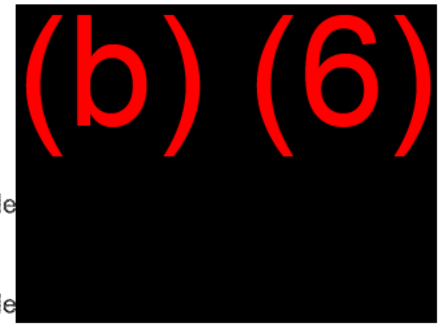

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/20/2022 9:14:24 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 9:30am: MEETING WITH SECRETARY BECERRA ON INFANT FORMULA

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+16468287666, US (New York)

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+1 646 828 7666 US (New York)
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+1 551 285 1373 US
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Find your local number: https://hhsgov.zoomgov.com(b) (6)

Join by SIP
(b) (6)

Join by H.323
(b) (6) (US West)
(US East)
Meeting ID: (b) (6)
Passcode: (b) (6)

From: Sigal, Ellen [esigal@focr.org]
Sent: 5/22/2022 3:04:13 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: [EXTERNAL] Baby Formula

Rob, would be helpful to understand the full responsibilities of Janet during this baby formula crisis.

It is well known that she has excellent organizational skills but would be nice to understand in more detail her remit in this area.

There is no doubt that her operational experience is great and feel strongly that the team will be able to address the concerns.

Ellen

Ellen V. Sigal
(202) 944-6710
Friends of Cancer Research

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/23/2022 8:14:23 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 8:30am: Infant Formula (IF) Daily Update

Standing Agenda Monday (30 min):

- Week Ahead (5 min) – OC
- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN
- Next Steps/Discussion (5 min) – OC

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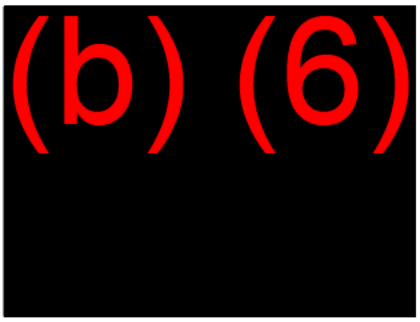

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Sent: 5/23/2022 1:06:49 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: RE: Personal Situation Update

How's this

We expect in-stock rates (shelf depletion) to be lower for next several weeks due to consumer purchase behavior and pantry loading. As production by all manufacturers continues to rev up and imports continue, there should be a gradual resumption of product on shelf and – that in turn is likely to lead to a resumption of normal purchasing behavior.

And when Abbott resumes production, we will be well on our way to total recovery.

Notable in-stock and consumer perceived improvements could begin within 1-2 months.

In the meantime, every little bit of assistance from increased domestic production, release of tested product from Abbott, and importation will release pressure, and it is very welcome.

From: Califf, Robert <(b) (6) @fda.hhs.gov>
Sent: Monday, May 23, 2022 12:58 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: Re: Personal Situation Update

Frank—getting ready to talk with HHS—all the divisions.

Is it fair to say this: We expect continuing shelf depletion through the next several weeks. As production continues to rev up and imports continue, there should be a gradual resumption of product on shelf and then a resumption of normal purchasing behavior. This will likely take 1-2 months. During that time every little bit of assistance from increased domestic production, release of tested product from Abbott and importation will release pressure, and it is very welcome.

Our primary focus is on insuring that medically special formulas are available case by case as they have been and that hypoallergenic formula is repleted as quickly as possible. In the meanwhile general formula will be welcome and necessary to build consumer confidence.

rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>
Date: Monday, May 23, 2022 at 12:53 PM
To: Robert Califf <(b) (6) @fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>
Subject: RE: Personal Situation Update

I'll be on the calls

From: Califf, Robert <(b) (6)@fda.hhs.gov>
Sent: Monday, May 23, 2022 12:39 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Re: Personal Situation Update

Frank,

Sorry to hear this. Your (b) (6)

Stay in touch.

rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>
Date: Monday, May 23, 2022 at 12:37 PM
To: Robert Califf <(b) (6)@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>
Subject: Personal Situation Update

Rob

Two quick updates:

(b) (6)

Frank

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/23/2022 2:29:25 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 2:45pm: Hearing Prep: Infant Formula Shortage (Agenda Attached)

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U.S. FOOD & DRUG ADMINISTRATION

Timeline of infant formula related activities

2020

- **11 March 2020** – World Health Organization declares COVID-19 a pandemic.
- **16 March 2020** – FDA begins to have concerns about infant formula and special medical food shortages given their production at a small number of facilities controlled by a handful of firms. FDA identifies a need for supply chain authorities and begins to draft a legislative proposal.
- **21 March 2020** – FDA submits a legislative proposal to Congress requesting supply chain authority for infant formula and special medical foods.
- **September 2020** – FDA stands up a proof-of-concept food supply chain monitoring system called 21 Forward to monitor the food supply chain for disruptions despite lack of dedicated funds or authorities. FDA initially uses the system to monitor for supply chain disruptions related to COVID-19, including infant formula-related disruptions. For example, we contacted an infant formula plant in a COVID rapid riser community in an attempt to minimize disruption.

2021

- **June 2021** – FDA requests infant formula and special medical food supply chain authorities in its FY 2022 budget request. FDA also requests funding for four additional infant formula staff.
- **20 – 24 September 2021** – FDA conducts a routine surveillance inspection at Abbott Nutrition's Sturgis, Michigan, facility. The FDA investigator searched the Agency's database for related consumer complaints days prior to inspection. FDA made five observations – including standing water and inadequate handwashing.[1]
- **20 September 2021** – FDA receives a consumer complaint report of Cronobacter illness in an infant from the Minnesota Department of Health (Case Complaint #1). The illness onset was 6 September 2021.
- **21 September 2021** – FDA informs Abbott Nutrition of the Cronobacter complaint it received (Case Complaint #1). Minnesota Department of Health sent product samples to CDC for sequencing earlier in September.
- **23 September 2021** – FDA collects product samples from the hospital where the patient was treated. The sample was sent to FDA's Southeast Food and Feed Laboratory for analysis (Case Complaint #1).
- **6 October 2021** – FDA's Southeast Food and Feed Laboratory reports no Cronobacter findings in samples (Case Complaint #1).
- **10 October 2021** – Minnesota Department of Health sends patient clinical sample to CDC (Case Complaint #1).

1 U.S. Food and Drug Administration, "Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility," September 20-24, 2021, available at https://www.fda.gov/media/156747/download?utm_medium=email&utm_source=govdelivery.

- **21 October 2021** – FDA receives a complaint from a confidential informant electronically. Complaint is reviewed by multiple FDA staff. FDA acknowledges receipt. FDA begins planning for an inspection at Abbott Nutrition's Sturgis facility.
- **26 October 2021**—FDA Detroit District Office receives a hard copy of a complaint from a confidential informant. FDA leadership do not receive direct copies of the complaint due to an isolated failure in FDA's mailroom, likely due to COVID-19 staffing issues.

FDA Staff in Receipt of Complaint; Dates of Receipt	
William Weissinger (Office of Human and Animal Food Operations-East Division 6, District Director, Office of Regulatory Affairs (ORA)	21 October 2021 – Received via email 26 October 2021 – Received via FedEx
Dr. Andrea Lotze (Medical Director, Infant Formula and Medical Foods Staff, CFSAN)	20 October 2021 – Received via email*
Cathy Hermsen (Assistant Commissioner for Criminal Investigations, ORA)	3 November 2021 – Alerted to existence by FDA staff 5 November 2021 – Received via UPS (FEDEX package with complaint)
Dr. Judith McMeekin (Associate Commissioner for Regulatory Affairs)	14 February 2022 – Received via email (forwarded from FDA staff)*
Dr. Susan Mayne (Director, CFSAN)	14 February 2022 – Received via email*
Dr. Janet Woodcock (then-Acting FDA Commissioner)	14 February 2022 – Received via email (forwarded from FDA staff)*
**Hard copies addressed to these individuals were not forwarded from the FDA mailrooms, likely due to COVID-19-related mail routing issues. In May 2022, the CFSAN mailroom located copies of the complaint sent to Susan Mayne and Andrea Lotze vie FedEx and forwarded to these individuals. The copies of the complaint sent via FedEx to Judith McMeekin and Janet Woodcock have not been located to date.*	

- **4 November 2021** – FDA Office of Human and Animal Food Operations (OHAFO) staff discuss confidential informant complaint with FDA's Office of Criminal Investigations.
- **8 November 2021** – FDA OHAFO staff discuss confidential informant complaint with the investigator and National Expert Investigator (whose expertise includes infant formula and medical food inspections) who inspected Sturgis facility in September 2021.
- **17 November 2021** – FDA receives a consumer complaint of a Salmonella illness potentially associated with an Abbott Nutrition powdered infant formula. After investigation, CDC and FDA eventually rule this case as unrelated to Abbott Nutrition.
- **1 December 2021** – FDA receives a consumer complaint of a Cronobacter death potentially associated with Abbott Nutrition powdered infant formula (Case Complaint #2). The date of illness onset was 20 November 2021. No positives for Cronobacter were among formula samples collected by FDA for follow-up testing.
- **2 December 2021** – FDA notifies Abbott Nutrition of the Salmonella and second Cronobacter consumer complaints (as previously noted, FDA and CDC later decide the Salmonella case is not related to Abbott Nutrition). FDA collected and analyzed product samples but did not find Cronobacter or Salmonella. No clinical isolate was available for the Cronobacter case.
- **7 December 2021** – FDA requests to interview the confidential informant, but due to scheduling limitations associated with the informant, the interview was not scheduled until 22 December 2021.

- **22 December 2021** – FDA interviews the confidential informant. This information informs the inspection that occurs in January 2022.
- **30 December 2021** – FDA contacts Abbott Nutrition to schedule a 3 January 2022 inspection pursuant to the Agency's policy to preannounce inspections during the COVID-19 pandemic. Abbott Nutrition requests FDA delay the inspection due to an ongoing COVID-19 outbreak among its staff. FDA agrees to a delay.

2022

- **11 January 2022** – FDA receives a third Cronobacter illness complaint. The date of illness onset was 18 December 2021. Samples collected by the Texas Department of State Health Services do not test positive for Cronobacter. This is the second case with a clinical isolate sample available for comparison to environmental samples that will be taken during FDA's inspection later this month at the Sturgis facility.
- **27 January 2022** – FDA contacts Abbott Nutrition to announce our intention to proceed with an inspection. Abbott Nutrition informs FDA of a continued COVID-19 outbreak among its employees.
- **31 January – 18 March 2022** – FDA proceeds with an inspection of Sturgis plant despite the COVID-19 outbreak given the fact pattern indicating a potential issue. FDA finds significant, fundamental sanitation, building, and equipment issues and takes multiple environmental samples.[2]
- **7 February 2022** – Seven of FDA's environmental swabs suggest the potential presence of Cronobacter, but require confirmatory testing.
- **9 February 2022** – FDA leadership informed of potential positive samples, defined as "Cannot Rule Out" (unconfirmed) taken during the inspection of Abbott Nutrition's Sturgis plant.
- **10 February 2022** –Food Program Leadership meets, and FDA's Coordinated Outbreak Response Network begins coordinating a response.
- **11 February 2022** – FDA notifies USDA's WIC program of potential action that could impact the infant formula supply.
- **13 February 2022** – FDA sequences six confirmed samples of Cronobacter collected from Abbott Nutrition's Sturgis facility environment during the recent inspection. Nineteen additional samples are being sequenced.
- **14 February 2022** – An FDA intra-agency group, including experts and leadership from OFPR and CFSAN, begins discussions of food safety, regulatory, and supply chain issues related to the response. FDA updates USDA WIC on the investigation status.
- **15 February 2022** – FDA recommends Abbott Nutrition voluntarily recall product. FDA receives additional Cronobacter sample results, meets with USDA WIC on the investigation, potential for a recall, and supply chain issues. Abbott Nutrition voluntarily ceases production. FDA seeks, and Abbott Nutrition agrees to, exclude and hold specialty metabolic products given the critical access need and Abbott Nutrition's lack of a mitigation plan to produce these formulas at one of its other facilities.

2 U.S. Food and Drug Administration, "Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility," January 31-March 18, 2022, available at https://www.fda.gov/media/157073/download?utm_medium=email&utm_source=govdelivery.

- **16 February 2022** – FDA again recommends Abbott Nutrition voluntarily recall product. FDA, as a Co-Sector Risk Management Agency of the Food and Agriculture Sector, submits a report to U.S. government (USG) partners on the potential recall and supply chain impacts given the significant market share held by Abbott Nutrition, as well as the Sturgis facility being a critical producer of specialty metabolic and amino acid formulas. FDA begins discussion with Abbott Nutrition on additional testing for these held products and a strategy to release products to those in dire need. FDA meets with the American Academy of Pediatrics to make them aware of a significant upcoming action involving infant formula that will have ramifications for supply chains. We share that our communications would advise parents to consult with the child's health care provider for advice, with additional communications forthcoming from FDA.

- **17 February 2022** – Following a third recommendation by FDA that Abbott Nutrition voluntarily recall product, FDA issues a consumer advisory warning consumers to avoid certain Abbott Nutrition products as Abbott Nutrition voluntary recalls product. FDA begins regular reports and coordination with USG partners on supply chain. CDC notifies FDA of a fourth case that may be related. Daily situation reports begin for FDA staff and leadership working on the response. FDA requests from IRi infant formula in-stock rates at the national level, which was not previously tracked by FDA. FDA requests that FMI, the Food Industry Association (FMI) ask retailers to limit sales to no more than five cans per shopper; FMI recommends the limit to retailers later that day.

- **18 February 2022** – FDA receives a fourth Cronobacter case report of a death potentially associated with Abbott Nutrition product. FDA contacts other infant formula manufacturers to discuss actions to address potential supply chain disruptions. The date of illness onset for this case was 4 January 2022. No clinical isolate is available, and product samples do not test positive for Cronobacter. FDA requests an independent expert conduct a batch review of held specialty metabolic product.

- **22 February 2022** – First infant formula data sets obtained by FDA from IRi.

- **24 February 2022** – Russia invades Ukraine. This leads to additional uncertainty in the infant formula supply chain as Ukraine is a major exporter of sunflower oil, an ingredient used in many infant formulas. Manufacturers begin to re-assess their supplies and make plans in consultation with FDA about possible substitutions.

- **28 February 2022** –Abbott Nutrition voluntarily expands its recall at FDA's recommendation to cover additional products associated with the fourth case complaint.

- **Late February – early March 2022** – FDA meets with retailers and other infant formula manufacturers throughout this period on actions to address infant formula supply chain and to seek supply chain information. FDA continues regular coordination with manufacturers. FDA follows up on several additional Cronobacter complaints but eventually determines them unrelated to Abbott Nutrition.

- **15 – 16 March 2022** – FDA inspection team returns to Sturgis facility to obtain additional records related to complaints received. FDA receives FY 2022 additional funding to hire four additional infant formula staff.

- **18 March 2022** – January 2022 inspection and related sampling activities conclude. Inspection is closed, and FDA issues its inspection observations (FDA Form 483).[3] Observations from inspection and FDA's lack of confidence in Abbott Nutrition's food safety culture inform FDA's decision to negotiate a consent decree with the goal of addressing these observations and safely resuming production at Sturgis as soon as possible.

- **28 March 2022** – FDA's FY 2023 budget request includes infant formula and medical foods supply chain legislative proposal.

3 U.S. Food and Drug Administration, "Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility," January 31-March 18, 2022, available at https://www.fda.gov/media/157073/download?utm_medium=email&utm_source=govdelivery.

- **31 March 2022** – Abbott Nutrition provides FDA the independent batch review of specialty metabolic product requested 18 February.
- **1 April 2022** – FDA stands up Agency-wide Incident Management Group to manage the response, including supply chain.
- **20 April 2022** – FDA communicates to Abbott Nutrition our decision not to object to release of specialty metabolic product broadly after enhanced finished product testing, and not to object to release on case-by-case basis for urgent need. This was communicated to Abbott Nutrition again on 20 April and 28 April.
- **29 April 2022** – FDA issues an updated advisory to ensure consumers are aware of Abbott Nutrition's process to release metabolic formulas on a case-by-case basis, in consultation with a healthcare provider, to those families who have no alternative supply.
- **16 May 2022** – FDA and Abbott Nutrition sign a proposed consent decree.
- **16 May 2022** – U.S. District Court for the Western District of Michigan enters the consent decree. FDA issues enforcement discretion guidance to provide flexibilities to boost the supply of infant formula.
- **20 May 2022** – FDA issues its first enforcement discretion letter for a specialty infant formula product. FDA is evaluating additional requests for enforcement discretion. FDA is working with USG partners to arrange air transport for amino acid and hypoallergenic hydrolyzed formulas to arrive in the United States on 23 May 2022.

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CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: 8:40am: Infant Formula (IF) Daily Update

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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Subject: 3:00pm: In-Person: FDA/Abbott

Where: WO2 / 2046

Abbott Participants:
Robert Ford (CEO Abbott)
Monica Wilkins (Divisional Vice President of Quality & Regulatory, Abbott)
Elizabeth Cushman (Division Vice President & Associate General Counsel, Legal Regulatory & Compliance, Abbott)
John Murphy (Vice President, Supply Chain, Nutrition, Abbott)

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Subject: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)
Location: Please see Zoom below

Start: 5/15/2022 3:30:00 PM
End: 5/15/2022 3:45:00 PM
Show Time As: Busy

Required Attendees: Robert M. Califf, MD; Robert.Ford@abbott.com; Hubert.allen@abbott.com; Thomas.evers@abbott.com; Tierney, Julia; Raza, Mark; Gorji, Perham

[redacted]

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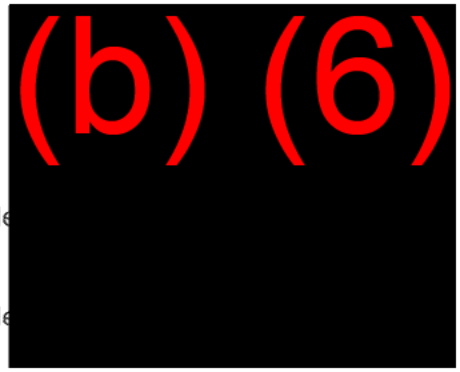

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/16/2022 5:33:51 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
CC: Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]

Subject: [TENTATIVE] Media Call: Actions to Increase Infant Formula Supply
Location: 1-800-857-9826; Speaker Code: (b) (6)

Start: 5/16/2022 6:55:00 PM
End: 5/16/2022 7:45:00 PM
Show Time As: Tentative

Required Attendees: Robert M. Califf, MD; Felberbaum, Michael; Susan Mayne; Yiannas, Frank; Rabin, Tara G.; Julia Tierney; Jefferson, Erica
Optional Attendees: Guevara, Bessy

Subject: TENTATIVE Media Call: Actions to Increase Infant Formula Supply

WHAT:
A media briefing to discuss the FDA's plans to exercise flexibilities regarding the importation of certain infant formula products from abroad in an effort to increase powdered infant formula supply in the U.S.

HOW:
- Speaker dial in: 800-857-9826
- Speaker passcode: (b) (6)

This call is voice-only; there is no video component. Please remember to use a fully-charged mobile phone with a strong signal or use a land line.

WHEN:
Monday May 16 at 7:30 p.m. ET
Speakers must dial-in 5 minutes before the scheduled call at 7:25 p.m. call for a sound check.

WHO:
- Robert Califf, M.D., FDA Commissioner

- Susan T. Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition
- Frank Yiannas, Deputy Commissioner for Food Policy and Response

POCs: Michael Felberbaum (Cell: (b) (6) Tara Rabin (Cell: (b) (6)

Please do not forward this invite

Invitees
Michael Felberbaum
Susan Mayne
Robert Califf
Frank Yiannas
Tara Rabin
Julia Tierney
Erica Jefferson

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/16/2022 6:43:47 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
CC: Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]

Subject: Media Call: Actions to Increase Infant Formula Supply ***updated media script attached (6:42PM)***
Attachments: PR_Infant Formula Import Flexibilities Updated_05.16.22_Final_METADATA.docx; PR_FDA Provides New Updates on Activities to Mitigate Infant Formula Supply Challenges_FINAL_520pm.docx; Importation Media Call TPs and QA 6pm.docx; Media Call Script_Infant Formula_FINAL 05.16.22_630pm.docx
Location: 1-800-857-9826; Speaker Code: (b) (6)

Start: 5/16/2022 6:55:00 PM
End: 5/16/2022 7:45:00 PM
Show Time As: Busy

Required Attendees: Robert M. Califf, MD; Felberbaum, Michael; Susan Mayne; Yiannas, Frank; Rabin, Tara G.; Julia Tierney; Jefferson, Erica
Optional Attendees: Guevara, Bessy

Updated media script, attached, noting that language reflects that the consent decree was just entered.

WHAT:
A media briefing to discuss the FDA's plans to exercise flexibilities regarding the importation of certain infant formula products from abroad in an effort to increase powdered infant formula supply in the U.S.

HOW:
- Speaker dial in: 800-857-9826
- Speaker passcode: (b) (6)

This call is voice-only; there is no video component. Please remember to use a fully-charged mobile phone with a strong signal or use a land line.

WHEN:
Monday May 16 at 7:00 p.m. ET
Speakers must dial-in 5 minutes before the scheduled call at 6:55 p.m. call for a sound check.

WHO:

- Robert Califf, M.D., FDA Commissioner
- Susan T. Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition
- Frank Yiannas, Deputy Commissioner for Food Policy and Response

POCs: Michael Felberbaum (Cell: (b) (6) ; Tara Rabin (Cell: (b) (6)

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Invitees
Michael Felberbaum
Susan Mayne
Robert Califf
Frank Yiannas
Tara Rabin
Julia Tierney
Erica Jefferson

METADATA
Title: FDA Encourages Importation of Safe Infant Formula and Other Flexibilities to Further Increase Availability
Short Title: FDA Allows Importation to Increase Availability of Infant Formula
Subtitle: n/a
Detailed Description: FDA announced guidance outlining increased flexibilities on importation of certain infant formula products to further increase the availability across the country while protecting the health of infants.
Short Description (formerly called Display Summary): FDA announced guidance on increased flexibilities on importation of certain infant formula products to further increase the availability in U.S.
Release Date: May 16, 2022
Media Contact Name: FDA Office of Media Affairs
Media Contact Phone: 301-796-4540
Media Contact E-mail: fdaoma@fda.hhs.gov
Contributing Office (center(s) associated with this announcement): CFSAN
Is this announcement related to health fraud? N
If Statement, author(s) name(s): n/a

FOR IMMEDIATE RELEASE
May 16, 2022

FDA Encourages Importation of Safe Infant Formula and Other Flexibilities to Further Increase Availability

Today, the U.S. Food and Drug Administration is announcing a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities.

"The FDA is leaving no stone unturned to further increase the availability of infant formula. We are doing 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," said FDA Commissioner Robert M. Califf, M.D. "Today's action paves the way for companies who don't normally distribute their infant formula products in the U.S. to do so efficiently and safely. We are hopeful this call to the global market will be answered and that international businesses will rise to the occasion to assist in bolstering the supply of products that serve as the sole source of nutrition for many infants. With these flexibilities in place, we anticipate that those products that can quickly meet safety and nutrition standards could hit U.S. stores in a matter of weeks."

The U.S. normally produces 98% of the infant formula it consumes, with the primary source of imports coming from trading partners in Mexico, Ireland and the Netherlands. However, given the production and distribution issues that have led to reduced supplies of infant formula in some parts of the country, the FDA has outlined a process by which the agency would not object to the importation of certain infant formula products intended for a foreign market or distribution in the U.S. of products manufactured here for export to foreign countries. It also may provide flexibilities to those who manufacturer infant formula products domestically for export and may be able to increase further domestically produced product for the U.S. market.

Companies seeking to take advantage of these flexibilities should submit information for the FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. For example, labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The agency intends to prioritize submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. The FDA is already in discussions with some manufacturers and suppliers regarding additional supply.

As part of a number of [HYPERLINK "https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products"] to increase supply, the agency had already implemented a streamlined process to facilitate the importation of infant formula at U.S. ports of entry so that formula coming from abroad can be dispersed quickly throughout the country. This work has already resulted in more infant formula coming into the U.S. Imports of infant formula year-to-date are up more than 300% from last year. The FDA has and will continue to actively work with the U.S. Department of Agriculture, U.K., and European authorities to expedite entry for products made abroad.

All of this around-the-clock work has already begun to improve supply and availability with most manufacturers, now producing at normal or expanded capacity. 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 Information Resources Inc. (IRI) indicate that in-stock rates in retail stores are improving and the 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. The agency's best current assessment is that with all of the current actions, including today's announcement, 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. In the meantime, the agency is encouraged to see that as of early May the amount of infant formula sold in the U.S. continues to rise.

It is important to understand that only facilities experienced in and already making essentially complete nutrition products are in the position to produce infant formula products that would not pose significant health risks to consumers. The agency continues to [HYPERLINK "https://www.fda.gov/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-make-or-feed-homemade-infant-formula-infants" \h]. Caregivers are encouraged to work with their child's health care provider for recommendations on changing feeding practices, if needed. The U.S. Department of Health and Human Services has also released a fact sheet with [HYPERLINK "https://www.hhs.gov/formula/index.html"].

The FDA will continue to dedicate all available resources to help ensure that infant formula products remain available for use in the U.S. and will keep the public informed of progress updates.

Additional Information:

- [HYPERLINK "https://www.fda.gov/food/cfsan-constituent-updates/fda-provide-flexibility-manufacturers-increase-infant-formula-supplies."]

- [HYPERLINK "https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products" \t "_blank"]
- [HYPERLINK "https://www.hhs.gov/formula/index.html"]
- [HYPERLINK "https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022" \t "_blank"]
- [HYPERLINK "https://www.fda.gov/consumers/powdered-infant-formula-recall-what-know" \t "_blank"]
- [HYPERLINK "https://www.cdc.gov/cronobacter/infection-and-infants.html" \t "_blank"]

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Media Contact: [HYPERLINK "mailto:fdaoma@fda.hhs.gov"], 301-796-4540
Consumer Inquiries: 888-723-3366

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

METADATA
Title: FDA Provides New Updates on Activities to Mitigate Infant Formula Supply Challenges, Abbott Nutrition Agrees to Take Corrective Actions at Facility to Produce Safe Infant Formula
Short Title: FDA Announces Abbott Will Take Action to Make Safe Infant Formula
Subtitle: n/a
Detailed Description: Under the proposed consent decree, Abbott has agreed to take corrective actions following an FDA inspection of its Sturgis, Michigan, facility.
Short Description (formerly called Display Summary): Under the proposed consent decree, Abbott has agreed to take corrective actions following an FDA inspection of its Sturgis, Michigan, facility.
Release Date: May 16, 2022
Media Contact Name: FDA Office of Media Affairs
Media Contact Phone: 301-796-4540
Media Contact E-mail: fdaoma@fda.hhs.gov
Contributing Office (center(s) associated with this announcement): CFSAN
Is this announcement related to health fraud? N
If Statement, author(s) name(s): n/a

FOR IMMEDIATE RELEASE
May 16, 2022

FDA Provides New Updates on Activities to Mitigate Infant Formula Supply Challenges, Abbott Nutrition Agrees to Take Corrective Actions at Facility to Produce Safe Infant Formula

The U.S. Food and Drug Administration is announcing important updates on its ongoing work to increase the supply and availability of infant formula in the U.S. On Feb. 17, the agency [HYPERLINK "https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022"] consumers not to use certain powdered infant formula products from Abbott Nutrition's Sturgis, Michigan infant formula production facility, and Abbott voluntarily ceased production at this facility as well as initiated a [HYPERLINK "https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant"] of certain products.

Today, a proposed consent decree of permanent injunction between the FDA and Abbott Nutrition, as well as three Abbott principals, was filed in the U.S. District Court for the Western District of Michigan. Under the proposed consent decree, which is subject to court approval and entry, Abbott has agreed to take corrective actions following an FDA inspection of its Sturgis, Michigan facility. The proposed consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while ensuring that the company undertakes certain actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the proposed consent decree and meet FDA food safety standards. If contamination is identified, the company must notify the FDA, identify the source of the problem and conduct a root-cause investigation before resuming production.

"Today's action means that Abbott Nutrition has agreed to address certain issues that the agency identified at their infant formula production facility in Michigan. The public should rest assured that the agency will do everything possible to continue ensuring that infant and other specialty formulas produced by the company meet the FDA's safety and

quality standards, which American consumers have come to expect and deserve," said FDA Commissioner Robert M. Califf, M.D. "We recognize the hardships that parents and caregivers have faced in obtaining infant formula and the FDA is focused on boosting the availability of the country's supply of these products, including new steps regarding importation. We are also taking a look at the supply of infant formulas developed by manufacturers across the country and around the world to determine if a reallocation of their distribution can be made to help get the right product to the right place, at the right time."

In the complaint, filed by the U.S. Department of Justice on behalf of the FDA, the government alleges that powdered infant formula products manufactured at Abbott Nutrition's Sturgis facility were adulterated because they were made under insanitary conditions and in violation of current good manufacturing practice requirements. On Jan. 31, the FDA commenced a for-cause inspection and identified *Cronobacter sakazakii*, a bacterium that can potentially cause severe foodborne illness primarily in infants, in the facility and observed significant [HYPERLINK "https://www.fda.gov/media/157073/download" \h]. While the agency's inspection was ongoing, Abbott Nutrition voluntarily recalled certain powdered infant formula products and voluntarily shut down its facility to implement corrective actions that address issues raised by the FDA.

Under the proposed consent decree, Abbott Nutrition will be required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. It also includes requirements for testing products, as well as ceasing production, and promptly notifying the FDA should contamination be detected. The proposed consent decree also requires the implementation of a sanitation plan, environmental monitoring plan and employee training programs.

In the meantime, the FDA is also continuing to implement several [HYPERLINK "https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products"] to improve the supply of infant and specialty formula products in the U.S. The agency has been in ongoing discussions with all infant formula manufacturers who are reporting that they are all producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of their infant formula available to consumers by approximately 50% in March and April and Reckitt is supplying more than 30% more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), 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.

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. This means that if a local supermarket normally carries 50 different infant formula products, an 80% in-stock rate would translate to 40 of those 50 product types being available.

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. With increased production by other manufacturers, forthcoming import actions and the potential for Abbott Nutrition's Sturgis facility

to resume production in the near-term, the FDA expects supply to continue to improve over the next couple of months. The FDA recognizes that there is variation in availability throughout the country and is working with federal partners to better understand where shortages of certain formulas exist at a more local level, as well as explore further ways to alleviate more immediate and geographical supply challenges through better distribution of products.

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 [HYPERLINK "https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022" \h] 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 as the agency works with the company to implement provisions of the proposed consent decree. In addition, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with the FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

The agency is also looking at ways to mitigate future, potential supply issues including building on work to date with its 21 Forward supply chain continuity system. It has made requests for new authorities from Congress to allow the FDA to regularly collect important supply data from the broader infant formula industry and is continuing to implement several [HYPERLINK "https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products"] to improve supply.

The FDA is committed to transparently communicating updates on this dynamic situation. The agency will continue to dedicate all available resources to help ensure that infant formula products remain safe and available for use in the U.S. and will keep the public informed of progress updates.

Additional Information:

- [HYPERLINK "https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products" \t "_blank"]
- [HYPERLINK "https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022" \t "_blank"]
- [HYPERLINK "https://www.fda.gov/media/157073/download" \t "_blank"]
- [HYPERLINK "https://www.fda.gov/consumers/powdered-infant-formula-recall-what-know" \t "_blank"]
- [HYPERLINK "https://www.cdc.gov/cronobacter/infection-and-infants.html" \t "_blank"]

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Media Contact: [HYPERLINK "mailto:fdaoma@fda.hhs.gov"], 301-796-4540
Consumer Inquiries: 888-723-3366

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the

safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/19/2022 6:53:28 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; 'Robert.Ford@abbott.com' [Robert.Ford@abbott.com]; 'Hubert.allen@abbott.com' [Hubert.allen@abbott.com]; 'Thomas.evers@abbott.com' [Thomas.evers@abbott.com]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; 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]; Dr. Califf [rmc001@fda.hhs.gov]

Subject: Abbott / FDA
Location: Please see Zoom below

Start: 5/20/2022 12:30:00 PM
End: 5/20/2022 1:00:00 PM
Show Time As: Busy

Required Attendees: Robert.Ford@abbott.com; Hubert.allen@abbott.com; Thomas.evers@abbott.com; Frank Yiannas; Beckerman, Peter; Julia Tierney; Tristan Colonius; Robert M. Califf, MD

Hi there,

FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

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Passcode:

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID:

Passcode

SIP:

Passcode

Sent: 5/13/2022 8:58:43 AM
To: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]; Robert.Ford@abbott.com; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Gorji, Perham [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27a75f0a884c4d62ad7f64a4a3fc0492-Perham.Gorj]

Subject: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Start: 5/13/2022 10:30:00 AM
End: 5/13/2022 11:00:00 AM
Show Time As: Busy

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/26/2022 9:36:32 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
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: 8:40am: Infant Formula (IF) Update

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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Meeting URL: https://fda.zoomgov.com(b) (6)
Meeting ID:
Passcode: (b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 669 216 1590 or +1 646 828 7666or +1 551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode:

International numbers

Join from an H.323/SIP room system

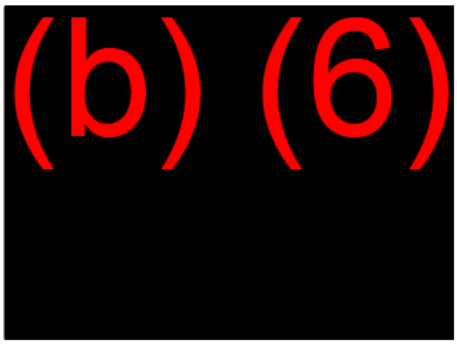
H.323:

Meeting ID:

Passcode:

SIP:

Passcode:



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Sent: 5/13/2022 9:16:34 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Robert M. Califf, MD; Robert.Ford@abbott.com; Tierney, Julia; Raza, Mark; Gorji, Perham; Hubert.allen@abbott.com; Thomas.evers@abbott.com

Subject: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)
Location: Please see Zoom below

Start: 5/13/2022 10:20:00 AM
End: 5/13/2022 10:35:00 AM
Show Time As: Tentative

Required Attendees: Robert M. Califf, MD; Robert.Ford@abbott.com; Tierney, Julia; Raza, Mark; Gorji, Perham; Hubert.allen@abbott.com; Thomas.evers@abbott.com

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Sent: 5/27/2022 12:11:24 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Tobias, Lindsay; Simms, Joshua; McMeekin, Judith

Subject: Infant Formula (IF) Morning Update
Location: Zoom, details below

Start: 5/28/2022 8:30:00 AM
End: 5/28/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:30 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Tobias, Lindsay; Simms, Joshua; McMeekin, Judith

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From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/4/2022 11:36:06 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: [HOLD] Infant Formula Update (60 mins / 30 mins as alternate)

Start: 3/9/2022 2:30:00 PM
End: 3/9/2022 3:30:00 PM
Show Time As: Busy

Required Attendees: Tierney, Julia; Janet Woodcock

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/14/2022 6:48:08 PM
To: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Judith McMeekin [Judith.McMeekin@fda.hhs.gov]

Subject: Commissioner Touch Base: Infant Formula Work
Location: Zoom, details below

Start: 3/16/2022 8:00:00 AM
End: 3/16/2022 8:30:00 AM
Show Time As: Busy

Required Attendees: Tierney, Julia; Yiannas, Frank; Susan Mayne; Judith McMeekin

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Sent: 3/14/2022 6:48:08 PM
To: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; 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]
CC: 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]

Subject: Commissioner Touch Base: Communications Strategy for Abbott
Location: Zoom, details below

Start: 3/17/2022 11:30:00 AM
End: 3/17/2022 12:00:00 PM
Show Time As: Busy

Required Attendees:	Tierney, Julia; Fristedt, Andi; Frank Yiannas; Mayne, Susan; Judith McMeekin; Jefferson, Erica; Raza, Mark; Tobias, Lindsay; Colonius, Tristan; Beckerman, Peter; Singleton, Shannon; Rabin, Tara G.; Rogers, Michael; Mettler, Erik; Harris, Stic; Kavanaugh, Claudine; Douglas Stearn; Caitlin Boon; Trzeciak, Kimberlee
Optional Attendees:	Janet Woodcock; Dickinson, Elizabeth (FDA); Felberbaum, Michael

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Subject: Infant Formula Update
Location: Zoom, details below

Start: 3/9/2022 2:45:00 PM
End: 3/9/2022 3:30:00 PM
Show Time As: Busy

Required Attendees:	Tierney, Julia; Woodcock, Janet; McMeekin, Judith; Yiannas, Frank; Mayne, Susan; Raza, Mark; Jefferson, Erica; Fristedt, Andi; Rogers, Michael; Mettler, Erik; Hermsen, Catherine; Stearn, Douglas; Harris, Stic; Boon, Caitlin; Dickinson, Elizabeth (FDA); Beckerman, Peter; Rabin, Tara G.; Colonius, Tristan
Optional Attendees:	Trzeciak, Kimberlee; Hodnette, Jonathan; Lockeed, Matthew

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Sent: 5/17/2022 10:54:50 AM
To: Alford, Katie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b99b7ca15a414f7dab3698d170c6d89e-Katie.Alfor]; Allen, Henry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbf3ff6aeb23450f8580ac4ed283c433-Henry.Allen]; Ames, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff3cfdb71c3245cda932df56ad287c64-Jeremy.Ames]; An, Haejung [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e7d1c9fc7094afe883bdd86e5d0a542-Haejung.An]; Anderson, Megan K [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd91fb54ebeb4c9a87ecfef39edbf23a-Megan.Ander]; Andujar, Lourdes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36d3c9491bd540438cc03235d95bfbc7-LANDUJAR]; Armstrong, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cdee40a4e514c71bdd3b024bd020956-Joshua.Arms]; Arsenault, Sam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f4304f5e82a4bb88d9210e1aa7ecc5b-Samuel.Arse]; Askar, Ahmed [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=892fc72b9ea845538b4046facf9b73fb-Ahmed.Askar]; Bajrami, Dilijeta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80f79d383ca7481bbcd94c5926075f25-Dilijeta.Ba]; Barnes, Tamayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f409533a7e444baf8ce5f3980fb9be27-Tamayo.Barn]; Baroletti, William B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b98c04e7b99e406d8f0a823dd8748193-WBAROLET]; Barringer, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4ccbbe016d413b9cc4bacd2cb9c64c-ABarring]; Bass, Glenn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe3653c665674696828418c8f22ae43f-GBass]; Bazaco, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a2f8d4fc61a47188b9c3555d9abbde2-Michael.Baz]; Beal, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a9adde26f7344bbbade9071b6accc8b3-Jennifer.Be]; Belk, Justin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaccaf26ccc54be7aa3f54a22e2113fe-Justin.Belk]; Bellmore, Christi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9e50a62e05a4912a274a14e4055cf1b-Christi.Bel]; Benasutti, Bradley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b20df73599a94b288c41e71b2b5ae193-Bradley.Ben]; Bertling, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=369358d712414ef7a59589e9459b9108-Lindsay.Ber]; Bivens, Tomika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ab52a734cf1496580a7aaffff2c9574-TBIVENS]; Bouvier, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31f6818fad554f69ba882242b3636a1f-Robert.Bouv]; Brathwaite, Crystal L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c8ce9a1651a42ac9e9a41ef83423338-CBrathwaite]; Burgess, Shelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5beb691d4bac4848945f6039974b29fa-Shelly.Burg]; Burgos, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02c1db53b3714a87b8cebcfde5ff73a5-BurgosJ]; Burton, Rory [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7556081ed4047feac61b3386839ed5d-Rory.Burton]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Campbell, Wendy

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CC: Zuckerman, Claudia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e65216132614566babcdc9cc0319277-Claudia.Zuc]; Weinfield, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acf3dd242e6043e1b5782486772d1051-Douglas.Wei]; DiPaola, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e6114e2a610423996e62a920add4e82-LDIPAOLA]

Subject: REMINDER PLEASE RESPOND: Abbott Nutrition/Infant Formula Litigation Hold

Importance: High

Attorney-Client Privileged Communication; Attorney Work Product; Deliberative Process Privileged

Abbott Nutrition/Infant Formula Litigation Hold

Please read this entire message carefully and respond using the voting button above. **You will need to respond using your laptop/desktop computer to access the voting button**, which does not appear on mobile devices.

You are receiving this e-mail because you may have documents and/or data related to Abbott Nutrition and the infant formulas and other food manufactured at the company's facilities in Sturgis, Michigan, that you must preserve for litigation purposes. These documents and/or data include, but are not limited to, records relating to establishment inspections, consumer complaints, outbreak investigations, product recalls, market disruptions and shortages, evaluations of third-party reviews and inspectional responses, and laboratory analyses of environmental samples collected at the Sturgis location and product samples of infant formula and other food manufactured at that location.*

You must preserve (i.e., do not delete) all your potentially relevant documents and/or data (described below), in whatever form they have been generated, and wherever and however they are currently maintained. During the course of this matter, parties may attempt to use the litigation process to obtain FDA documents, communications, records, and other information related to the matter.

The law requires FDA to preserve the documents and/or data described below in this litigation hold. Failure to preserve and retain documents and/or data may result in sanctions. Consequently, if you are unsure whether certain information should be preserved, err on the side of caution and preserve the information. If you have any questions about what information should be preserved, please contact me, Lauren (DiPaola) Kisner, at Lauren.Dipaola@fda.hhs.gov. If you have any questions about how to preserve information, please contact Doug Weinfield, OCC's Associate Chief Counsel for Discovery, at Douglas.Weinfield@fda.hhs.gov.

Unless you have already been instructed otherwise, you do not need to collect, copy, or produce documents and/or data at this time; rather, you are required not to destroy or delete existing or future documents and/or data related to the Abbott Nutrition matter described above, until further notice from OCC. As an FDA employee or contractor, you are required to preserve all information related to this matter. These documents and/or data must be preserved regardless of whether you believe the documents and/or data may ultimately be withheld as privileged or confidential. Any document retention schedule that calls for the destruction or deletion of these documents and/or data is suspended for the duration of this litigation hold.

You must preserve and retain (i.e., do not delete) the following kinds of documents and/or data until you receive notice from OCC that you may return to your normal document retention schedule.

A. All relevant Electronically Stored Information (ESI) contained within computer systems and on removable or portable electronic storage media.

Sources of ESI include, but are not limited to, FDA-issued devices, such as a laptop or desktop computer, BlackBerry, iPhone, tablet, or other mobile device, IronKey, CDs and DVDs, flash drives, thumb drives, or memory cards; and individual network drives, shared network drives, databases, and SharePoint sites.

Types of ESI include, but are not limited to, computer files of all kinds, such as emails and other electronic communications, FDA email accounts for which you are responsible (such as those where you are the manager, business owner, group contact, or custodian of record), word-processing documents, spreadsheets, databases, calendars, digital photographs, telephone logs, information on other kinds of media, and voicemail and instant messages (including on mobile devices).

B. All relevant non-electronic documents and other tangible things, including, but not limited to, environmental and product samples, laboratory samples, equipment, hard-copy documents, personal or desk files, journals, drawings, graphs, charts, photographs, sound recordings, calendars, notes, correspondence, drafts (partial or complete), policies, manuals, and other things relevant to the Abbott Nutrition matter described above.

Please notify me or Doug Weinfield if you plan to leave FDA or transfer to a different office within FDA so that your relevant documents may be retained as required.

If you know of additional agency personnel, including contractors, who have not received this notice and who may have potentially relevant documents or data, please contact me directly with their names and contact information. Please do not forward this litigation hold notice to any individual or group without first contacting me.

Please respond from your laptop/desktop computer using the voting button to confirm that you have received this notice, understand your obligations, and agree to comply with the instructions.

---

* The relevant FDA sample numbers for environmental and product samples include the following:

975273, 1033010, 1033011, 1033012, 1033030, 1033049, 1033050, 1033050, 1033051, 1033051, 1033052, 1033053,
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1033064, 1097176, 1097177, 1097178, 1097179, 1097180, 1097181, 1097182, 1097183, 1116368, 1117355, 1117356, 1117357, 1117906, 1117907, 1123113, 1128011, 1128012, 1129702, 1129704, 1134358, 1134359, 1135127, 1135128, 1136244, 1136245, 1136246, 1136247, 1136248, 1136249, 1149849, 1150803, 1150803, 1154525, 1160969, 1160970, 1160971, 1167122, 1167125, 1168526, 1168526, 1168527, 1171371, 1171371, 1171528, 1177247, 1177248, 1181598, 1181599, 1182172, 1182318, 1182695, 1182696, 1182697, 1182698, 1182699, 1186618, 1186619, 1186620, and 1186908.

Lauren (DiPaola) Kisner
Litigation Project Manager
FDA, Office of Chief Counsel
Office: 301-796-3910
Cell: (b) (6)
Lauren.DiPaola@fda.hhs.gov

From: Zoom [no-reply@zoomgov.com]
Sent: 3/7/2022 5:54:19 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Infant Formula Update

Meeting Time: Mar 9, 2022 02:45 PM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) or +16692161590,(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US : +1 669 254 5252 or +1 669 216 1590 or +1 646 828 7666 or +1 551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode: (b) (6)

International numbers

Join from an H.323/SIP room system

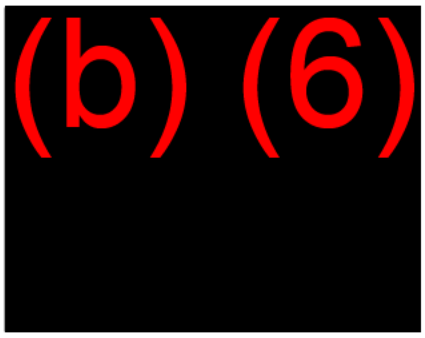
H.323:

Meeting ID:

Passcode:

SIP:

Passcode:



Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 3/15/2022 4:02:24 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: Frank Olivarria invites you to join a Zoom meeting as alternative host

[redacted]

Hi Rob Califf,

Frank Olivarria (Frank.Olivarria@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Commissioner Touch Base: Infant Formula Work

Meeting Time: Mar 16, 2022 08:00 AM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com/(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,,(b) (6) or +16692161590,,(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US : +1 669 254 5252 or +1 669 216 1590 or +1 646 828 7666 or +1 551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode: (b) (6)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID:

Passcode:

SIP:

Passcode:

(b) (6)

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 3/15/2022 4:03:05 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: Zoom meeting is canceled - Commissioner Touch Base: Infant Formula Work

[redacted]

Hi Rob Califf,

Frank Olivarria (Frank.Olivarria@fda.hhs.gov) canceled the meeting below.

Meeting Topic: Commissioner Touch Base: Infant Formula Work

Meeting ID: (b) (6) [redacted]

Meeting Time: Mar 16, 2022 08:00 AM Eastern Time (US and Canada)

From: Zoom [no-reply@zoomgov.com]
Sent: 3/15/2022 4:03:31 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Commissioner Touch Base: Infant Formula Work

Meeting Time: Mar 16, 2022 08:00 AM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com/s(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) +16692161590,(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US : +1 669 254 5252 or +1 669 216 1590 or +1 646 828 7666 or +1 551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode: (b) (6)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID:

Passcode:

SIP:

Passcode:

(b) (6)

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 3/15/2022 6:05:55 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

[redacted]

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Commissioner Touch Base: Communications Strategy for Abbott

Meeting Time: Mar 17, 2022 11:30 AM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) or +16692161590,(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US : +1 669 254 5252 or +1 669 216 1590 or +1 551 285 1373 or +1 646 828 7666 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:

(b) (6)

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/13/2022 8:58:41 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Meeting Time: May 13, 2022 10:30 AM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) +16468287666,(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:

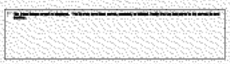
SIP:

Passcode:

(b) (6)

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/13/2022 9:01:21 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host



Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Meeting Time: May 13, 2022 10:20 AM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com/(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) +16468287666,(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

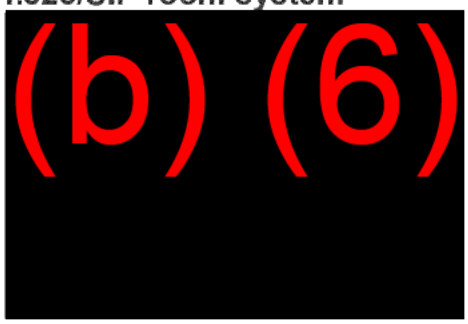
H.323:

Meeting ID:

Passcode:

SIP:

Passcode:



Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/13/2022 9:15:43 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Your Meeting - Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA) Is Deleted

Hi FDA Commissioner,

You have successfully deleted the below Zoom meeting.

Meeting ID: (b) (6)
Topic: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)
Time: May 13, 2022 10:30 AM Eastern Time (US and Canada)

If you want to recover this meeting, please go to Recently Deleted. Recently deleted meetings will be permanently deleted after 7 days.

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/13/2022 9:52:59 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Chicago 7N 10000441059 has joined your meeting - Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Hi FDA Commissioner,

Chicago (b) (6) has joined your meeting:

Topic	**Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)**
Meeting ID	(b) (6)
Time	May 13, 2022 10:20 AM Eastern Time (US and Canada)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/13/2022 9:15:43 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: Zoom meeting is canceled - Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) canceled the meeting below.

Meeting Topic: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Meeting ID: (b) (6)

Meeting Time: May 13, 2022 10:30 AM Eastern Time (US and Canada)

From: Zoom [no-reply@zoomgov.com]
Sent: 5/14/2022 6:25:52 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Infant Formula (IF) Daily Update

Meeting Time: May 16, 2022 08:45 AM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) # or +16692161590,(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US : +1 669 254 5252 or +1 669 216 1590 or +1 646 828 7666 or +1 551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode: (b) (6)

International numbers

Join from an H.323/SIP room system

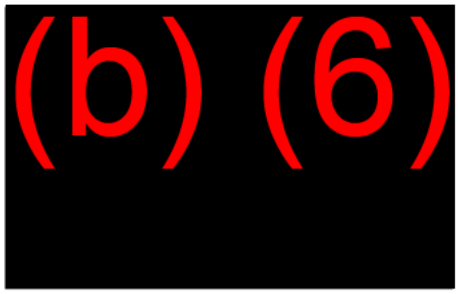
H.323:

Meeting ID:

Passcode:

SIP:

Passcode:



Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/14/2022 6:28:41 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Your Meeting - Infant Formula (IF) Daily Update Is Deleted

Hi FDA Commissioner,

You have successfully deleted the below Zoom meeting.

Meeting ID: (b) (6)
Topic: Infant Formula (IF) Daily Update
Time: May 16, 2022 08:45 AM Eastern Time (US and Canada)

If you want to recover this meeting, please go to Recently Deleted. Recently deleted meetings will be permanently deleted after 7 days.

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/14/2022 6:28:35 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Infant Formula (IF) Daily Update

Meeting Time: This is a recurring meeting Meet anytime

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) or +16692161590,(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US : +1 669 254 5252 or +1 669 216 1590 or +1 646 828 7666 or +1 551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode: (b) (6)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting ID:

Passcode:

SIP:

Passcode:

(b) (6)

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/14/2022 6:28:41 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: Zoom meeting is canceled - Infant Formula (IF) Daily Update

Hi Rob Califf,

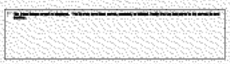
FDA Commissioner (Commissioner@fda.hhs.gov) canceled the meeting below.

Meeting Topic: Infant Formula (IF) Daily Update

Meeting ID: (b) (6)

Meeting Time: May 16, 2022 08:45 AM Eastern Time (US and Canada)

From: Zoom [no-reply@zoomgov.com]
Sent: 5/15/2022 8:36:20 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host



Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Meeting Time: May 15, 2022 03:30 PM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com/(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) or +16468287666,(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:

(b) (6)

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/15/2022 3:15:44 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Robert Ford has joined your meeting - Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)

Hi FDA Commissioner,

Robert Ford has joined your meeting:

Topic **Telecon: Mr. Robert Ford (Abbott) / Dr. Rob Califf (FDA)**

Meeting ID (b) (6)

Time May 15, 2022 03:30 PM Eastern Time (US and Canada)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/15/2022 3:58:47 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Tristan.Colonius-iphone has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Tristan.Colonius-iphone has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/15/2022 6:35:45 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Internal FDA Media Prep: Infant Formula Supply Rollout

Meeting Time: May 16, 2022 09:30 AM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) or +16468287666,(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:

(b) (6)

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/16/2022 8:48:51 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Frank Yiannas has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Frank Yiannas has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/16/2022 9:00:43 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Frank Yiannas has joined your meeting - Infant Formula (IF) Daily Update

[redacted]

Hi FDA Commissioner,

Frank Yiannas has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/16/2022 9:14:33 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Mark.Raza@fda.hhs.gov has joined your meeting - Infant Formula (IF) Daily Update

[redacted]

Hi FDA Commissioner,

Mark.Raza@fda.hhs.gov has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/16/2022 9:29:37 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Claudine.Kavanaugh@fda.hhs.gov has joined your meeting - Internal FDA Media Prep: Infant Formula Supply Rollout

Hi FDA Commissioner,

Claudine.Kavanaugh@fda.hhs.gov has joined your meeting:

Topic	**Internal FDA Media Prep: Infant Formula Supply Rollout**
Meeting ID	(b) (6)
Time	May 16, 2022 09:30 AM Eastern Time (US and Canada)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/17/2022 8:43:09 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Caitlin.Boon@fda.hhs.gov has joined your meeting - Infant Formula (IF) Daily Update

[redacted]

Hi FDA Commissioner,

Caitlin.Boon@fda.hhs.gov has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/18/2022 8:39:09 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Mark.Raza@fda.hhs.gov has joined your meeting - Infant Formula (IF) Daily Update

[redacted]

Hi FDA Commissioner,

Mark.Raza@fda.hhs.gov has joined your meeting:

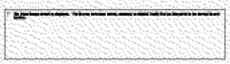
Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/18/2022 10:47:10 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host



Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: ADM Levine / Dr. Califf (specialty infant formula and healthcare professional engagement)

Meeting Time: May 18, 2022 03:30 PM Eastern Time (US and Canada)

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) or +16468287666,,(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

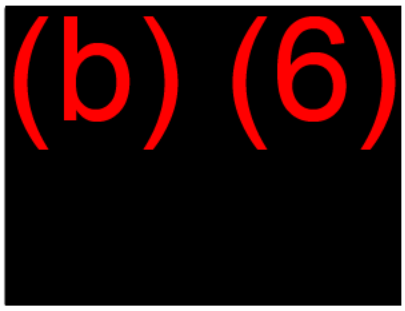
H.323:

Meeting ID:

Passcode:

SIP:

Passcode:



Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/18/2022 3:27:52 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: ADM Rachel Levine has joined your meeting - ADM Levine / Dr. Califf (specialty infant formula and healthcare professional engagement)

Hi FDA Commissioner,

ADM Rachel Levine has joined your meeting:

Topic	**ADM Levine / Dr. Califf (specialty infant formula and healthcare professional engagement)**
Meeting ID	(b) (6)
Time	May 18, 2022 03:30 PM Eastern Time (US and Canada)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/19/2022 8:39:34 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Susan Mayne FDA has joined your meeting - Infant Formula (IF) Daily Update

[redacted]

Hi FDA Commissioner,

Susan Mayne FDA has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/20/2022 8:37:57 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Erica Jefferson has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Erica Jefferson has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/20/2022 12:14:48 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Chicago 7E 10000441060 has joined your meeting - Abbott / FDA

Hi FDA Commissioner,

Chicago 7E 10000441060 has joined your meeting:

Topic	**Abbott / FDA**
Meeting ID	(b) (6)
Time	May 20, 2022 12:30 PM Eastern Time (US and Canada)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/23/2022 8:27:23 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Teresa.Croce@fda.hhs.gov has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Teresa.Croce@fda.hhs.gov has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/24/2022 8:31:56 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Julie Tierney has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Julie Tierney has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/24/2022 8:37:45 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Frank.Yiannas-iPhone has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Frank.Yiannas-iPhone has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/23/2022 8:27:36 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Caitlin.Boon@fda.hhs.gov has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Caitlin.Boon@fda.hhs.gov has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/25/2022 8:37:45 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Frank Yiannas has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Frank Yiannas has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/26/2022 8:37:02 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Your participant has joined your meeting - Infant Formula (IF) Daily Update

Hi FDA Commissioner,

Your participants have joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: no-reply@zoomgov.com [no-reply@zoomgov.com]
Sent: 5/27/2022 8:38:08 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Josh has joined your meeting - Infant Formula (IF) Daily Update

[redacted]

Hi FDA Commissioner,

Josh has joined your meeting:

Topic **Infant Formula (IF) Daily Update**

Meeting ID (b) (6)

Start Meeting

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/27/2022 12:10:53 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Infant Formula (IF) Morning Update

Meeting Time: This is a recurring meeting Meet anytime

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com/(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,(b) (6) or +16692161590,,(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US : +1 669 254 5252 or +1 669 216 1590 or +1 551 285 1373 or +1 646 828 7666 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:

(b) (6)

Thank you for choosing Zoom.
-The Zoom Team

From: Zoom [no-reply@zoomgov.com]
Sent: 5/27/2022 12:36:05 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Subject: FDA Commissioner invites you to join a Zoom meeting as alternative host

Hi Rob Califf,

FDA Commissioner (Commissioner@fda.hhs.gov) invited you to a Zoom meeting as alternative host.

Meeting Topic: Afternoon Infant Formula (IF) Sync

Meeting Time: This is a recurring meeting Meet anytime

Add to Calendar Add to Google Calendar Add to Yahoo Calendar

Start Meeting

As a host, you have the ability to start and end the meeting.

If the above button is not clickable, try copying and pasting the following link into the address bar of your web browser

https://fda.zoomgov.com(b) (6)

Or join meeting with the following methods

Phone one-tap

Phone one-tap: US: +16692545252,,(b) (6) or +16692161590,(b) (6)

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For higher quality, dial a number based on your current location.

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US : +1 669 254 5252 or +1 669 216 1590 or +1 551 285 1373 or +1 646 828 7666 or 833 568 8864 (Toll Free)

Meeting ID: (b) (6)

Passcode: (b) (6)

International numbers

Join from an H.323/SIP room system

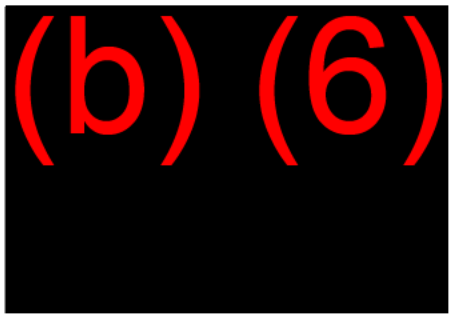
H.323:

Meeting ID:

Passcode:

SIP:

Passcode:



Thank you for choosing Zoom.
-The Zoom Team

(b) (6)

From: Bureau Chemistry [redacted]
Sent: 5/13/2022 9:44:21 PM
To: Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]; Denise.Hinton@fda.hhs.gov; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Warren, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=546233fb0a44418797de983c1e94f790-MWarren]; Lemery, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddda27dc07314f7595e2a9270208542c-LemeryS]; Summers, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc5b3eba53f40d2a72a6f738d143cf3-SUMMERSJ]; Beaver, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82282cb5fd5e452fabe98079c5f09721-BEAVERJ]; Pierce, William (OCE) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5bf9274f9c4baab3becb02b6f72f36-PIERCEW]; Ibrahim, Amna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=998ae13342184012b629b9a35da4fed7-IBRAHIMA]; Lowy, Douglas R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=573f83e4718445c6b76f6fac82aa5d5a-HHS-LowyD-m]; (b) (6) [redacted]; michael.strong@cihr-irsc.gc.ca; Kelly, Halonna R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32af50df84fb4d2bab8ed0b162c52cac-HHS-halonna]; Langevin, Helene M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c9c18f6030f4317b860058c8d25fae8-HHS-helene.]; Kiley, James P (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47964c0318054e7c98c149a93cfe6ada-HHS-kileyj-]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; (b) (6) [redacted]; alex.azar@hhs.gov; Pazdur, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cff15d9383ab41478e6a59bc8b50570a-PAZDURR]; Kluetz, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d7780adb82f4fa08221ad5eb64cc44e-KLUETZPA]; Behr, Virginia L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69a943257c434ce38547965aa35068b7-BEHRV]; FDAOncology [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60c2f0a82baf4577b9f5d69b7413c659-FDAOncology]; CDER Formal Dispute Resolution Program [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01c800781f41412cac069d86e9d1d7b0-CDER Formal]; Theoret, Marc [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8721b19b24748138673b0b1929c6645-THEORETM]; Kim, Tamy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b125ac02c55448b2b3c95437b432b45c-KIMTA]; Barclay, Lisa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18c6508b15a249799140fcd8d9ddc1ac-HHS-Lisa.Ba]; Paul.Rodriguez1@hhs.gov; Keveney, Sean (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=392a6133e7244f488b3efcc8cb164514-HHS-Sean.Ke]; Elizabeth.Gianturco@hhs.gov; Frye, Buddy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=988b69b7fbb448878fd48e39d7ba850f-HHS-Buddy.F]; Lyles, Arlene (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73f1946b1d1e490fbb3d887cfa15d297-HHS-Arlene.]; Mullins, Tracey (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e686f1d593d430185e56d4596995579-HHS-Tracey.]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Schuham, Aaron D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bd872482545445db940bb03bbd1f2cb-HHS-Aaron.S]; Wiggins, Audrey (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f306742f0634b08ba757f9616a0cfa4-HHS-Audrey.]; Hall, Randall (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ac9108d41db4408bd53eeb45ba0a0fe-HHS-randall]; Hancock, Glenn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0bb8c32a9c64ceda09e41b2e3682330-HHS-Glenn.H]; Dickinson, Elizabeth (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05cb143d66ed470ebe4dba5c54a88074-EDickins]; annamarie.kempic@fda.hhs.gov; Gorji, Perham [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27a75f0a884c4d62ad7f64a4a3fc0492-Perham.Gorj]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Goulding, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4826f6835e3b4a9d81aa0878217c77d7-HHS-Michael]; lyueh@cdc.gov; Clark, Tamara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a8da60f30e0459f866d68f07a427638-HHS-Tamara.]; Pierce, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43493e09f54b467fa677fcdf1f4ca093-HHS-Julia.P]; Naimon, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=088dafe978fd471c9cc9a6409a008e96-HHS-David.N]; (b) (6)

Subject: [EXTERNAL] FDA people ... (they know they are failures)

https://nypost.com/2022/05/13/ex-fda-official-reveals-how-agency-caused-baby-formula-crisis/

"The whole situation could have been done with a sense of urgency when you look at the population that ingests this product," said Mitzi Baum, chief executive of the non-profit STOP Food Borne Illness.

Baum added that the delay is a reflection of "the dysfunction of the system," which is not protecting public health.
"The majority of the FDA's funding goes towards drugs and devices and the food part of the agency is severely underfunded and lacking clear leadership," Baum said.
"We need a dedicated food agency," King said.
....
anyways this is a different topic.
You are hereby declared persona non grata,
who knew, I can be diplomatic too.
let's stand and clap for the true morons of the entire world, Duke CRI, UNC Lineberger

Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University.
somebody send me a memo when they finally catch up, I'll bet it will be the year 2075.
and cut.
<salutes>
the wonderful, whimsical
Legendary Alchemist

From: (b) (6)
Sent: 4/7/2022 9:02:36 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: [EXTERNAL] Babies and Toddlers don't need COVID shots!

Dear FDA Commissioner Robert Califf,

I think the FDA, CDC and even the EPA have been asleep on the damn job. Vaccines without proper testing and I am not just talking about COVID, plastics in baby formula, toxic pesticides in general but in baby formula. What the hell are you letting these industry shills get away with?

Regards,

(b) (6)

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 5/26/2022 7:57:26 PM
To: McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/20/2022 8:40:00 AM
End: 5/20/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Fristedt, Andi; Tobias, Lindsay; Simms, Joshua; Dr. Califf; Tierney, Julia; Yiannas, Frank; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Croce, Teresa; Beckerman, Peter; McMeekin, Judith
Optional Attendees: Fristedt, Andi

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

Hi there,

FDA Commissioner is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile: US: +16692545252, (b) (6) or +16692161590,, (b) (6),,,,

Meeting URL: https://fda.zoomgov.com/j (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 +1 669 216 1590 or +1 646 828 7666 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: (b) (6) (US West)
(b) (6) (US East)

Meeting ID: (b) (6)

Passcode (b) (6)

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

Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:34 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Canceled: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/22/2022 8:45:00 AM
End: 5/22/2022 9:00:00 AM
Show Time As: Free

Importance: High

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Tobias, Lindsay

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Meeting ID: (b) (6)

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Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:26 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/19/2022 8:40:00 AM
End: 5/19/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Tobias, Lindsay

Standing Agenda Tues-Fri (20 min):

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  - Domestic (including Sturgis restart)
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- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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Meeting URL: https://fda.zoomgov.com/j/(b) (6)(b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

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Meeting ID: (b) (6)

Passcode (b) (6)

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

Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:20 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/20/2022 8:40:00 AM
End: 5/20/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Croce, Teresa; Tobias, Lindsay
Optional Attendees: Fristedt, Andi

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
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Meeting ID: (b) (6)

Passcode (b) (6)

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Meeting ID: (b) (6)

Passcode (b) (6)

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

Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:30 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Canceled: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/21/2022 8:45:00 AM
End: 5/21/2022 9:00:00 AM
Show Time As: Free

Importance: High

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Tobias, Lindsay

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Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:16 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/24/2022 8:40:00 AM
End: 5/24/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Croce, Teresa; Tobias, Lindsay
Optional Attendees: Fristedt, Andi

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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Passcode (b) (6)

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Meeting ID: (b) (6)

Passcode (b) (6)

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

Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:10 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/26/2022 8:40:00 AM
End: 5/26/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Tobias, Lindsay

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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Passcode (b) (6)

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Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:18 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/23/2022 8:30:00 AM
End: 5/23/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Croce, Teresa; Tobias, Lindsay
Optional Attendees: Fristedt, Andi

Standing Agenda Monday (30 min):

- Week Ahead (5 min) – OC
- Short Term Supply of Formula (5 min) – OFPR/CFSAN
  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN
- Next Steps/Discussion (5 min) – OC

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Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:14 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/25/2022 8:40:00 AM
End: 5/25/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Croce, Teresa; Tobias, Lindsay
Optional Attendees: Fristedt, Andi

Standing Agenda Tues-Fri (20 min):

- Short Term Supply of Formula (5 min) – OFPR/CFSAN
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  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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Passcode (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/18/2022 11:15:04 AM
To: Lindsay Tobias (Lindsay.Tobias@fda.hhs.gov) [Lindsay.Tobias@fda.hhs.gov]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/27/2022 8:40:00 AM
End: 5/27/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Tobias, Lindsay

Standing Agenda Tues-Fri (20 min):

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  - Domestic (including Sturgis restart)
  - Imports
- Short Term Supply of Specialty Metabolics (5 min) – OFPR/CFSAN
- Communications + External Engagements (5 min) – OEA/OPLIA
- Long Term Supply Fixes (5 min) – OFPR/CFSAN

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From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/14/2022 9:06:48 PM
To: Dr. Califf [(b) (6)fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; 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]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]

Subject: [HOLD] Infant Formula (IF) Daily Update KIckoff Meeting (30 mins)
Location: Zoom, details below

Start: 5/15/2022 4:00:00 PM
End: 5/15/2022 4:30:00 PM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Susan Mayne; Raza, Mark; Caitlin Boon; Colonius, Tristan

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From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/14/2022 6:33:26 PM
To: Dr. Califf [(b) (6) fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; 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]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]

Subject: [HOLD] Infant Formula (IF) Daily Update KIckoff Meeting (30 mins)
Location: Zoom, details below

Start: 5/15/2022 11:30:00 AM
End: 5/15/2022 12:00:00 PM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Susan Mayne; Raza, Mark; Caitlin Boon; Colonius, Tristan

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Meeting ID: (b) (6)

Passcode (b) (6)

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Sent: 5/14/2022 6:35:59 PM
To: Dr. Califf [(b) (6)fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; 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]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]

Subject: [HOLD/If needed] Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/22/2022 8:45:00 AM
End: 5/22/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Susan Mayne; Raza, Mark; Caitlin Boon; Colonius, Tristan

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From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/14/2022 6:34:36 PM
To: Dr. Califf [(b) (6)fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; 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]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]

Subject: [HOLD/IF NEEDED] Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/21/2022 8:45:00 AM
End: 5/21/2022 9:00:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Susan Mayne; Raza, Mark; Caitlin Boon; Colonius, Tristan

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From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/14/2022 6:36:41 PM
To: Dr. Califf [(b) (6) fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; 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]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]

Subject: Infant Formula (IF) Daily Update
Location: Zoom, details below

Start: 5/16/2022 9:15:00 AM
End: 5/16/2022 9:30:00 AM
Show Time As: Tentative

Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Susan Mayne; Raza, Mark; Caitlin Boon; Colonius, Tristan

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(b) (6) (US East)

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From: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Sent: 5/20/2022 1:36:46 PM
To: Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]
Subject: RE: [EXTERNAL] Thank you - For Dr. Califf's awareness. We will log it in for the record.

Thanks!

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Friday, May 20, 2022 1:36 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: FW: [EXTERNAL] Thank you - For Dr. Califf's awareness. We will log it in for the record.
Importance: High

From: Claire Babineaux-Fontenot <cbfontenot@feedingamerica.org>
Sent: Friday, May 20, 2022 12:23 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; FDA Commissioner <commissioner@fda.hhs.gov>
Cc: Erika Thiem <ethiem@feedingamerica.org>; Vince Hall <vince.hall@feedingamerica.org>; Kathryn Strickland <kstrickland@feedingamerica.org>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: [EXTERNAL] Thank you

Dear Frank,

Sincere gratitude to you and Commissioner Cahill for facilitating a rich discussion today regarding Feeding America's readiness to assist with increasing access to infant formula.
Approximately 53 million Americans accessed the charitable food system last year, mostly through Feeding America's network of 200 food banks and over 60,000 faith-based and nonprofit partner agencies. Our robust national distribution system reaches people facing hunger in every county in the United States and Puerto Rico. Last year we distributed over 5.5 billion meals of food and over 11 billion meals since the pandemic started.

Simply stated, we stand ready and able to help the FDA provide free infant formula to the most vulnerable infants in our communities nationwide. Following today's call, we began preliminary discussions with food bank CEOs from our network and received enthusiastic support for continued development of this concept.

I have asked that three members of my Executive Team serve as your primary points of contact in this work. They are: Erika Thiem, Chief Supply Chain Officer, Kathryn Strickland, Chief Network Officer, and Vince Hall, Chief Government Relations Officer (all are CCed on this email). Naturally I am also personally available as needed.

As I mentioned on today's call, we are impressed by and grateful for the fact that your focus will include undeserved communities who are being particularly hard hit by this crisis. The opportunity to be a part of your continuing and expanding response aligns perfectly with our mission. We are eager to get started.

Best regards,
Claire

Claire Babineaux-Fontenot
Chief Executive Officer

Feeding America
National Organization
161 N. Clark Street
Suite 700
Chicago, IL 60601
tel +1.312.641.5664
cbfontenot@feedingamerica.org

Learn more and see how you can help at feedingamerica.org

From: Courtney Scarbin [no-reply@zoom.us]
Sent: 5/16/2022 7:00:43 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: [EXTERNAL] Infant Formula Shortage Briefing Confirmation

Flag: Follow up

zoom

NATIONAL GOVERNORS ASSOCIATION

fant Formula Shortage Briefing. You can find information about this meeting below.

ge Briefing

May 17, 2022 12:00 PM Eastern Time (US and Canada)

(b) (6)

o: CScarbin@NGA.ORG.

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888 475 4499 (Toll Free)

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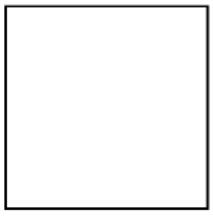
From: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Sent: 5/16/2022 7:21:35 PM
To: Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]
Subject: RE: [EXTERNAL] Infant Formula Shortage Briefing Confirmation - For Dr. Califf

Thanks so much, Wanda! -j

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Monday, May 16, 2022 7:20 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: FW: [EXTERNAL] Infant Formula Shortage Briefing Confirmation - For Dr. Califf
Importance: High

From: Courtney Scarbin <no-reply@zoom.us>
Sent: Monday, May 16, 2022 7:01 PM
To: FDA Commissioner <commissioner@fda.hhs.gov>
Subject: [EXTERNAL] Infant Formula Shortage Briefing Confirmation



fant Formula Shortage Briefing. You can find information about this meeting below.

riefing

May 17, 2022 12:00 PM Eastern Time (US and Canada)

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o: CScarbin@NGA.ORG.

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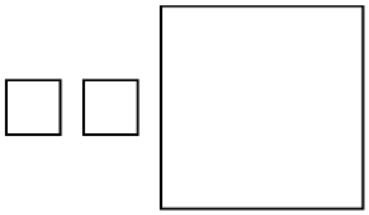
US: +1 301 715 8592 or +1 312 626 6799 or +1 929 205 6099 or +1 253 215 8782 or +1 346 248 7799 or +1 669 900 6833 or
888 475 4499 (Toll Free)

(b) (6)



From: Russ, Wanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2900752ACF81445785FB0F5B23C728C8-WRUSS]
Sent: 5/19/2022 6:56:42 PM
To: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
CC: Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]; Green, Marlyce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65207b23fcb543cea380cc63abfacfe4-Marlyce.Gre]
Subject: FW: [EXTERNAL] Abbott

Importance: High

Hi Janice.

See below. They are requesting another meeting with Dr. Califf for next week. OES will log in and send to Chrissy.

Wanda

From: Ford, Robert B (b) (6)@abbott.com>
Sent: Thursday, May 19, 2022 6:35 PM
To: FDA Commissioner <commissioner@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: [EXTERNAL] Abbott

Dear Commisioner Califf

I would like to first thank you for meeting with me last week so that we could resolve some of the pending issues regarding the Consent Decree.

Our immediate focus now is restarting the Sturgis facility and ensuring that we do it in compliance with all the terms of the consent decree. Rebuilding trust with regards to this site is my top priority and I am personally involved so that my team has all the resources it needs. I have put in place an experienced and dedicated team focused exclusively on this. And while there is a lot of complexity I can assure you that we are making progress.

I believe it would be helpful for both Abbott and FDA that we can share what our short and medium term ramp up plan looks like, with focus on the Specialty Formulas. To that end I would like to propose that a small group of Abbott leaders meet with you and your team so that we can share our plan to restart our Sturgis facility. We have completed many activities as part of our 483 response and would like to share the remaining activities and their respective timelines plus gain alignment on specific interactions and approvals required under the Consent Decree. The ultimate goal would be to work off an aligned set of expectations so as to ensure clarity, transparency and consistency with the public. My team and I would be open to meet with you and your team in person at the FDA anytime on Monday or Tuesday or Friday of next week.

I reaffirm that this is my top priority and hope that you will accept my offer.
Sincerely,

Robert Ford
Abbott

Proposed Abbott Attendees to the Meeting

1. Robert Ford (CEO)
2. Monica Wilkins (VP, Corporate Regulatory)
3. John Murphy (VP, Abbott Nutrition Supply Chain)
4. Lori Randall (DVP, Abbott Nutrition Quality)

From: Michelle Koross [redacted (b) (6)]
Sent: 5/14/2022 10:17:43 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: [EXTERNAL] Proper Formula Preparation Not Followed

Dr. Califf,

LABELS ON POWDERED FORMULA MUST CLEARLY STATE THAT IT HAS TO BE PREPARED WITH BOILING WATER.

With all due respect, I blame the CDC and FDA for the current formula crisis, which began as a recall of Abbott Laboratories powdered formula.

As a WIC nutritionist and Certified Lactation Counselor, (CLC) I learned through a breastfeeding CDC webinar that powdered formula is not sterile and therefore should be made with boiling water. This bit of information, if better disseminated, perhaps could have saved those poor infants.

I ask every formula-feeding WIC participant with whom I come in contact if they are aware that formula should be made with boiling water and offer them a handout that explains proper preparation. Although some know this fact, most are surprised that neither the hospital nor their pediatrician informed them. Formula labels don't provide instruction to use boiling water. I even called Mead Johnson to inquire about this long before the crisis.

Please ensure that formula labels contain information on using only boiling water to prepare the formula and make this education available to healthcare providers and the public.

Thank you for listening. I hope this information can make an impact.

Warmly,

Michelle A. Koross, MPH, MS, RDN, CLC

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From: Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]
Sent: 2/10/2022 12:49:36 PM
To: Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]
Subject: FW: [EXTERNAL] Regulate Novel, Potentially Hazardous Nanomaterials in Infant Formula

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

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

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

Re: Regulate Novel, Potentially Hazardous Nanomaterials in Infant Formula

Dear Commissioner:

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

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

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

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

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

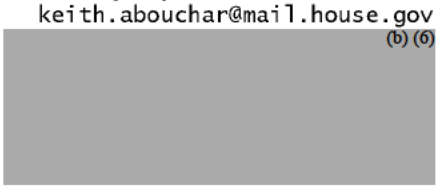
FDA should enact new regulations directed at the agency's oversight of nanomaterials, including that any infant formula undergo rigorous testing for the presence of nanomaterials and that the products be labeled as containing nanotechnology. Additionally, FDA should declare all currently available infant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

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

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

Yours sincerely,
Robert E. Rutkowski

cc:
Legislative Correspondence Team
1705 Longworth House Office Building
Washington DC 20515
Office: (202) 225-4131
Fax: (202) 225-4300
keith.abouchar@mail.house.gov
(b) (6)



From: Mitzi Baum [mbaum@STOPfoodborneillness.org]
Sent: 3/7/2022 4:48:27 PM
To: Califf, Robert (OLD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ed636c1d744f9a83d2cbbf53ec891c-Robert.Cali]; rpw1@cdc.gov
CC: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; director@cdc.gov
Subject: [EXTERNAL] Letter from Stop Foodborne Illness
Attachments: STOPcronobacterletter.pdf

Flag: Follow up

Support and engage people directly impacted by foodborne illness and mobilize them to help prevent illness and death by driving change through advocacy, collaboration and innovation.

Stop Foodborne Illness

March 7, 2022

Dr. Rochelle P. Walensky
Director
U.S. Centers for Disease
Control and Prevention

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration

Drs. Walensky and Califf,

Stop Foodborne Illness (STOP), the "Voice for Safe Food," represents all consumers and works to prevent foodborne disease. I am writing to call for *Cronobacter sakazakii* to be added to the Nationally Notifiable Disease List.

The current international infant formula recall, which has been linked to illnesses in at least five children and has been linked to the tragic deaths of two infants, calls for an urgent and expedited response. Although rare, *Cronobacter sakazakii* is extremely deadly to infants younger than three months of age, yet it is *not* included in CDC's important pathogens that local and state health partners must report identifying.

The lack of inclusion of this devastating pathogen on the Nationally Notifiable Disease List only adds to the potential of underreporting of illnesses, making it difficult for epidemiologists to do their important job of identifying clusters of illnesses to better understand sources and root causes of outbreaks. Lack of reporting also reduces the chances that FDA will become aware of incidents that need swift response and corrective action to protect infants.

Federal agencies have focused their efforts on infant and maternal health for detection of *Listeria monocytogenes;* STOP appeals to both agencies to institute the same standards for *Cronobacter sakazakii*. There must be equivalent surveillance for both deadly bacteria.

Now is the time to act. How can parents have trust in a system that does not protect the most vulnerable?

Sincerely,

Mitzi D. Baum
CEO

stopfoodborneillness.org | 4809 N. Ravenswood Ave, #214 Chicago, IL 60640 | 773.883.3098 fax | 773.269.6555

Mitzi D. Baum, M.Sc. | CEO | Stop Foodborne Illness
312.626.2762

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amazonsmile

Support and engage people directly impacted by foodborne illness and mobilize them to help prevent illness and death by driving change through advocacy, collaboration and innovation.

Stop Foodborne Illness

March 7, 2022

Dr. Rochelle P. Walensky
Director
U.S. Centers for Disease
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Now is the time to act. How can parents have trust in a system that does not protect the most vulnerable?

Sincerely,

Mitzi D. Baum
CEO

stopfoodborneillness.org | 4809 N. Ravenswood Ave, #214 Chicago, IL 60640 | 773.883.3098 fax | 773.269.6555

From: Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]
Sent: 3/10/2022 2:31:28 PM
To: Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]
Subject: FW: [EXTERNAL] Call on Abbott and FDA to clarify the scope of the infant formula recall

-----Original Message-----
From: Robert Rutkowski (b) (6)>
Sent: Thursday, March 10, 2022 2:24 PM
To: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Keith Abouchar <keith.abouchar@mail.house.gov>
Subject: [EXTERNAL] Call on Abbott and FDA to clarify the scope of the infant formula recall

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

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

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

Dear Commissioner:

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

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

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

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

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

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

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

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

Yours sincerely,
Robert E. Rutkowski

cc:
Legislative Correspondence Team
1705 Longworth House Office Building

Washington DC 20515
Office: (202) 225-4131
Fax: (202) 225-4300
keith.abouchar@mail.house.gov

(b) (6)

[redacted]

From: MICHAEL MACDERMOTT (b) (6)
Sent: 5/25/2022 4:28:17 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: [EXTERNAL] Abbott

Dr. Califf, you have my sympathy. Bureaucrats in the FDA, FBI (Dr. Nassar case) or other goverment agencies, work at their own pace. Not all are dedicated or competent. Sometimes, as here, that leads to a crisis. Regards. Michael

From: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Sent: 5/16/2022 4:38:50 PM
To: Robert M. Califf, MD (b) (6) fda.hhs.gov]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Julia Tierney [Julia.Tierney@fda.hhs.gov]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
CC: Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]

Subject: Media Call: Actions to Increase Infant Formula Supply
Attachments: Media Call Script_Infant Formula_FINAL 05.16.22.docx; PR_Infant Formula Import Flexibilities Updated_05.16.22_Final_METADATA.docx; PR_FDA Provides New Updates on Activities to Mitigate Infant Formula Supply Challenges_FINAL_520pm.docx; Importation Media Call TPs and QA 6pm.docx
Location: 1-800-857-9826; Speaker Code (b) (6)

Start: 5/16/2022 6:55:00 PM
End: 5/16/2022 7:45:00 PM
Show Time As: Busy

Required Attendees: Robert M. Califf, MD; Felberbaum, Michael; Susan Mayne; Yiannas, Frank; Rabin, Tara G.; Julia Tierney; Jefferson, Erica
Optional Attendees: Guevara, Bessy

WHAT:
A media briefing to discuss the FDA's plans to exercise flexibilities regarding the importation of certain infant formula products from abroad in an effort to increase powdered infant formula supply in the U.S.

HOW:
- Speaker dial in: 800-857-9826
- Speaker passcode: (b) (6)

This call is voice-only; there is no video component. Please remember to use a fully-charged mobile phone with a strong signal or use a land line.

WHEN:
Monday May 16 at 7:00 p.m. ET
Speakers must dial-in 5 minutes before the scheduled call at 6:55 p.m. call for a sound check.

WHO:
- Robert Califf, M.D., FDA Commissioner
- Susan T. Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition
- Frank Yiannas, Deputy Commissioner for Food Policy and Response

POCs: Michael Felberbaum (Cell: (b) (6)); Tara Rabin (Cell: (b) (6))

Please do not forward this invite

Invitees
Michael Felberbaum
Susan Mayne
Robert Califf
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Tara Rabin
Julia Tierney
Erica Jefferson