
From: Thomas, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3A2C3BBC2BD0426BB3DD8E1EF7EC3686-JACQUELINE.]
Sent: 3/28/2022 12:49:31 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Subject: [HOLD] Congressional Briefing on Infant Formula/Medical Food Authorities and Needs
Start: 4/5/2022 3:30:00 PM
End: 4/5/2022 4:00:00 PM
Show Time As: Tentative

POC: Shera Moxley

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 5/4/2022 7:59:31 AM
To: DiPaola, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E6114E2A610423996E62A920ADD4E82-LDIPAOLA]
Subject: Read: PLEASE RESPOND: Abbott Nutrition/Infant Formula Litigation Hold

Your message

CC: Lee, Marguerite; Weinfield, Douglas; DiPaola, Lauren; Litigation Hold
Subject: PLEASE RESPOND: Abbott Nutrition/Infant Formula Litigation Hold
Sent: 5/3/2022 6:51:23 PM

was read 5/4/2022
on 7:59:22
AM

From: Moxley, Shera [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2DBDDBF813674D38AC4A43176E2398E4-SHERA.MOXLE]
Sent: 4/6/2022 11:30:28 AM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Carey, Emily Rose [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21a4cf80bae6477ea95932ffe37b4fc3-EmilyRose.C]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Goitom, Mahlet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3476ef7044d54ad88f0d8c8639fdc9d8-Mahlet.Goit]
Subject: Summary of Briefing: Video Briefing for staff of Sen. HELP maj/Sen. Duckworth/Sen. Klobuchar on FDA's Regulation of Infant Formula

The summary is for internal FDA use only and may not fully reflect all issues, discussions, or comments from the briefing.

Video Briefing with staff of Senate HELP Majority, Sen. Duckworth, and Sen. Klobuchar on FDA's Regulation of Infant Formula

April 5, 2022

(b) (5)

(b) (5)

Shera A. Moxley, PhD
Congressional Affairs Specialist

Office of Legislation
Office of Policy, Legislation, and International Affairs
U.S. Food and Drug Administration
Tel: 240.402.1594
Mobile: (b) (6)
shera.moxley@fda.hhs.gov



From: Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]
Sent: 5/13/2022 12:21:09 PM
To: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Subject: (HOLD) Infant Formula Hearing Prep
Start: 5/23/2022 3:30:00 PM
End: 5/23/2022 5:00:00 PM
Show Time As: Busy

C. Pennington – POC

From: Hattis, Daniel [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EEA12BDAA04F42F0AFB9DD6ABF39793A-DANIEL.HATT]
Sent: 5/13/2022 2:04:01 PM
To: Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bdaa04f42f0afb9dd6abf39793a-Daniel.Hatt]; 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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Christin, Charlotte - OC [Charlotte.Christin@fda.hhs.gov]; Pillsbury, Laura [Laura.Pillsbury@fda.hhs.gov]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Colonius, Tristan [Tristan.Colonius@fda.hhs.gov]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Klimczak, Katherine [Katherine.Klimczak@fda.hhs.gov]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
Subject: House/Senate Ag Approps Staff Briefing on Infant Formula
Location: <https://fda.zoomgov.com/join/92545252> (b) (6)
Start: 5/16/2022 11:30:00 AM
End: 5/16/2022 12:15:00 PM
Show Time As: Busy

Required Attendees: Yiannas, Frank; Mayne, Susan; Woodcock, Janet
Optional Attendees: Christin, Charlotte - OC; Pillsbury, Laura; Rogers, Michael; Colonius, Tristan; Boon, Caitlin; Klimczak, Katherine; McBride, Maren

Hi all. This is the infant formula briefing for the House and Senate Ag Appropriations Staff. Please let us know if you have any questions. Thanks!

Hi there,

Daniel.Hattis@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

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From: Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]
Sent: 5/20/2022 11:36:56 PM
To: Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4a1b04704e9a3a0b3f3-Kimberl.Trz]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Goitom, Mahlet [Mahlet.Goitom@fda.hhs.gov]; Hodnette, Jonathan [Jonathan.Hodnette@fda.hhs.gov]; Moxley, Shera [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dbddb813674d38ac4a43176e2398e4-Shera.Moxle]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Schmalz, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20557f36dca0413f8bb2ab2bc008a3f2-HHS-Jennife]; Barstow, Kevin (HHS/IOS) [Kevin.Barstow@hhs.gov]; Cha, Stephen (HHS/IOS) [Stephen.Cha@hhs.gov]; Despres, Sarah (HHS/IOS) [Sarah.Despres@hhs.gov]; 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]; James, Carrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85ef2ab0209843f6aad4c00717594c09-Carrie.Scru]; Zuckerman, Claudia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e65216132614566babcdc9cc0319277-Claudia.Zuc]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
Subject: Hearing Prep: Infant Formula Shortage
Location: WO-Bldg 02 - 2051/52 OR Microsoft Teams Meeting
Start: 5/23/2022 2:45:00 PM
End: 5/23/2022 4:45:00 PM
Show Time As: Tentative

Required Attendees: Woodcock, Janet; Yiannas, Frank; Mayne, Susan; Goitom, Mahlet; Hodnette, Jonathan; Moxley, Shera; Califf, Robert; Colonius, Tristan; Boon, Caitlin; Tierney, Julia
Optional Attendees: Tantillo, Andrew; Schmalz, Jennifer (OS); Barstow, Kevin (OS); Cha, Stephen S (OS); Despres, Sarah (OS); Beckerman, Peter; Singleton, Shannon; James, Carrie; Zuckerman, Claudia; Jefferson, Erica; McBride, Maren

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From: Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]
Sent: 5/22/2022 10:21:11 PM
To: Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; 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]; Goitom, Mahlet [Mahlet.Goitom@fda.hhs.gov]; Hodnette, Jonathan [Jonathan.Hodnette@fda.hhs.gov]; Moxley, Shera [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dbddb813674d38ac4a43176e2398e4-Shera.Moxle]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Schmalz, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20557f36dca0413f8bb2ab2bc008a3f2-HHS-Jennife]; Barstow, Kevin (HHS/IOS) [Kevin.Barstow@hhs.gov]; Cha, Stephen (HHS/IOS) [Stephen.Cha@hhs.gov]; Despres, Sarah (HHS/IOS) [Sarah.Despres@hhs.gov]; 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]; James, Carrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85ef2ab0209843f6aad4c00717594c09-Carrie.Scru]; Zuckerman, Claudia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e65216132614566babcdc9cc0319277-Claudia.Zuc]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
Subject: Hearing Prep: Infant Formula Shortage (Agenda Attached)
Attachments: FDA Agenda for Prep Session for E&C O&I hearing.docx
Location: WO-Bldg 02 - 2051/52 OR Microsoft Teams Meeting

Start: 5/23/2022 2:45:00 PM
End: 5/23/2022 4:45:00 PM
Show Time As: Tentative

Required Attendees: Woodcock, Janet; Yiannas, Frank; Mayne, Susan; Goitom, Mahlet; Hodnette, Jonathan; Moxley, Shera; Califf, Robert; Colonius, Tristan; Boon, Caitlin; Tierney, Julia
Optional Attendees: Tantillo, Andrew; Schmalz, Jennifer (OS); Barstow, Kevin (OS); Cha, Stephen S (OS); Despres, Sarah (OS); Beckerman, Peter; Singleton, Shannon; James, Carrie; Zuckerman, Claudia; Jefferson, Erica; McBride, Maren

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**FDA Prep Session for
House Energy and Commerce Subcommittee on Oversight & Investigations
Hearing on Infant Formula Shortages**

**Monday, May 23, 2022, 2:45 to 4:45pm
WO-Bldg. 02, Room 2051/52 or Microsoft Teams Meeting**

AGENDA

(b) (5)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]
Sent: 5/17/2022 8:53:31 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Dr. Califf [rmc001@fda.hhs.gov]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; 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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tobias, Lindsay [Lindsay.Tobias@fda.hhs.gov]
Subject: Infant Formula (IF) Daily Update
Attachments: Canceled: [HOLD/If needed] Infant Formula (IF) Daily Update; Canceled: [HOLD/IF NEEDED] Infant Formula (IF) Daily Update; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: Zoom, details below
Start: 5/15/2022 8:45:00 AM
End: 5/15/2022 9:00:00 AM
Show Time As: Busy
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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From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 5/17/2022 3:35:56 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Janet Woodcock; Dr. Califf [rmc001@fda.hhs.gov]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; 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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Canceled: [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: Free
Importance: High
Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Janet Woodcock

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 5/17/2022 3:36:09 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Janet Woodcock; Dr. Califf [rmc001@fda.hhs.gov]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; 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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Canceled: [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: Free
Importance: High
Recurrence: Daily
every day from 8:45 AM to 9:00 AM
Required Attendees: Dr. Califf; Julia Tierney; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Janet Woodcock

To: Dr. Califf [rmc001@fda.hhs.gov]; 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]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; 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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]

Location: Zoom, details below

Start: 5/18/2022 8:40:00 AM

End: 5/18/2022 9:00:00 AM

Show Time As: Busy

Recurrence: (none)

Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet

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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To: Dr. Califf [rmc001@fda.hhs.gov]; 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]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; 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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]

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: (none)

Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet

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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CC: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]

Location: Zoom, details below

Start: 5/24/2022 8:40:00 AM

End: 5/24/2022 9:00:00 AM

Show Time As: Busy

Recurrence: (none)

Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Croce, Teresa

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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CC: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]

Location: Zoom, details below

Start: 5/25/2022 8:40:00 AM

End: 5/25/2022 9:00:00 AM

Show Time As: Busy

Recurrence: (none)

Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet; Croce, Teresa
Optional Attendees: Fristedt, Andi

Standing Agenda Tues-Fri (20 min):

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Location: Zoom, details below

Start: 5/27/2022 8:40:00 AM

End: 5/27/2022 9:00:00 AM

Show Time As: Busy

Recurrence: (none)

Required Attendees: Dr. Califf; Tierney, Julia; Yiannas, Frank; Fristedt, Andi; Jefferson, Erica; Mayne, Susan; Raza, Mark; Boon, Caitlin; Colonius, Tristan; Woodcock, Janet

Standing Agenda Tues-Fri (20 min):

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From: Colonius, Tristan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2B3590C046734A2E928858BD579ED852-TRISTAN.COL]
Sent: 4/22/2022 5:49:13 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: Special metabolic product update

Internal/confidential/deliberative

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



From: Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]
Sent: 2/25/2022 9:06:09 PM
To: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]
Subject: RE: Update on Infant Formula Discussions with Abbott Nutrition

Good Evening,

A quick update to let you know that Abbott just sent in information related to the production at Strugis and other manufacturing facilities. We'll be going through this over the weekend and determining whether we have everything we need.

Thank you,
Caitlin

Caitlin Boon, Ph.D.
Associate Commissioner for Food Policy and Response

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b) (6)

Caitlin.Boon@fda.hhs.gov



From: Boon, Caitlin

Sent: Thursday, February 24, 2022 9:31 PM

To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Califf, Robert <RMC001@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>

Subject: Update on Infant Formula Discussions with Abbott Nutrition

Good Evening,

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

In addition, we had initial discussions on whether production for certain products, particularly the EleCare amino acid-based product, could be moved to an alternate facility. The initial assessment is that options are limited because the

(b) (4)

. Abbott is currently considering next steps and appreciated our willingness to work with them as needed.

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

Thank you,
Caitlin

Caitlin Boon, Ph.D.

Associate Commissioner for Food Policy and Response

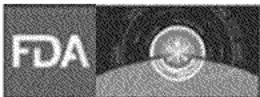
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(b) (6)

Caitlin.Boon@fda.hhs.gov



From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>

Sent: Thursday, February 24, 2022 1:20 PM

To: Califf, Robert <RMC001@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith

<Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Boon, Caitlin
<Caitlin.Boon@fda.hhs.gov>

Subject: Infant Formula Update #5 - Recall, Supply Chain Implications, & Potential Mitigation Measures

FOOD SAFETY UPDATE

From the Office of Food Policy and Response



U.S. FOOD & DRUG
ADMINISTRATION

Internal, Privileged, & Confidential

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

Recall Data and Information Provided by Abbott

- There has been general consensus that the recall started messy, because of a lack of detailed info being provided by Abbott, but that it improved over time.
- Abbott announced the recall on Thursday night, Feb 21, but initial info available to retailers was vague.
- Abbott was eventually able to provide more specific info, such as product descriptions, UPCs affected, and batch codes. Thereafter, they also started to provide info about specific products and quantities received by customers, but it came in in sequential manner....and over time.
- Abbott's UPCs are unique to specific products, and as do all UPCs, they do not discriminate or identify where the product (UPC) was made. That information can be determined via the batch code on each container.
- It should be positively noted that Abbott does use appropriate case labels that identifies on the case the batch number, which does allow one to determine where the product was produced by simply looking at the case (without opening it).
- There was NO mixing of multiple batch numbers within a case – this was an initial concern being expressed within government, but that did not end up being a practice used by the firm.

Recall Execution by Retailers

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

WIC

- All retailers were complimentary and grateful for the prompt action taken by USDA's WIC program to provide temporary waivers to allow WIC recipients to purchase any available infant formula brand, although they did report it was rough for the first few days, until they received the guidance.
- A few have expressed some inconsistencies on WIC execution at the State/geographical area, although specifics were not given. They've simply heard of challenges from their stores.
- In regards to the WIC program, there were two specific requests:
 - 1) If possible, retailers requested that any direction regarding the WIC program, be issued or shared with the retailers corporate office, so they can in-turn cascade it to their stores with further instruction. It sounded like in some states, info was being shared directly with stores.
 - 2) It was reported that the current WIC temporary waiver expires on March 31. Multiple retailers expressed concern that they expect the current supply chain shortages to last well beyond March 31, so they hope that the waiver can be extended until the supply chain challenges are resolved.

Current Supply Chain Insights and Status

- FDA has been monitoring the infant formula supply chain status, as reports of shortages and bottlenecks had been previously reported prior to the recall.
- Prior to the Abbott's recall, data from IRI summarized infant formula in-stock rates for the category at retail to be **88% at the end of January**, as compared to 95% the year prior.
- Based on discussions with retailers, after Abbott's recall last week, in-stock rates are lower. One major retailer reported their in-stock rate across the infant formula category to be currently be at 84%.
- Retailers that carry broader assortments and their own Store Brand infant formula products (such as Walmart's Parents Choice brand, Kroger's Comforts brand, Walgreen's Well Beginnings brand, etc.) appear to be faring better than those chains that only carry national brands.
- Retailers expressed a large dependency on Abbott-made infant formula products. Retailers report that Abbott provides them anywhere from 40% to 50% of the volume/and or SKUs they carry in this category.
- As a reminder, there are four major companies that produce the majority of infant formula for the U.S. and just over 20 manufacturing facilities that serve the U.S. market.
- FDA estimates Abbott produces just over 40% of domestic sales for powdered infant formula, primarily under the Similac brand.
- There are three major Abbott facilities that produce powdered infant formula for the U.S. market – the facility that is the subject of the current investigation in MI, one in AZ, and one in Ireland.
- However, disturbingly, the Sturgis facility is reported to be their sole source of production of their dietary/allergy sensitive formulations such as Elecare and Alimentum, although there are comparable products produced by National Brand (Nestle, Mead Johnson) and Private Brand (Perrigo) competitors, and retailers have reported they are attempting to switch their assortment to carry these comparable brands/products.

Outlook, Replenishment, and Mitigation Measures

- Most retailers have reported that they have instituted a maximum order limit of 5 cans/units of infant formula per customer to prevent hoarding.
- Post the Abbott recall, we expect in-stock rates of infant formula to be lower than rates reported through the end of January.
- Again, one major retailer reported their in-stock rate across the infant formula category to be currently at **84% this week**.
- It's expected that these in-stock rates could get a little worse before they get better and the supply could be stressed for months to come.
- Retailers are contacting other major infant formula manufacturers, such as Nestle, Mead Johnson, and Perrigo to offset the productions losses at Abbott. They also hope Abbott can increase production at other plants to offset the loss in production at the Sturgis facility.
- Beginning today, FDA will be monitoring sales data on a daily basis available through IRI to estimate in-stock rates of select infant formula UPCs at the national and regional level.
- In the short term, these are the **specific actions we think could be taken**, in order of suggested priority:

(b) (5)

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

Frank Yiannas

Deputy Commissioner, Food Policy & Response

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From: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Sent: 2/16/2022 8:36:29 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: RE: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

Susan, CDC told the Department just now that there are five cases. Do we know the status of the 5th infant if that's right?

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, February 16, 2022 8:33 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

Let us know if we can help in any way, for example activating an emergency team or something else. Is OMA fully up to speed? jw

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Tuesday, February 15, 2022 11:06 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: FW: Food Safety Update #2 - Environmental Positives of Cronobacter sakazakii Confirmed in Infant Formula Investigation

As Andi is aware, USDA WIC expects this to create very significant challenges to the WIC program (approximately 60% of the formula they use is the product that is subject to the actions below). The program has a call with WIC at 8:30. Caitlin is reaching out (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Let me know what else you may need in this rapidly evolving situation.

Susan

From: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>

Sent: Tuesday, February 15, 2022 9:04 PM

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

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

FOOD SAFETY UPDATE



U.S. FOOD & DRUG
ADMINISTRATION

From the Office of Food Policy and Response

Internal, Privileged, & Confidential

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

Epi Status

- The epi status remains unchanged from the first update.
- There remain 4 cases of infant illnesses reported to various FDA district offices between Sept 2021 to January 2022. All of the cases are reported to have consumed powdered infant formula (IF) produced in Abbott's facility in Sturgis, MI.
- Three (3) of the cases were ill due to *Cronobacter sakazakii* and one (1) due to Salmonellosis. All 4 cases were hospitalized and 1 resulted in a death attributed to *Cronobacter*.
- For more details, see attached Food Safety Update #1.

Investigation Status

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

- On February 1, FDA initiated environmental sampling in the firms powdered infant formula manufacturing areas collecting 160 swabs; all in Zone 2. No Zone 1 samples were collected during the initial environmental investigation as the firm had not disassembled equipment such as dryers.
- To date, **4 environmental subs have been confirmed positive for C. sakazakii**. From those 4 subs, **11 isolates of C. sakazakii have been whole genome sequenced with multiple genotypes being detected**.
- As of today, there has not been a match to the limited clinical isolates available from CDC.
- An additional **14 isolates of C. sakazakii are pending WGS** and they too will be analyzed to determine if they match clinical isolates.
- Abbott independently found two positives for C. sakazakii on sister swabs taken at the same time as FDA sampling. FDA received isolates from these samples on 2/15/22 and is initiating WGS.
- The inspection is ongoing at the firm. Current initial inspection observations identified significant Good Manufacturing Practice concerns, such as cracks in dryers used for other dried infant products.
- On February 14, FDA contacted the manufacturer to relay the confirmed C. sakazakii isolates from environmental sampling at their Sturgis facility. The firm relayed they were not amenable to a recall or market withdrawal.
- Today, February 15, FDA spoke further with the firm to repeat the request for a recall of all products produced since November 2020, and to inform the firm that FDA plans to issue a consumer advisory as early as tomorrow (2/16/22). We have asked for a response on the request for recall by tomorrow (2/16) at noon EST.
- The firm continues to hold all powdered products produced between January 4 to present (the last clean in place cycle) that are still stored at the production facility.

Next Step

- FDA will issue our routine Outbreak Investigation Table on Thursday, 2/16/22. In the table, consistent with our routine practice, we will list that FDA is conducting an investigation into multiple C. sakazakii cases.
- Also, if Abbott declines to initiate a voluntary recall, FDA plans to issue a public Consumer Advisory tomorrow that warns consumers who have the Abbott brand Similac formula to avoid using products with specific lot codes and dates produced in Abbott's facility in Sturgis, Mi.
- CFSAN is also keeping the WIC Program up to date on our actions since 60% of infants in the WIC Program are using Abbott formulas and this may have implications for state WIC programs.
- FDA is also preparing a briefing paper to provide situational awareness to the White House Supply Chain Taskforce.
- FDA will return to the Sturgis facility, taking more samples including Zone 1 samples.

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

Frank Yiannas

Deputy Commissioner, Food Policy & Response

U.S. Food and Drug Administration

10903 New Hampshire Ave.

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From: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Sent: 2/17/2022 5:47:17 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbb07102b-MCMEEKINJ]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARN]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: RE: Update: Infant formula recall rollout

We came a long way with the firm in less than 24 hours. Thanks everyone for the strong collaboration!

Good outcome for some of the most vulnerable consumers that we serve.

Frank

Subject: RE: Update: Infant formula recall rollout

And the Abbott release has been issued: [Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant \(prnewswire.com\)](https://prnewswire.com).

From: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Sent: 2/19/2022 5:08:39 PM
To: McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARN]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Prater, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=291b4eab842148baba96df3bd8c31058-DPRATER]; Farrar, Jeff A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c862ce01b6714d4c9c5057306240469e-Jeff.Farrar]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
CC: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Food Safety Update #4 - Abbott Infant Formula, Recall and Investigation Status

FOOD SAFETY UPDATE

From the Office of Food Policy and Response



**U.S. FOOD & DRUG
ADMINISTRATION**

Internal, Privileged, & Confidential

As we begin the holiday weekend, we want to provide you with a brief update on the status of Abbott's infant formula recall and our investigation. As a reminder, the FDA has been working on an important investigation of

Cronobacter illnesses potentially associated with powdered infant formula (IF) manufactured by Abbott Nutrition in their facility located in Sturgis, MI.

Epi Summary

- The official epi status remains unchanged from the first update.
- There have been 4 infant illnesses reported to various FDA district offices between Sept 2021 to January 2022. It's reported that all 4 infants consumed powdered IF produced in Abbott Nutrition's facility in Sturgis, MI.
- Three (3) of the infants were ill due to *Cronobacter sakazakii* and one (1) due to salmonellosis. All 4 infants were hospitalized and *Cronobacter* may have contributed to the death of 1 case.
- On Wednesday, as *Cronobacter* is not a reportable disease, CDC asked States to report any illnesses of *Cronobacter*.
 - As of Friday, CDC had received 7 new reports of *Cronobacter* infections.
 - CDC is working through the States to determine if the infant formula consumed by the infants was made in the Sturgis facility.

Investigation Status

- On January 31, FDA initiated an inspection at the Abbott Nutrition facility in MI in response to consumer complaints received.
- As part of the inspection, FDA initiated environmental sampling in the firm's powdered IF manufacturing areas collecting swabs in Zone 2 areas of the facility.
- To date, **4 environmental subs** have been confirmed **positive for *C. sakazakii***. From those 4 subs, **17 isolates of *C. sakazakii*** have been whole genome sequenced and **4 different *C. sakazakii* strains** have been detected.
- Again, as *Cronobacter* is not a reportable disease, the States and CDC had limited visibility into these illnesses and only **1 clinical isolate** from one of the illnesses in their possession, as well as isolates of *Cronobacter sakazakii* recovered from an opened container of infant formula consumed by the infant (and materials used to reconstitute the powder).
- As of Friday, there has not been a match to the single clinical isolate retained by CDC.
- From the swabs taken by FDA, there are an additional **8 isolates of *C. sakazakii* pending WGS**, which we expect to complete this weekend. They too will be analyzed to determine if they match the clinical isolate.
- **Abbott** also independently found **two positives for *C. sakazakii*** on swabs taken at the same time as the FDA sampling. FDA received these isolates and WGS results are also pending.
- This week, FDA conducted additional sampling with a focus on Zone 1 areas that are now accessible given the firm's breakdown of equipment. Additional sampling, including sampling of retained lots, is planned for next week.

Noteworthy Developments

- As our investigation proceeded this past week, a review of the firm's internal records indicated Abbott had, in June 2020 and September 2019, **detected *Cronobacter sakazakii* in finished product** and discarded the contaminated lots in question.
- Thus, given the findings to date of:
 - a) four infant illnesses all with a link to IF produced in Abbott Nutrition's Sturgis, MI facility,

- b) several positive *Cronobacter sakazakii* results from environmental samples taken by FDA,
- c) adverse inspectional observations by FDA investigators, and
- d) the detection of *Cronobacter sakazakii* by the firm in both food and environmental samples

on Thursday, FDA issued an advisory informing consumers to not to use powdered infant formula produced in Abbott Nutrition's Sturgis, Mi facility. The firm also agreed to voluntarily recall powdered infant formula produced in their Sturgis, Mi facility.

- As of yesterday, most of major media outlets have covered the recall. Coverage has included FDA's key messages about the public warning, product recall information, and the agency's ongoing investigational efforts.
 - Two outlets, WSJ and Politico, asked questions related to the timeline of FDA's response. A timeline of events is being developed and reactive Q&A is being drafted for any further timeline-related questions.
 - NBC nightly news included aspects related to how the recall, unique formulations, and supply-chain issues are affecting consumers and their families.
 - We'll be closely monitoring for any reports of hoarding or widespread shortages related to the Abbott infant formula recall.

This remains a very fluid situation. As usual, we will keep you informed of any noteworthy developments.

Frank Yiannas

Deputy Commissioner, Food Policy & Response

U.S. Food and Drug Administration

10903 New Hampshire Ave.

Silver Spring, Maryland 20993

Tel: 301-796-4665

frank.yiannas@fda.hhs.gov

From: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Sent: 5/12/2022 9:28:14 AM
To: Singleton, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b70632897eee4a66a8e6bf7681210a85-Shannon.Chi]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]
CC: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: AF CD status update

thanks

From: Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Sent: Thursday, May 12, 2022 9:06 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: AF CD status update

All-

(b) (5)

Thanks,
Shannon

Shannon M. Singleton

Acting Assistant Deputy Chief Counsel for Litigation

FDA, Office of Chief Counsel

Office: 301-796-8717

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Shannon.Singleton@fda.hhs.gov

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From: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Sent: 5/12/2022 10:15:16 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: Fwd: URGENT BY 10:50 - White House Fact Sheet Input, POTUS Infant Formula

I suspect youve all seen this, but just to be sure

FY

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From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Sent: Thursday, May 12, 2022 9:04 AM
To: Yiannas, Frank; Mayne, Susan; Boon, Caitlin; Toerner, Joseph; Kavanaugh, Claudine; Hansen, Patricia A
Cc: Ramos, Melissa *; Smith-Dulley, Jasmine *; Hetlage, Daniel; Dooren, Jennifer; Butler, Kristine
Subject: URGENT BY 10:50 - White House Fact Sheet Input, POTUS Infant Formula

All – **Review/input needed no later than 10:50AM!** Attached is a draft fact sheet that the White House intend to release later this afternoon, after the President has individual calls with the CEOs of Walmart, Target, Reckett, and Gerber. I will also be concurrently live editing with the Commissioner's input. Please take a quick look for any major pieces of feedback. We don't want to bombard with line-edits, but rather any showstoppers/factual inaccuracies and essential pieces of information that must be added.

 [WH Infant Formula Factsheet FOR AGENCIES.docx](#)

Thanks,

Tara

Tara G. Rabin

Media Relations Director

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



From: Ladapo, Joseph [Joseph.Ladapo@flhealth.gov]
Sent: 5/13/2022 10:07:04 PM
To: sandy.benton-davis@usda.gov; stacy.dean@usda.gov; Willie.Taylor2@usda.gov; izra.brown@usda.gov; lilly.bouie@usda.gov
CC: Robert.M.Califf@fda.hhs.gov; Califf, Robert (OLD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ed636c1d744f9a83d2cbbf53ec891c-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Julia.C.Tierney@fda.hhs.gov; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; robertford@abbott.com; Robert.ford@abbott.com; Schepke, Kenneth A [Kenneth.Schepke@flhealth.gov]; Pasley, Cassandra [Cassandra.Pasley@flhealth.gov]; Jordan, Melissa Murray [Melissa.Jordan@flhealth.gov]; Khoury, Weesam [Weesam.Khoury@flhealth.gov]
Subject: [EXTERNAL] RE: IMMEDIATE ATTENTION REQUESTED: Infant Formula Shortages
Attachments: Florida's Letter to FDA- Formula Shortage 5-12-22[30].pdf

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.

Dear Deputy Under Secretary Dean –

We appreciate your correspondence.

However, Florida proactively responded to the initial recall to prepare for anticipated supply issues. All of the recommendations you outlined have already been initiated, but Floridians are not experiencing any relief or ease getting formula.

Per the letter we sent to the FDA on May 12, 2022, attached to this email, states deserve regular and consistent updates from the federal government regarding this life-threatening issue - which surpasses the WIC flexibilities your letter focus on.

Our questions remain:

1. What is the timeframe that Abbott's Sturgis facility will resume production? The company states upon initial approval from the FDA, manufacturing will take an additional six to eight weeks for formula to reach consumers.
2. How often will you be providing updates and through what channels? The communication from the federal government has been sporadic, and unnerving.
3. Will you be prioritizing medical specialty formula production for those who are most in need?

Additionally, Abbott Nutrition released information regarding how families, with a doctor recommendation, can receive certain medical specialty formulas that previously were on hold. What was the federal government's role in this? With mixed messages from multiple sources, families are not getting consistent or reliable information to subside concerns.

Florida looks forward to participating in your listening session and continuing to receive updates so we can serve our residents.

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

**Ron DeSantis**

Governor

Joseph A. Ladapo, MD, PhD

State Surgeon General

Vision: To be the **Healthiest State** in the Nation

May 12, 2022

Robert M. Califf, MD, MACC
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Springs, MD 20993

Sent via e-mail and U.S. Postal Service

Dr. Califf,

On February 17, 2022, the U.S. Food and Drug Administration (FDA) issued a warning and a voluntary recall on numerous powdered infant formula produced by Abbott Nutrition's facility in Sturgis, Michigan. As you know, this facility produces a majority of the formula supply for the United States and has since been shut down, causing baby formula supplies nationwide to dwindle.

The Florida Department of Health (Department) proactively contacted all retailers that accept Women, Infants, and Children (WIC) benefits to recommend ordering an alternative supply of powdered infant formula, when the initial recall was issued in February by Abbott Nutrition. The Department also serves medically complex children whose lives depend on medical specialty formula. While we found alternative products in an effort to off-set the shortage caused by the FDA's lack of oversight, the cost of these alternatives remains high, and the availability is low.

Floridians are worried about the lack of formula availability. Our agency is charged with the protection of public health and needs as much information as possible to continue serving our most vulnerable residents and prevent potentially catastrophic public health consequences.

As you know, the FDA has recently acknowledged the formula shortage, caused by its warning and recall. Time is of the essence to restart production at the Abbott facility, yet the FDA has failed to produce any preliminary findings necessary to begin the reopening process and update the nation on this issue.

As a father, doctor, and Surgeon General for the State of Florida, I respectfully request open channels of communication for routine updates on the expected time the supply chain will be impacted and the most viable path to resuming sufficient nationwide formula supplies.

We stand ready to assist in any capacity that we are able in order to expedite a resolution of this pressing problem for immunocompromised infants and their families across the great state of Florida and our blessed Nation.

Sincerely,

Joseph A. Ladapo, MD, PhD
State Surgeon General

cc Robert B. Ford, Chairman of the Board and Chief Executive Officer, Abbott

Florida Department of Health**Office of the State Surgeon General**

4052 Bald Cypress Way, Bin A-00 • Tallahassee, FL 32399

PHONE: 850/245-4210

FloridaHealth.gov**Accredited Health Department**
Public Health Accreditation Board

From: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Sent: 5/13/2022 8:13:32 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Baby Formula Powder availability

No worries.

Maybe think of it this way, percent in stock from a consumer's perspective means that what percentage of time, when a consumer wants to buy a very specific product (at the stock keeping unit level/UPC) at their local store or platform, is it available for purchase.

Does that help?

If a retailer carries 50 different infant formula products, and they have an in stock rate of 80%, then 40 different items are available, there are 10 (maybe the common Abbott lines) that are not available.

FY

From: Califf, Robert <RMC001@fda.hhs.gov>
Sent: Friday, May 13, 2022 8:06 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Baby Formula Powder availability

Frank, sorry—get one more step down to basic

% in stock must assume some normal amount of stock, or is it just a % of what has been ordered?

Sorry to be basic, but we really need to have an explanation that people can understand (and if I can understand it, maybe others can too)

rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>
Date: Thursday, May 12, 2022 at 10:36 PM
To: Robert Califf <RMC001@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Baby Formula Powder availability

The numbers are reported by IRI as a % in stock rate.

However, they use a formula to calculate it vs actually visiting stores. They use sales data per UPC and have developed a logarithm that assumes when expected sales are not seen, that means the item is out of stock. It's a pretty good proxy because going to thousands of stores is not practical.

This methodology is commonly used by groups like IRI and Nielsen. It's the gold standard for attempting to calculate in stock rates.

The method the company "data assembly" has been using is novel and majorly flawed.

Right now, I think Erika (as well as contacts in the WH) are thinking we put up the IRI expert to explain methodologies and let him cast shade on the Data Assembly metrics being reported by news outlets.

Frank

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From: Califf, Robert <RMC001@fda.hhs.gov>

Sent: Thursday, May 12, 2022 9:02:31 PM

To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: Re: Baby Formula Powder availability

Frank-- what do these numbers actually mean? 89% has what as the numerator and what as the denominator? I feel like these #s are being flung around by the press with no context and I want to be sure we have something like an FAQ that clarifies what the #s actually mean.

rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>

Date: Thursday, May 12, 2022 at 8:58 PM

To: Robert Califf <RMC001@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>

Subject: Baby Formula Powder availability

Rob/Janet

The in-stock rates being reported by some media outlets is based on data by a group called Data Assembly. They use a method that has a lot of bias and is flawed. They basically scrape websites to see if the top 200 infant formula SKUs are availability for pick-up primarily at two retailers (Walmart and Kroger). In fact, 55% of their data points are from Walmart yet Walmart doesn't have that market share. Plus, by only looking at the top 200 skus (many of which were ABBOTT's), they miss over 300 skus available of less popular brands

The best sources of data are either Neilson or IRI, who get sales data by the retailers under contact and report sales in an anonymized fashion. Take a look at the IRI chart below by week for in-stock infant formula at major retailers and drug chains.

Yes, there's been a 10% drop since the recall, but it's no we are nowhere near as bad as what has been ginned up in some of these stories. Plus, production volume and sales are higher now than pre-recall and the outlook is improvements every week. Plus, if Abbott Sturgis gets back up, the overall category can look back to pre-pandemic levels in a couple of month.

Erika and I have talked and she's working on messaging.

FY

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

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

From: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]
Sent: 5/15/2022 10:56:59 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: question

We're working on it. Certainly will be helpful for internal use and developing mitigation strategies.

Erica - I'm not sure daily updates will be useful for public facing representation, as the fluctuations may not be that revealing day to day. We'll just have to look at the data first and make a determination.

On it. More to come.

Frank

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From: Califf, Robert <RMC001@fda.hhs.gov>
Sent: Sunday, May 15, 2022 8:33 AM
To: Yiannas, Frank; Colonius, Tristan; Mayne, Susan; Jefferson, Erica; Tierney, Julia; Woodcock, Janet
Subject: Re: question

Infant formula, daily updates by state would be spectacular

rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>
Date: Saturday, May 14, 2022 at 7:42 PM
To: Robert Califf <RMC001@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, Erica Jefferson <Erica.Jefferson@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Subject: RE: question

Here's the link I promised to their more general dashboard. It may take a few seconds to load.

<https://indices.iriworldwide.com/covid19/?i=5>

As you will see, all categories of food have in-stock rates well below pre-pandemic levels. (everything is coded red, below 90%)

Again, seeing if we can stand up something for infant formula with daily updates.

FY

From: Califf, Robert <RMC001@fda.hhs.gov>

Sent: Saturday, May 14, 2022 6:10 PM

To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: Re: question

Frank, when you get up with them find out how granular and frequent the report should be. I feel like the more we can do to keep people apprised of where things stand, the sooner this will settle down—I know how hard everyone is working, but the media coverage is continuing to worry people, so we need to keep moving as quickly as we can.

rmc

From: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>

Date: Saturday, May 14, 2022 at 3:13 PM

To: Robert Califf <RMC001@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, Erica Jefferson <Erica.Jefferson@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Frank Yiannas <Frank.Yiannas@fda.hhs.gov>

Subject: Re: question

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From: Califf, Robert <RMC001@fda.hhs.gov>

Sent: Saturday, May 14, 2022 11:49:16 AM

To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: Re: question

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rmc

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Subject: question

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Sent: 5/14/2022 7:32:51 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
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Internal, Deliberative, Confidential

- I connected w IRI this evening. They can provide daily in-stock figures that will lag by a day or so. We're going to see if we can put something in place by Monday.

(b) (5)

- IRI talked to WSJ today and more media interviews planned for tomorrow

FY

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Sent: Saturday, May 14, 2022 6:10 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
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From: Dean, Stacy - OSEC, Washington, DC [Stacy.Dean@usda.gov]
Sent: 5/14/2022 8:59:42 AM
To: Ladapo, Joseph [Joseph.Ladapo@flhealth.gov]; Benton-Davis, Sandy - FNS [sandy.benton-davis@usda.gov]; Taylor, Willie - FNS [Willie.Taylor2@usda.gov]; Brown, Izra - FNS [izra.brown@usda.gov]; Bouie, Lilly - FNS [lilly.bouie@usda.gov]
CC: Robert.M.Califf@fda.hhs.gov; Califf, Robert (OLD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74ed636c1d744f9a83d2cbbf53ec891c-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Julia.C.Tierney@fda.hhs.gov; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; robertford@abbott.com; Robert.ford@abbott.com; Schepcke, Kenneth A [Kenneth.Schepcke@flhealth.gov]; Pasley, Cassandra [Cassandra.Pasley@flhealth.gov]; Jordan, Melissa Murray [Melissa.Jordan@flhealth.gov]; Khoury, Weesam [Weesam.Khoury@flhealth.gov]; Kriviski, Diane - FNS [diane.kriviski@usda.gov]; Long, Cindy - FNS [cindy.long@usda.gov]; Hard, Alison - FNS, Alexandria, VA [Alison.Hard@usda.gov]; Swerdlow, Deborah - OSEC, Washington, DC [Deborah.Swerdlow@usda.gov]
Subject: [EXTERNAL] RE: IMMEDIATE ATTENTION REQUESTED: Infant Formula Shortages

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.

Dr. Ladapo,

Thank you so much for your note. This is an incredibly difficult situation and you make an excellent point that we'll all be better positioned to address it if we have access to the best possible information. I'll regroup with the team and see what we can do within the federal family to better support you and your team.

Please feel free to contact me anytime.

Stacy

From: Ladapo, Joseph <Joseph.Ladapo@flhealth.gov>
Sent: Friday, May 13, 2022 10:07 PM
To: Benton-Davis, Sandy - FNS <sandy.benton-davis@usda.gov>; Dean, Stacy - OSEC, Washington, DC <Stacy.Dean@usda.gov>; Taylor, Willie - FNS <Willie.Taylor2@usda.gov>; Brown, Izra - FNS <izra.brown@usda.gov>; Bouie, Lilly - FNS <lilly.bouie@usda.gov>
Cc: Robert.M.Califf@fda.hhs.gov; Robert.Califf@fda.hhs.gov; Janet.Woodcock@fda.hhs.gov; Julia.C.Tierney@fda.hhs.gov; Julia.Tierney@fda.hhs.gov; Mark.Raza@fda.hhs.gov; Frank.Yiannas@fda.hhs.gov; robertford@abbott.com; Robert.ford@abbott.com; Schepcke, Kenneth A <Kenneth.Schepcke@flhealth.gov>; Pasley, Cassandra <Cassandra.Pasley@flhealth.gov>; Jordan, Melissa Murray <Melissa.Jordan@flhealth.gov>; Khoury, Weesam <Weesam.Khoury@flhealth.gov>
Subject: RE: IMMEDIATE ATTENTION REQUESTED: Infant Formula Shortages

Dear Deputy Under Secretary Dean –

We appreciate your correspondence.

However, Florida proactively responded to the initial recall to prepare for anticipated supply issues. All of the recommendations you outlined have already been initiated, but Floridians are not experiencing any relief or ease getting formula.

Per the letter we sent to the FDA on May 12, 2022, attached to this email, states deserve regular and consistent updates from the federal government regarding this life-threatening issue - which surpasses the WIC flexibilities your letter focus on.

Our questions remain:

1. What is the timeframe that Abbott's Sturgis facility will resume production? The company states upon initial approval from the FDA, manufacturing will take an additional six to eight weeks for formula to reach consumers.
2. How often will you be providing updates and through what channels? The communication from the federal government has been sporadic, and unnerving.
3. Will you be prioritizing medical specialty formula production for those who are most in need?

Additionally, Abbott Nutrition released information regarding how families, with a doctor recommendation, can receive certain medical specialty formulas that previously were on hold. What was the federal government's role in this? With mixed messages from multiple sources, families are not getting consistent or reliable information to subside concerns.

Florida looks forward to participating in your listening session and continuing to receive updates so we can serve our residents.

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From: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
Sent: 5/17/2022 7:43:16 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37466aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
Subject: One pager
Attachments: 20220517 Infant Formula One Pager.docx

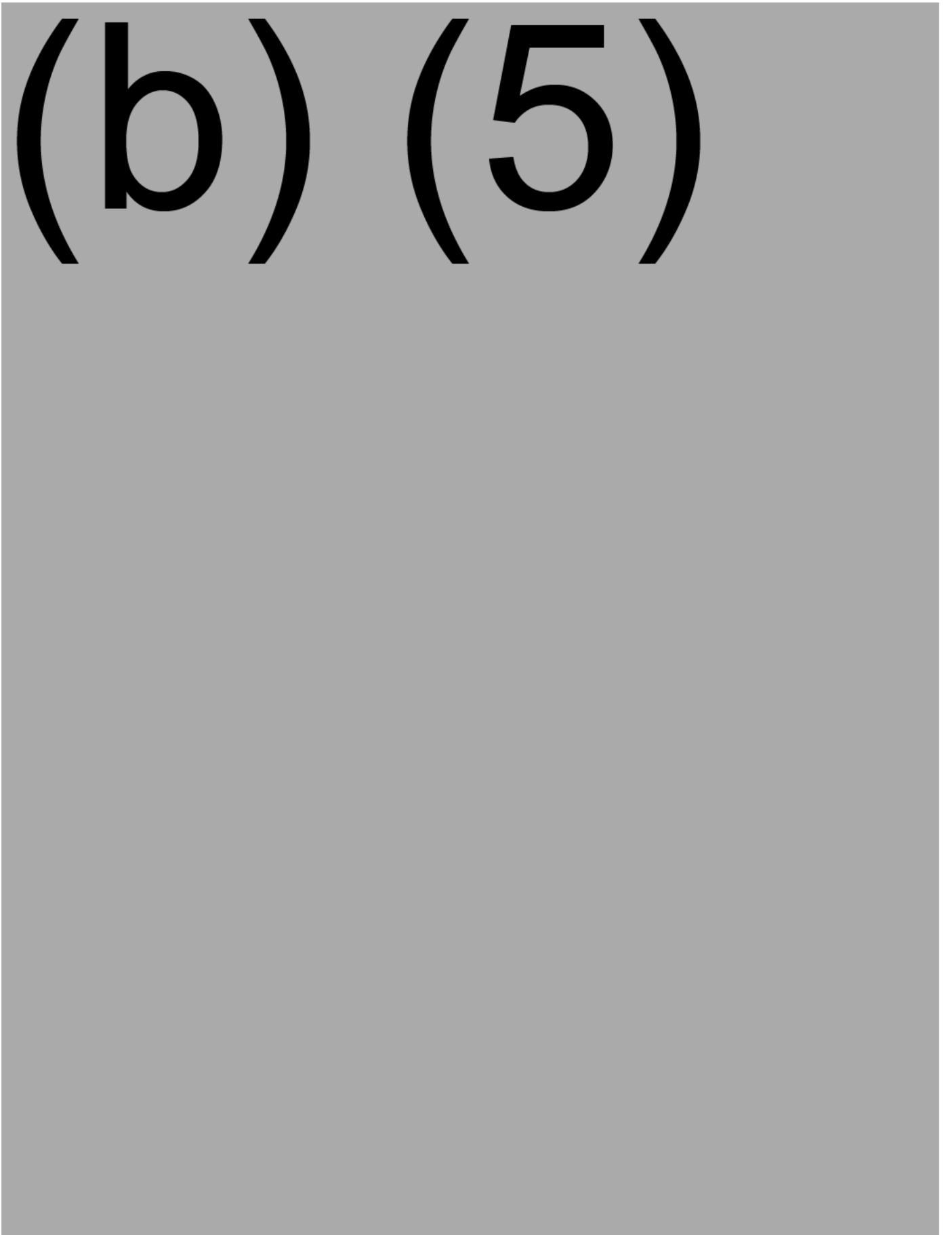
Friends,

Quite a day yesterday. I saw a team in high gear putting it all out for many days to get these key elements in place. I've tried to distill our key strategy down to one page based on what you've told me.. I realize that each element has many tactical components that will take a huge amount of work by people who are already at the max. If this is off course or there are major additional steps, please let me know, and feel free to edit.

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

rmc

(b) (5)



From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 5/13/2022 8:06:02 AM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: Draft Responses to Rep. DeLauro on Infant Formula


I think this is excellent. Thanks for putting in the work on it.

rmc

From: Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Date: Thursday, May 12, 2022 at 9:55 PM
To: Robert Califf <RMC001@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Cc: Julie Tierney <Julia.Tierney@fda.hhs.gov>
Subject: Draft Responses to Rep. DeLauro on Infant Formula

Hi,

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

For your review/input, if interested, the responses are here:  [Draft responses to Rep DeLauro.docx](#)

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

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



From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 5/14/2022 6:29:08 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
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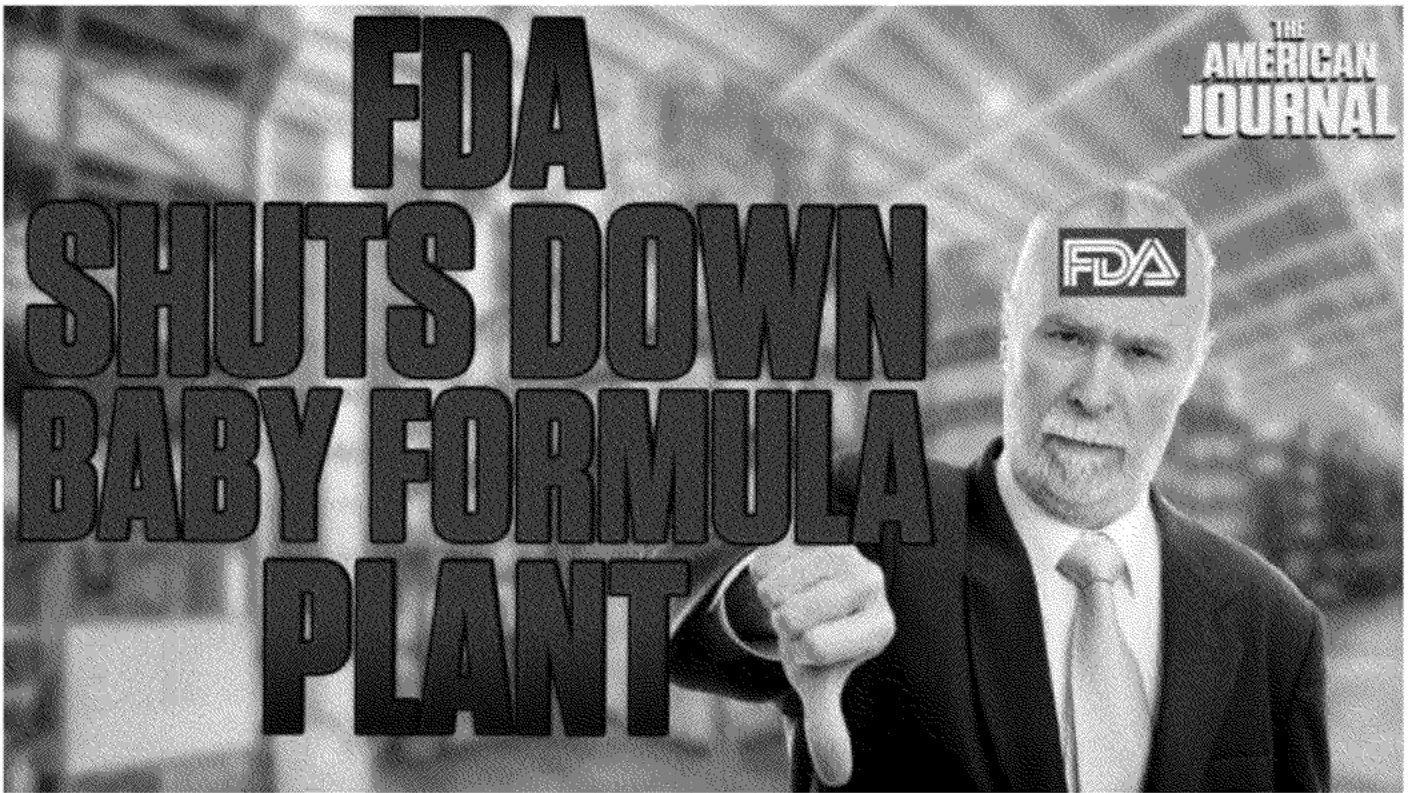
rmc

From: Jim Ainsworth (b) (6)
Sent: 5/12/2022 10:41:24 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Varnado, Martina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad1d1bc50f7941718b0feeb194cbaff1-Martina.Var]; Desai, Vid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91b722d8adf748aaa8e91f77ad37a272-Vidyut.Desa]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: [EXTERNAL] How The FDA Shut Down America's Largest Baby Formula Manufacturer

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How The FDA Shut Down America's Largest Baby Formula Manufacturer

The American Journal
March 12, 2022



Watch the report below in MP4 video:

<https://assets.infowarsmedia.com/videos/02014c15-8fcf-45af-9dc0-8cb037ff2dba.mp4>

From: Wasserman, Jill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A757986D59F4210A83E2DE2B6DD23A8-JILL.WASSER]
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Subject: Two Week Look through 5/27: Comms on Upcoming Agency Actions

Internal – Confidential -- Deliberative

For your awareness, below is a list of upcoming anticipated agency actions and their associated planned communications for the next two weeks (through Fri., May 27).

COMMISSIONER SPEAKING EVENTS

- 5/16: Remarks at American Association for Thoracic Surgery 102nd Annual Meeting (4 p.m., closed press)
- 5/16: Pre-recorded opening remarks at Pharmacokinetic Evaluation in Pregnancy Public Workshop (10 a.m., open press)
- 5/16: Pre-recorded fireside chat at Reagan-Udall Foundation for the FDA Annual Public Meeting (2:30 p.m., followed by an in-depth discussion with Janet Woodcock, Andi Lipstein Fristedt, James Sigg, Frank Yiannas, open press)
- 5/17: Keynote speech at 43rd Annual Meeting of the Society for Clinical Trials (5 p.m., open press)
- 5/22: Pre-recorded remarks at American Psychiatric Association Annual Meeting's session, Artificial Intelligence and the Future of Psychiatry (4 p.m., open press)

CONGRESSIONAL HEARINGS

1. 5/19: House Committee on Appropriations - Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee Hearing on the agency's Fiscal Year 2023 budget request (10 a.m., Dr. Califf will testify)
2. 5/25: House Committee on Energy and Commerce - Oversight and Investigations Subcommittee Hearing on infant formula shortages (time TBD; Janet Woodcock, Frank Yiannis and Susan Mayne will testify)

Monday, May 16

1. FDA authorizes home collection COVID test that can also detect the flu and RSV (Press Release, Social Media, Stakeholder Outreach)

Tuesday, May 17

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. FDA expands eligibility for Pfizer-BioNTech COVID-19 booster dose to individuals 5 through 11 years of age initiatives (Press Release, Social Media, Stakeholder Outreach)
3. Day 1: FDA & American College of Rheumatology Virtual Summit (CDER, 10 a.m. to 4 p.m.)

Wednesday, May 18

1. FDA encourages safe importation of infant formula and other flexibilities to further increase supply (Press Release, Media Advisory, Call & Script, Stakeholder Call, Responsive QAs, Social Media, Stakeholder Outreach)
2. FDA will communicate about the June 13 and June 15 public listening sessions for the menthol and cigar flavor proposed rules (Social Media)
3. Day 1: Science Advisory Board to the National Center for Toxicological Research 2021 Meeting (NCTR, 9 a.m. to 6:55 p.m.)
4. Day 2: FDA & American College of Rheumatology Virtual Summit (CDER, 10 a.m. to 3 p.m.)

Thursday, May 19

1. FDA limits the use of certain phthalates in food packaging and issues request for information for safety data and more information (FDA Roundup)
2. FDA publishes new guidance on temporary enforcement discretion policy that aims to increase safety information about dietary supplement marketplace (Press Release, Social Media, Stakeholder Outreach)
3. Day 2: Science Advisory Board to the National Center for Toxicological Research 2021 Meeting (NCTR, 9 a.m. to 12:30 p.m.)

Friday, May 20

1. FDA Roundup: Latest COVID and non-COVID information and news from FDA centers and offices on activities, efforts, guidance, and initiatives (Press Release, Social Media, Stakeholder Outreach)
2. Keynote remarks with QA at 16th Annual Personalized Medicine Conference (Janet Woodcock, 11:35 a.m., open press)

Week of May 16 // Tentative:

1. [REDACTED] (b) (5) (Press Release, Social Media, Stakeholder Outreach)
2. FDA enters consent decree with Abbott Nutrition requiring correction of safety issues to quickly resume infant formula production (Press Release, Social Media)
3. FDA updates medical devices reports for Philips breathing devices, including CPAP (Reactive Statement)
4. FDA urges drug manufacturers to develop risk management plans to promote a stronger, resilient drug supply chain (Statement, Social Media, Stakeholder Outreach)
5. FDA Develops Quality Management Maturity Framework for Drug Manufacturing Sites (FDA Voices by Patrizia Cavazzoni and Michael Kopcha)
6. FDA's "All-In" Approach to Enterprise Transformation (FDA Voices by Janet Woodcock and Meredith Chuk)
7. Coronavirus Q&A: Updates for Consumers (Consumer Update)
8. Know Your Treatment Options for COVID-19 (Consumer Update)
9. Vaccines and Babies (Video)

Monday, May 23

N/A

Tuesday, May 24

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

Wednesday, May 25

N/A

Thursday, May 26

1. FDA approves first treatment for eosinophilic esophagitis, a chronic immune disorder (Press Release, Social Media, Stakeholder Outreach)
2. FDA informs health care providers and laboratories about a cybersecurity vulnerability affecting software in two Illumina in vitro diagnostic devices and five research use only next generation sequencing instruments (Responsive QAs)

Friday, May 27

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

Week of May 23 // Tentative:

1. Generic Drugs Undergo Rigorous FDA Review (Consumer Update)
2. CoolSculpting: Know Before You Go (Consumer Update)

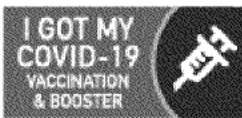
Best,

Jill Wasserman, MPH

Rollout Coordinator, Office of External Affairs

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From: Malais, Tanya [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F13699D67E9C491EAB11150A04F7FC6C-TANYA.MALAI]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a91adbf75534c9991ff1b909cbba546-Nina.Zimdah]; Christin, Charlotte - OC

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 5/15/2022 3:52:25 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: RE: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

Thanks. I'll see if we can fine-tune that sentence – lots of people had fingerprints on it. ☺

From: Califf, Robert <RMC001@fda.hhs.gov>
Sent: Sunday, May 15, 2022 3:51 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Subject: Re: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

I'm ok with this—looks like it gets all the key points across quite well. The sentence about our “custom definition” is awkward and I'm not sure what it meant, Otherwise it'll be interesting to see what HHS wants to change.

rmc

From: Michael Felberbaum <Michael.Felberbaum@fda.hhs.gov>
Date: Sunday, May 15, 2022 at 2:09 PM
To: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Robert Califf <RMC001@fda.hhs.gov>
Cc: Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Andi Fristedt <Andi.Fristedt@fda.hhs.gov>, Erica Jefferson <Erica.Jefferson@fda.hhs.gov>, "Rabin, Tara G." <Tara.Rabin@fda.hhs.gov>
Subject: RE: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

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

Companies seeking to import product 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 imports. The FDA will carefully continue to monitor supply chain data to determine how long to exercise enforcement discretion.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, May 15, 2022 2:05 PM

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Califf, Robert <RMC001@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>

Subject: Re: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

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

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Sent: Sunday, May 15, 2022 1:52:30 PM

To: Califf, Robert <RMC001@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>;

Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: FOR RMC REVIEW ASAP: Formula Importation and Consent Decree Press Releases

Good afternoon Dr. Califf,

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

Thanks!

Michael

Michael Felberbaum

Assistant Commissioner for Media Affairs

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-9548 / Cell: (b) (6)

michael.felberbaum@fda.hhs.gov



**U.S. FOOD & DRUG
ADMINISTRATION**



From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 5/19/2022 8:36:18 AM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Thomas, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a2c3bbc2bd0426bb3dd8e1ef7ec3686-Jacqueline.]
Subject: 5/19, Agenda: Biweekly OPLIA Meeting with the Commissioner
Attachments: 1530-Biweekly OPLIA Meeting Agenda_05.19.2022.docx

Good morning,

Attached please find the agenda for reference at today's "3:30pm - Biweekly OPLIA Meeting with the Commissioner".

Thank you,

Jakea Copeland

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



Biweekly OPLIA Meeting with the Commissioner

Thursday, May 19, 2022 – 3:30-3:55pm

Virtual/Zoom

Materials: none

AGENDA

1. OMB follow-up
2. OTC hearing aids rule
3. IGA update
4. Infant formula authorities
5. Durbin update
6. Upcoming leave

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 5/19/2022 8:43:54 AM
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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]
CC: Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: Re: Sharing: 5/18 -- Update on Infant Formula Media Activities

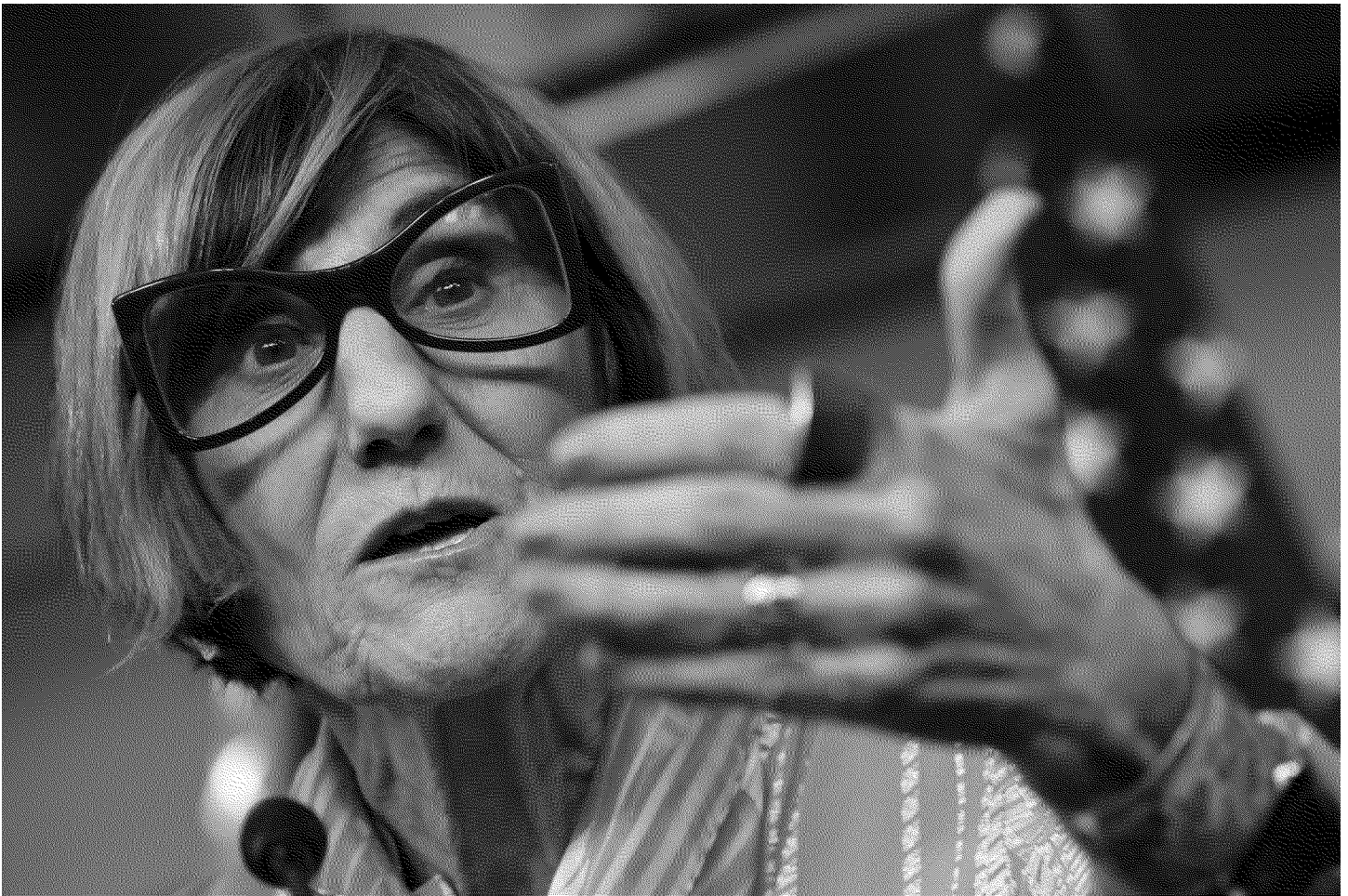
Here's Bloomberg story, basically a curtain raiser for the hearing and what DeLauro is expected to raise.

<https://www.bloomberg.com/news/articles/2022-05-19/top-house-democrat-set-to-grill-fda-chief-on-formula-plant-plans>

‘They Lied’: Abbott’s Formula Deal With FDA Stirs Democrat’s Ire

Agency hasn’t addressed whistle-blower’s claims, DeLauro says Abbott says there’s no link between its formula, infections

Anna Edney May 19, 2022, 5:00 AM EDT



Rosa DeLauro *Photographer: Ting Shen/Bloomberg*

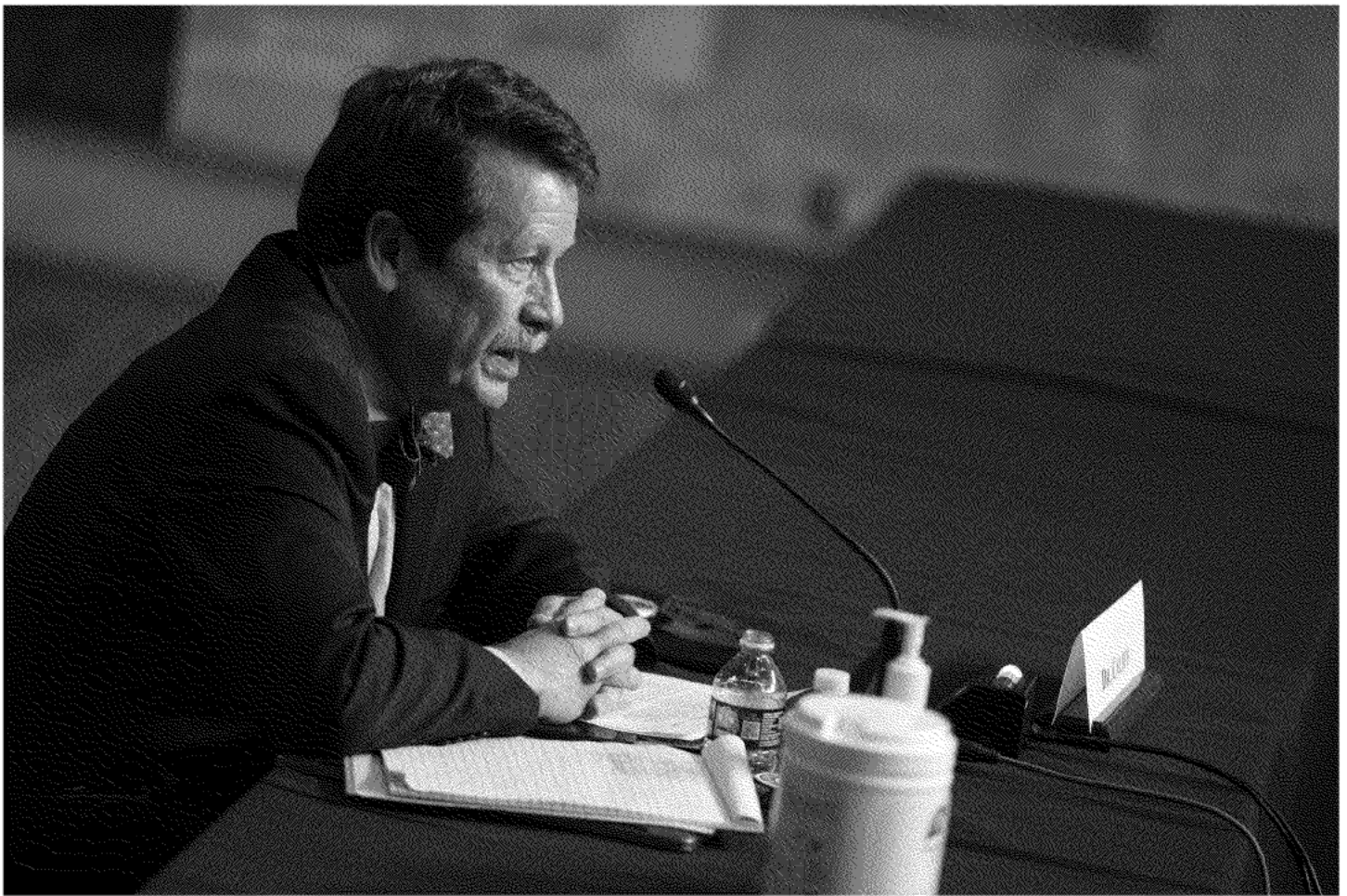
A leading House Democrat plans to grill the Food and Drug Administration's chief about plans to reopen an Abbott Laboratories infant formula plant without first addressing a whistle-blower's allegations.

House Appropriations Chairwoman Rosa DeLauro said she wants to know why FDA Commissioner Robert Califf entered an agreement that will allow formula production to resume at Abbott's plant in Sturgis, Michigan. While Abbott is facing fallout from sickness in four babies given infant formula in recent months, DeLauro is concerned that the agency hasn't dealt with the whistle-blower's report of earlier quality lapses and falsified records at the company's plant.

"They lied," DeLauro, a Connecticut Democrat, said in an interview Wednesday. "They knowingly sold a product that was contaminated. I want to know the reasons why the FDA thinks it's safe enough to reopen."

Abbott said in a statement that it's still reviewing the whistle-blower's report and the former employee "was dismissed due to serious violations of Abbott's food safety policies."

"We empower our employees to identify and report any issues that could compromise our product safety or quality, which comes before any other considerations," the company said.



Food and Drug Administration Commissioner Robert Califf

Photographer: Sarah Silbiger/Bloomberg

In a hearing Thursday, DeLauro will get a chance to question Califf on a key point in the nationwide shortage of infant formula that's rocked both parents and Congress. While formula makers say the pandemic disrupted their supply chains, the closure of the Abbott plant amid a major recall earlier this year made the shortfall a crisis, prompting President Joe Biden on Wednesday to invoke the Defense Production Act to boost supplies.

The hearing where Califf is scheduled to appear is focused on FDA's fiscal 2023 budget request. His opening statement on the committee's website mentions infant formula only once.

Under Scrutiny

Abbott has been under scrutiny since four babies who consumed formula made at its plant were infected with cronobacter, and two of them died, leading to the recall. The FDA said it was no longer investigating reports of illnesses linked to the product, without providing information on what it found.

Abbott has said there's no conclusive evidence linking its products to the infections, and analysis of the bacterial strains that sickened infants doesn't match those found in its plant.



Abbott's Sturgis, Michigan plant

Photographer: Jeff Kowalsky/AFP/Getty Images

The whistle-blower, an anonymous former Abbott employee, claimed that during a 2019 inspection, plant workers kept FDA staff from discovering evidence regarding a batch of formula that had tested positive for microorganisms. Abbott workers destroyed a portion of the batch without testing the rest before it was distributed, according to the report.

The former employee described a culture of cronyism at the plant that turned a blind eye to many problems, including an ongoing issue with seams in cans of infant formula. Powdered formula sometimes appeared in the seams of cans at the plant, meaning they weren't sealed tight, allowing moisture and bacteria to enter, according to the report.

[Read More: Biden Rushes to Free Up Baby Formula Constraints as Uproar Grows](#)

More recently, the agency didn't send inspectors to Abbott's plant until the end of January and then recalled formula made there in February, five months after the agency was alerted to the first case of a sickened infant. DeLauro has asked the Department of Health and Human Services Inspector General to investigate the FDA's response to the situation.

The whistle-blower gave the report to FDA officials in October. At that time, the agency had received at least one report of an infant who fell ill from *cronobacter* after being fed with

formula from Abbott's plant. FDA officials didn't interview the whistle-blower until December, DeLauro said.

September Inspection

DeLauro released the report shortly after receiving it last month. The agency hasn't given her an update on whether it's made a determination about the allegations, she said.

The FDA declined to comment on its assessment of the allegations because they're part of a commitment the agency has made to evaluate its policies around illnesses and recalls related to infant formula once the immediate crisis around supply is resolved, Tara Rabin, a spokeswoman said.

[Read More: Tainted Baby-Formula Risk Was Seen Months Before Abbott's Recall](#)

The latest in global politicsGet insight from reporters around the world in the Balance of Power newsletter.

Califf may also face questions about a routine FDA inspection of the Michigan plant that began Sept. 20, the same day Minnesota officials reported the first infant sick with *Cronobacter* to the agency. Inspectors found records detailing five instances of positive tests for *Cronobacter* in environmental, non-food samples from the plant from January 2019 to August 2021, [according](#) to a detailed inspection report obtained by Bloomberg.

They also reported that Abbott had found *Cronobacter* in finished infant formula in 2019 and 2020. The September *Cronobacter* findings weren't included in a summary of the inspection the FDA released publicly.

The Centers for Disease Control and Prevention closed an investigation into the four cases and Abbott's formula on May 12, saying that no further infections had emerged. Califf said Monday that it was too early to tell whether there's a link between the product and the illnesses.

"There are many factors involved in this investigation and we're just not in a position yet to make any definitive statements," he said. The FDA said April 1 that it set up an incident management group to work on supply-chain and food safety issues.

Stepped-Up Oversight

The agreement reached Monday with the US will allow Abbott to resume making formula in Michigan under stepped-up oversight, once the FDA gives its okay. The company said then that it anticipates restarting the plant in two weeks, and that it would take six to eight weeks to get formula made there on stores shelves.

DeLauro said she's sure she isn't the only member with formula-related questions for the FDA chief.

Califf is also set to face lawmakers May 25 at a House Energy & Commerce oversight panel hearing investigating the FDA's slow response. An Abbott executive is also scheduled to

testify before the panel the same day as well as executives from the other two main infant formula suppliers in the US, Reckitt Benckiser Group PLC and Nestle SA.

From: Califf, Robert <RMC001@fda.hhs.gov>

Sent: Wednesday, May 18, 2022 9:11:04 PM

To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>

Subject: Re: Sharing: 5/18 -- Update on Infant Formula Media Activities

I'm not sure how you guys are still going. Thanks. This one tonight from WaPo really bothered me because I expected better—they cite the inaccurate 40% # and claim that Canada is replete with formula—complete wrong and I have pictures from friends and family to prove it!

<https://www.washingtonpost.com/opinions/2022/05/18/how-fix-baby-formula-crisis/>

I hate it when our best are not thorough!

rmc

From: Erica Jefferson <Erica.Jefferson@fda.hhs.gov>

Date: Wednesday, May 18, 2022 at 9:03 PM

To: Robert Califf <RMC001@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Andi Fristedt <Andi.Fristedt@fda.hhs.gov>, "Safford, Melissa" <Melissa.Safford@fda.hhs.gov>, Emily Helms Williams <Emily.HelmsWilliams@fda.hhs.gov>, Maren McBride <Maren.McBride@fda.hhs.gov>, Kimberlee Trzeciak <Kimberlee.Trzeciak@fda.hhs.gov>

Cc: Michael Felberbaum <Michael.Felberbaum@fda.hhs.gov>, "Rabin, Tara G." <Tara.Rabin@fda.hhs.gov>

Subject: Sharing: 5/18 -- Update on Infant Formula Media Activities

Good evening all,

Providing a update on multiple media inquiries that we are working on and tracking.

New York Times – expected to run as soon as this weekend

- As noted last night, they are working on an in-depth story on the events leading up to the current infant formula situation. It is basically a timeline story. She is exploring, among other things, the history of issues with the Sturgis plant, inspections and overall dynamics with Cronobacter (e.g. only 'reportable' in one state)? The reporter is reviewing the redacted 483s and EIRs and we are working with ORA and CFSAN on specific questions to the reporter's questions.
- We are also working to address the reporter's question about our 2014 final rule on CGMPs for infant formula, which discusses Cronobacter testing. While she hasn't confirmed, it appears she could be pursuing the narrative laid out in [this story](#), which paints a picture of lobbying influence on the rule that weakened our Cronobacter testing requirements. Per the team, the reporter has referred to it as "the '14 regulations battle." After speaking with SMEs, this may not be exactly accurate and our response will explain that our rule was based on science, is in alignment with the WHO and CODEX recommendations, and that industry comments were taken into consideration as part of the required

regulatory process with only changes being made that were grounded in science and necessary to meeting public health needs.

- Finally, Frank has agreed to do a background interview with the reporter tomorrow morning Frank to discuss the size of the samples taken - less than a pound - that might be from a 50,000 pound lot and how it's hard to draw conclusions from a sample of this size.

Bloomberg – expected tomorrow before the hearing begins

- Has been working on a multi-part, longer form story related to timeline, 483s, and whistleblower events leading up to today.
- The reporter has requested details on FDA's outcome/findings related the whistleblower complaint. We have noted that this is part of an ongoing investigation. The reporter has pushed up on why we can disclose 483s, but not outcomes of the whistleblower complaint. In our response back to her we have noted that all 483s represent inspectional observations and do not constitute final FDA determinations of whether any condition was or is in violation of the Federal Food, Drug, and Cosmetic Act or any of its implementing regulations.

CNN – expected as soon as Friday

- Asking if FDA received any reports of adverse outcomes related to the formula shortage. Story regarding children hospitalized in Tennessee who were unable to access formula.

Reuters – currently unknown, could follow tomorrow's hearing

- The reporter followed up after hearing at a Rep. DeLauro news conference that she was told there were only 9 people at the FDA who could review infant formula product submissions for approval. He asked for FDA to comment on our staffing for inspections.

Wall Street Journal – expected tomorrow

- FDA budget requests for the Foods program.

We will share articles as they publish.

Thanks to Tara, Michael and Foods media team for all their work over the past several weeks. It's definitely been an all hands on deck approach.

Erica

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



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



From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 5/19/2022 9:11:34 AM
To: 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]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: FW: CNN on Children Hospitalizations Due to Shortage

Just for awareness; our reporting systems have not identified any shortage-related adverse events. Details below.

From: Choiniere, Conrad <Conrad.Choiniere@fda.hhs.gov>
Sent: Thursday, May 19, 2022 9:08 AM
To: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>
Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>; Nolan, Nichole <Nichole.Nolan@fda.hhs.gov>
Subject: Re: CNN on Children Hospitalizations Due to Shortage

From FCIC:

All – out of the 344 Infant Formula related cases, received since February 17, through today, none are specific to Children Hospitalizations due to the shortage. The 15 shortage related questions range from suggestions for alternatives, like using goat milk to asking about using products from Europe to speeding up approval of other manufactures infant formula to what is the government doing about this shortage.

From CAERS:

We do not have any related reports for anyone becoming ill due to infant formula shortages.

We are checking with the National Consumer Complaint coordinator in case any recent reports have come into their system that would not yet be in our system and will let you know if they find anything.

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Wednesday, May 18, 2022 5:48:11 PM
To: Choiniere, Conrad <Conrad.Choiniere@fda.hhs.gov>; Das, Sharmi <Sharmi.Das@fda.hhs.gov>; Price, Deborah S <Deborah.Price@fda.hhs.gov>
Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Pillsbury, Laura <Laura.Pillsbury@fda.hhs.gov>
Subject: FW: CNN on Children Hospitalizations Due to Shortage

Let me know if questions but this is in relation to two infants who were hospitalized after being switched off the formula they had as they could not get that. If we hear about any shortage related adverse events, please send to the email address copied here and cc me as well.

We are looking at a different mechanism for health care providers that would likely involve IFMFS.

Thanks!
Susan

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>

Sent: Wednesday, May 18, 2022 5:38 PM

To: Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Koontz, Devin <Devin.Koontz@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>

Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Pfaeffle, Veronika <Veronika.Pfaeffle@fda.hhs.gov>; Goodwin, Janell <Janell.Goodwin@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Mangia, Julia <Julia.Mangia@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>; Kelly, Susan <Susan.Kelly@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>

Subject: RE: CNN on Children Hospitalizations Due to Shortage

Thanks, Joe. Just reupping this question to the group again - does CFSAN track/accept such complaints via CARES for example? Or is the key takeaway that we don't officially track reports of supply related adverse events related to infant formulas, but that we have heard about them through the grapevine?

From: Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>

Sent: Wednesday, May 18, 2022 5:21 PM

To: Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; Koontz, Devin <Devin.Koontz@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>

Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Pfaeffle, Veronika <Veronika.Pfaeffle@fda.hhs.gov>; Goodwin, Janell <Janell.Goodwin@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Mangia, Julia <Julia.Mangia@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>; Kelly, Susan <Susan.Kelly@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>

Subject: RE: CNN on Children Hospitalizations Due to Shortage

Hope this is not too late - see my addition below.

Thanks,
Joe

From: Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>

Sent: Wednesday, May 18, 2022 4:19 PM

To: Koontz, Devin <Devin.Koontz@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>

Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Pfaeffle, Veronika <Veronika.Pfaeffle@fda.hhs.gov>; Goodwin, Janell

<Janell.Goodwin@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Dooren, Jennifer
<Jennifer.Dooren@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Mangia, Julia
<Julia.Mangia@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>; Kelly, Susan
<Susan.Kelly@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>

Subject: RE: CNN on Children Hospitalizations Due to Shortage

Just one note: FDA communicated to Abbott on April 20, and again on April 22, and then once again on April 28, that FDA was willing to work with them on a case-by-case basis to release product falling into the specialty/metabolic category. April 29 was the day that we communicated this to the public as well.

From: Koontz, Devin <Devin.Koontz@fda.hhs.gov>

Sent: Wednesday, May 18, 2022 4:13 PM

To: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>

Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Pfaeffle, Veronika <Veronika.Pfaeffle@fda.hhs.gov>; Goodwin, Janell <Janell.Goodwin@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Mangia, Julia <Julia.Mangia@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>; Kelly, Susan <Susan.Kelly@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>

Subject: RE: CNN on Children Hospitalizations Due to Shortage

ORA has no concerns.

From: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>

Sent: Wednesday, May 18, 2022 2:07 PM

To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Harris, Stic <stic.harris@fda.hhs.gov>; Stearn, Douglas <Douglas.Stearn@fda.hhs.gov>; Irvin, Kari <Kari.Irvin@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>

Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>; Pfaeffle, Veronika <Veronika.Pfaeffle@fda.hhs.gov>; Goodwin, Janell <Janell.Goodwin@fda.hhs.gov>; ORA Press <ORAPress@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Newhart, Corinne <Corinne.Newhart@fda.hhs.gov>; Mangia, Julia <Julia.Mangia@fda.hhs.gov>; Smith-Dulley, Jasmine * <Jasmine.Smith-Dulley@fda.hhs.gov>; Kelly, Susan <Susan.Kelly@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>

Subject: CNN on Children Hospitalizations Due to Shortage

All – CNN is asking if FDA received any reports of adverse outcomes related to the formula shortage. I suspect they are also driving at the same story NYT published this morning with regarding to children hospitalized in Tennessee. Pulled language from information we received in OEA from Frank earlier. Please let me know if any questions/concerns before we proceed at 5pm.

Thanks,

Tara

Question: Has FDA received any reports of adverse outcomes related to the formula shortage?

Answer (from Frank's doc):

(b) (5)

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: 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: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: You've joined the 2022 Infant Formula IMG group

Welcome Email



Work Brilliantly Together



Welcome to the 2022 Infant Formula IMG Group

OEO's Infant Formula IMG Response Page

Private group with 72 members



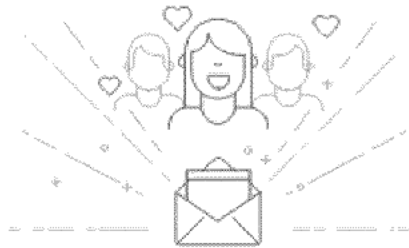
[View group in Outlook](#)

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.

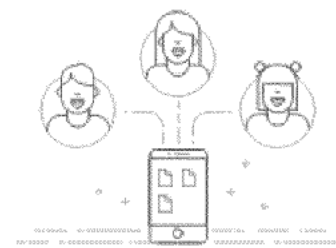
Follow in inbox

Follow in inbox



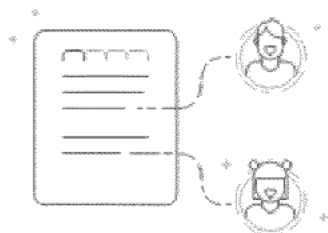
Get the conversation rolling

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



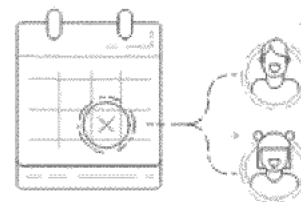
Keep things together

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.



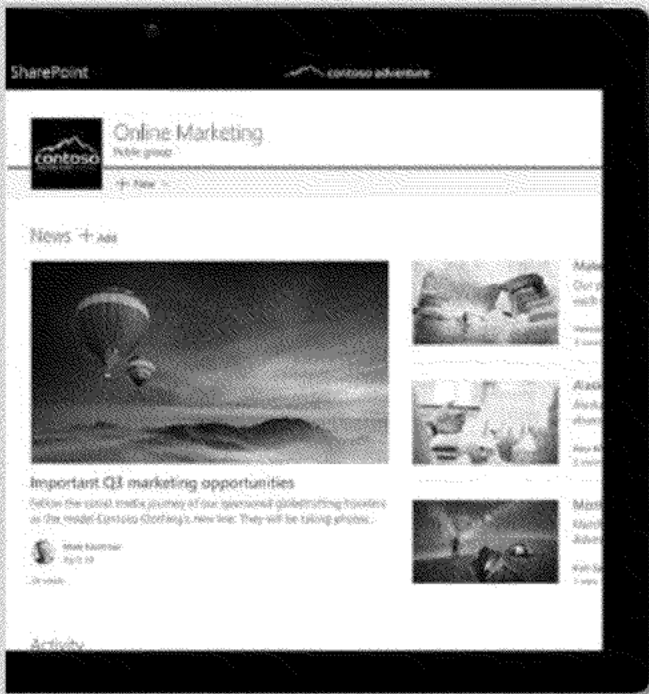
Collaborate with your group across Microsoft 365

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 Corporation
One Microsoft Way
Redmond, WA 98052 USA

You are receiving this email because you have subscribed to Microsoft 365.
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From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 5/17/2022 9:15:47 AM
To: Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Coli]; 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]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Draft Standing Agenda for Daily Formula Update

It does for me. Thanks Tristan.

Erica

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 9:15 AM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Califf, Robert <RMC001@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Draft Standing Agenda for Daily Formula Update

Does this work for a standing agenda for these daily formula updates? We will likely extend these to 20 minute meetings to ensure we have time.

- Short Term Supply of Formula (5 min)
 - Domestic (including Sturgis restart)
 - Imports
- Short Term Supply of Specialty Metabolics (5 min)
- Communications + External Engagements (5 min)
- Long Term Supply Fixes (5 min)

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

Office of the Commissioner

O: 301.796.2624 | M: (b) (6)



From: Trzeciak, Kimberlee [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B24F98D119FA4FA1B04704E9A3A0B3F3-KIMBERL.TRZ]
Sent: 5/17/2022 12:13:46 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: RESPONSE NEEDED: E&C Witness Request

Thank you. I apologize for the last minute shuffle.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 11:53 AM
To: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Subject: RE: RESPONSE NEEDED: E&C Witness Request

Talked to Rob, fine for him to be the witness. jw

From: Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 11:14 AM
To: Califf, Robert <RMC001@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RESPONSE NEEDED: E&C Witness Request

Dr. Califf and Dr. Woodcock –

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

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

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

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

Please let us know how you would like to proceed.

Thanks,
Kim

Kimberlee Trzeciak
Associate Commissioner for Legislative Affairs

Office of Legislation
U.S. Food and Drug Administration

(b) (6)
kimberlee.trzeciak@fda.hhs.gov

From: Wulff, Kacey (OS/ASPR/IO) [Kacey.Wulff@hhs.gov]
Sent: 5/20/2022 5:13:47 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cha, Stephen S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38f075dd58f14eb0a5d405cdcf094eb3-HHS-Stephen]
Subject: follow up with Sean

Hi all,

Sean requested a follow up on infant formula asap – I just sent an invite for 5:30pm. Here's the zoom:

<https://hhs.gov.zoomgov.com> (b) (6)

Thanks,
Kacey

From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 5/20/2022 3:52:34 PM
To: Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; 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]; Toerner, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=042f3cdd9e89494ea8977f6be4b2b9a7-TOERNERJ]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95dfa06e432-Jennifer.Do]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
Subject: RE: TIME-SENSITIVE // INPUT NEEDED: IF Comms [POSSIBLY] TODAY and MONDAY

+ Tristan and Julie

From: Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>
Sent: Friday, May 20, 2022 3:51 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>
Cc: Califf, Robert <RMC001@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Subject: RE: TIME-SENSITIVE // INPUT NEEDED: IF Comms [POSSIBLY] TODAY and MONDAY

Updates on ED letters:

Kendall Nutricare is not ready, we are still reviewing but it looks promising. Earliest is Monday late

Bubs Australia received a red flag on review today and we have to f/u with the company. Please remove from your list for now.

Claudine

Claudine Kavanaugh, PhD, MPH, RD
Director Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
FDA

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Friday, May 20, 2022 3:46 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>
Cc: Califf, Robert <RMC001@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Subject: TIME-SENSITIVE // INPUT NEEDED: IF Comms [POSSIBLY] TODAY and MONDAY
Importance: High

All,

Michael, Tara and I just met to review the current state of play as we understand it and map out comms.

POSSIBLY TODAY: Friday, May 20th

Danone (Nutricia)

- We have confirmed that the Danone enforcement discretion letter was sent earlier today.
- We just spoke to the head of comms for Danone who is OK with us tweeting, but needs to run our proposed tweets (below) through the appropriate channels within the company. She has requested we hold until Saturday or Monday. The tweets would be pushed out from the FDA Twitter account (Retweeted by Drs. Califf, Woodcock and Frank Y.)

FOR REVIEW:

(b) (5)

(b) (5)

#

Is there anything missing from the list of current product that we are tracking? (b) (5)

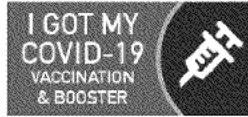
so we are not including that here as that is a separate workstream.

Thank you.
Erica

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



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



From: McMeekin, Judith [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D824F07697784FCB9ECE28CBBA07102B-MCMEEKINJ]
Sent: 5/20/2022 3:58:02 PM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: Timeline Meeting Monday

Yes I can be at WO on Monday, thanks

Get Outlook for iOS

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Thursday, May 19, 2022 8:31:21 PM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Timeline Meeting Monday

Yes I can be at WO on Monday.

Susan

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Thursday, May 19, 2022 8:18 PM
To: McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Timeline Meeting Monday

Internal/confidential/draft

Hi -

Dr. Califf would like us to prioritize meeting as a small principals' group Monday to sync on saying more on the timeline.

There would be a lot of value for us all being in the room together. Frank and Susan, I understand y'all will already be coming to WO for the hearing that is on Wednesday, as well as some prep ahead of that.

Attached is one of the more comprehensive draft timelines I've seen put together, but I know it may not be fully cleared or represent consensus. However, we critically need a crisp, truthful, and cohesive narrative for external audiences.

I know there's a lot going on and Rob's schedule is very in flux with infant formula, but this is a priority to land Monday.

Thank you,
Tristan

Tristan Colonius, DVM, MPA, DACVPM

Acting Deputy Chief of Staff

Office of the Commissioner

O: 301.796.2624 | M: (b) (6)

FDA U.S. FOOD & DRUG
ADMINISTRATION



From: Jefferson, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BC0BD0F8766484B803F584EB491ACE6-ERICA.JEFFE]
Sent: 5/20/2022 3:53:04 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Toerner, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=042f3cdd9e89494ea8977f6be4b2b9a7-TOERNERJ]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Kavanaugh, Claudine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beckerman, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
Subject: RE: TIME-SENSITIVE // INPUT NEEDED: IF Comms [POSSIBLY] TODAY and MONDAY

+ Tristan and Julie

From: Califf, Robert <RMC001@fda.hhs.gov>
Sent: Friday, May 20, 2022 3:48 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Kavanaugh, Claudine <Claudine.Kavanaugh@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Dooren, Jennifer <Jennifer.Dooren@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Subject: Re: TIME-SENSITIVE // INPUT NEEDED: IF Comms [POSSIBLY] TODAY and MONDAY

The tweets LGTM

rmc

From: Erica Jefferson <Erica.Jefferson@fda.hhs.gov>

Date: Friday, May 20, 2022 at 3:45 PM

To: Frank Yiannas <Frank.Yiannas@fda.hhs.gov>, Susan Mayne <Susan.Mayne@fda.hhs.gov>, "Toerner, Joseph" <Joseph.Toerner@fda.hhs.gov>, Caitlin Boon <Caitlin.Boon@fda.hhs.gov>, "Kavanaugh, Claudine" <Claudine.Kavanaugh@fda.hhs.gov>, Mark Raza <Mark.Raza@fda.hhs.gov>, "Beckerman, Peter" <Peter.Beckerman@fda.hhs.gov>

Cc: Robert Califf <RMC001@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Michael Felberbaum <Michael.Felberbaum@fda.hhs.gov>, "Rabin, Tara G." <Tara.Rabin@fda.hhs.gov>, "Dooren, Jennifer" <Jennifer.Dooren@fda.hhs.gov>, "Kimberly, Brad" <Brad.Kimberly@fda.hhs.gov>

Subject: TIME-SENSITIVE // INPUT NEEDED: IF Comms [POSSIBLY] TODAY and MONDAY

All,

Michael, Tara and I just met to review the current state of play as we understand it and map out comms.

(b) (5)

(b) (5)

Is there anything missing from the list of current product that we are tracking? (b) (5)

Thank you.

Erica

Erica V. Jefferson (she/her)

Associate Commissioner for External Affairs

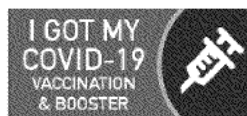
U.S. Food and Drug Administration

Tel: 240-702-3994

erica.jefferson@fda.hhs.gov



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



From: Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]
Sent: 5/21/2022 12:18:20 PM
To: Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]
CC: Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Trzeciak, Kimberlee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24f98d119fa4fa1b04704e9a3a0b3f3-Kimberl.Trz]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: MASTER DOC - Tough Q&A

Please disregard mine – Tristan’s combines OL’s with Dr. Califf’s and is the one we should edit.

From: Mayne, Susan <Susan.Mayne@fda.hhs.gov>
Sent: Saturday, May 21, 2022 12:12 PM
To: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Califf, Robert <RMC001@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Cc: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: MASTER DOC - Tough Q&A

We have two sharepoint sites now and documents have different names; which one should we edit?

From: Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Sent: Saturday, May 21, 2022 12:10 PM
To: Califf, Robert <RMC001@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Cc: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: MASTER DOC - Tough Q&A

Voilà!

From: Califf, Robert <RMC001@fda.hhs.gov>
Sent: Saturday, May 21, 2022 12:04 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Cc: Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Trzeciak, Kimberlee <Kimberlee.Trzeciak@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: For Review: Tough Q&A

Thanks,

I've asked Tristan to get this into sharepoint so we don't have a version control problem.

rmc

From: Andrew Tantillo <Andrew.Tantillo@fda.hhs.gov>
Date: Saturday, May 21, 2022 at 11:57 AM
To: Robert Califf <RMC001@fda.hhs.gov>
Cc: Susan Mayne <Susan.Mayne@fda.hhs.gov>, Frank Yiannas <Frank.Yiannas@fda.hhs.gov>, Kimberlee Trzeciak <Kimberlee.Trzeciak@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Subject: For Review: Tough Q&A

Commissioner –


Attached please find a draft “tough questions” document for infant formula hearing prep. I understand you are working on a document of your own and you may wish to integrate them.

Once you have reviewed I propose to share this with the Department, at their request for awareness of the types of questions we are anticipating.

Thank you.

Andrew Tantillo

Deputy Director

Office of Legislation
U.S. Food and Drug Administration
301-796-8919 M 
andrew.tantillo@fda.hhs.gov



From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 5/19/2022 10:25:48 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: [EXTERNAL] Abbott

Agree. A call tomorrow would be great.

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From: Califf, Robert <RMC001@fda.hhs.gov>
Sent: Thursday, May 19, 2022 7:56:09 PM
To: Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] Abbott

Just saw this. Seems like a good idea, although a call tomorrow should be good.

rmc

From: Janice Sheehy <Janice.Sheehy@fda.hhs.gov>
Date: Thursday, May 19, 2022 at 6:37 PM
To: Robert Califf <RMC001@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>
Subject: FW: [EXTERNAL] Abbott

From: Ford, Robert B <Robert.Ford@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

| |
|---|
| 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. |
|---|

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: Beckerman, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182E3800DB204BB88CF3863BAD5259B6-PBECKERM]
Sent: 5/26/2022 4:01:30 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Reinspection Options for Abbott Nutrition, Sturgis, Michigan Facility

Thank you!

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, May 26, 2022 3:59 PM
To: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Subject: RE: Reinspection Options for Abbott Nutrition, Sturgis, Michigan Facility

Thanks, I have talked to Judy McMeekin about this fairly extensively, have forwarded to her. Obviously there needs to be planning. (b) (5)

:. jw

From: Beckerman, Peter <Peter.Beckerman@fda.hhs.gov>
Sent: Thursday, May 26, 2022 2:31 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: Reinspection Options for Abbott Nutrition, Sturgis, Michigan Facility

This has likely made its way to you, or will, but I want to make sure you are aware that CFSAN Office of Compliance has raised the question of when and how to reinspect Sturgis, so if the Commissioner's office should have input on this, I expect the discussion will be happening in the near future.

-Pete

From: Dugan, Erin <Erin.Dugan@fda.hhs.gov>
Sent: Thursday, May 26, 2022 7:29 AM
To: Infant Formula FDA IMG Leadership <InfantFormulaFDAIMGLeadership@fda.hhs.gov>
Cc: Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>
Subject: FW: Reinspection Options for Abbott Nutrition, Sturgis, Michigan Facility

Good Morning-

Operations Food Safety Unit has developed the attached paper outlining FDA's reinspection strategies for Abbott Nutrition. Please review the attached paper. After review we will have Plans set up a call to discuss.

Respectfully,

Erin C. Dugan
Acting Staff Manager/Operations Section Chief Infant Formula IMG
Office of Emergency Operations
U.S. Food and Drug Administration

Desk: (913) 495-5110
Cell (b) (6)
24 hour Emergency Number: 1-866-300-4374



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From: Oxenham, Ann <Ann.Oxenham@fda.hhs.gov>
Sent: Wednesday, May 25, 2022 7:34 PM
To: Dugan, Erin <Erin.Dugan@fda.hhs.gov>
Cc: Infant Formula FDA IMG Planning <InfantFormulaFDAIMGPlanning@fda.hhs.gov>; Toerner, Joseph <Joseph.Toerner@fda.hhs.gov>; Anania, Frank <Frank.Anania@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Subject: Reinspection Options for Abbott Nutrition, Sturgis, Michigan Facility

Erin,

As mentioned in the FSRU's Daily Update on the Resumption of Operations at Abbott and IMG calls, we have been developing the attached Options paper outlining potential first reinspection strategies for the Abbott Nutrition facility in Sturgis, MI. We note that Abbott's current start date for Specialty Operations is projected to be June 4, 2022. In order to give all options in the paper the maximum viability, we recommend that the IMG and AEG leadership review the attached paper and convene a meeting with experts from the IMG Operations Unit, both FSRU and SCU, and operations experts from ORA as soon as possible.

Ann M. Oxenham

Director
Office of Compliance
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Unit Leader
Food Safety & Response Unit, Operations Section
Infant Formula IMG
U.S. Food and Drug Administration

ann.oxenham@fda.hhs.gov

Amy Barringer
Acting Deputy Director
CFSAN Office of Compliance
240-402-1988

From: Rabin, Tara G. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D6E14C0D07AD46CA812A39A72C751BFE-TARA.GOODIN]
Sent: 5/26/2022 3:11:26 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a05ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]
Subject: RE: REVIEW REQUEST, 2PM TODAY: PR, FDA Flexibilities, Collaboration to Yield Millions of Bottles of Specialized Medical Infant Formula in Coming Months to Increase U.S. Supply

Thanks much!

From: Califf, Robert <RMC001@fda.hhs.gov>
Sent: Thursday, May 26, 2022 2:58 PM
To: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Croce, Teresa <Teresa.Croce@fda.hhs.gov>
Subject: Re: REVIEW REQUEST, 2PM TODAY: PR, FDA Flexibilities, Collaboration to Yield Millions of Bottles of Specialized Medical Infant Formula in Coming Months to Increase U.S. Supply

Yep; looks good . sorry for the delay.

rmc

From: "Rabin, Tara G." <Tara.Rabin@fda.hhs.gov>
Date: Thursday, May 26, 2022 at 11:47 AM
To: Robert Califf <RMC001@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>
Cc: Erica Jefferson <Erica.Jefferson@fda.hhs.gov>, Michael Felberbaum <Michael.Felberbaum@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Andi Fristedt <Andi.Fristedt@fda.hhs.gov>, "Flahive, James" <James.Flahive@fda.hhs.gov>, "Croce, Teresa" <Teresa.Croce@fda.hhs.gov>
Subject: REVIEW REQUEST, 2PM TODAY: PR, FDA Flexibilities, Collaboration to Yield Millions of Bottles of Specialized Medical Infant Formula in Coming Months to Increase U.S. Supply

Dr. Califf and Dr. Woodcock,

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

Agency/Office: Infant Formula IMG/OFPR/CFSAN

Subject: FDA Flexibilities, Collaboration to Yield Millions of Bottles of Specialized Medical Infant Formula in Coming Months to Increase U.S. Supply

Deadline for comments: REQUESTING BY 2:00PM, THURSDAY 5/26

Planned release date: Thursday, May 26

Driving event: About 500,000 additional cans of specialized medical formula manufactured by Danone's Nutricia business will be headed to the U.S.

Many thanks,
Tara

Tara G. Rabin

Media Relations Director

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-3157 / Cell: (b) (6)

Tara.Rabin@fda.hhs.gov



From: Califf, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD88732BE1ED4912A058EE9DD9906F66-ROBERT.CALI]
Sent: 5/27/2022 10:00:16 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Croce, Teresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3abf9312c3984913bde628d5e6fa48d1-Teresa.Croc]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
Subject: Re: ASAP REVIEW REQUEST: PR, FDA Efforts to Result in Millions of Additional Bottles of Infant Formula to Further Increase U.S. Supply

LGTM, please proceed

From: Michael Felberbaum <Michael.Felberbaum@fda.hhs.gov>
Date: Friday, May 27, 2022 at 9:57 AM
To: Robert Califf <RMC001@fda.hhs.gov>
Cc: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, Erica Jefferson <Erica.Jefferson@fda.hhs.gov>, Julie Tierney <Julia.Tierney@fda.hhs.gov>, Tristan Colonius <Tristan.Colonius@fda.hhs.gov>, Andi Fristedt <Andi.Fristedt@fda.hhs.gov>, "Flahive, James" <James.Flahive@fda.hhs.gov>, "Croce, Teresa" <Teresa.Croce@fda.hhs.gov>, "Rabin, Tara G." <Tara.Rabin@fda.hhs.gov>
Subject: ASAP REVIEW REQUEST: PR, FDA Efforts to Result in Millions of Additional Bottles of Infant Formula to Further Increase U.S. Supply

Dr. Califf,

We're aiming to issue a press release AROUND 11 AM TODAY about our enforcement discretion regarding Bubs Australia's plans to provide about 1.5 million cans of several varieties of its infant formula that will make around 67.5 million full-size, 8-ounce bottles. The press release includes a proposed quote attributed to you and is attached here for your urgent review. Pulling out the quote below if helpful for quicker review.

"We continue to work around the clock with our government partners and industry to ensure there's adequate infant formula available wherever and whenever parents and caregivers need it," said FDA Commissioner Robert M. Califf, M.D. "Steps like the one the agency is taking today means more infant formula will be available to parents and caregivers in the weeks and months ahead. We will not rest until our shelves are replete with safe and nutritious infant formula."

We are moving this concurrently to HHS and WH.

Thanks,

Michael

Michael Felberbaum

Assistant Commissioner for Media Affairs

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-9548 / Cell (b) (6)

michael.felberbaum@fda.hhs.gov



From: Tobias, Lindsay [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A4766773C717470BBC55D204B5F067B2-LINDSAY.STO]
Sent: 5/25/2022 3:55:39 PM
To: Despres, Sarah (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e5f3d3f26584babb7b48c3cac8bba82-HHS-Sarah.D]; Cha, Stephen S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38f075dd58f14eb0a5d405cdcf094eb3-HHS-Stephen]; Miller - Tolbert, Kimberly (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21042a6131464fa2a593edfffd7ff655-HHS-Kimberl]
CC: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Koplow, Bret [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f4498a3b2fd41a59bd627fdb2dc5d2e-Bret.Koplow]; Kahn, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]
Subject: Night Note for Thursday, 5/26 - Internal, Confidential, Deliberative

PRESS PAPERS:

- Nothing to report at this time.

OTHER FLAGS:

INTERNAL, CONFIDENTIAL, MARKET SENSITIVE, NOT FOR PUBLIC DISTRIBUTION

(b) (5)

(b) (5)

Congressional Hearings

- **Infant Formula Hearing**

On Thursday at 10:30 a.m., FDA Commissioner Robert M. Califf will testify before the U.S. Senate Committee on Health, Education, Labor & Pensions in a hearing titled, "Infant Formula Crisis: Addressing the Shortage and Getting Formula On Shelves." The hearing will be webcast and held at 430 Dirksen Senate Office Building, Washington, D.C.

Lindsay R. Tobias

Special Assistant to the Chief of Staff

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



From: Croce, Teresa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3ABF9312C3984913BDE628D5E6FA48D1-TERESA.CROC]
Sent: 5/27/2022 6:28:16 PM
To: Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Cali]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: Readout from the WH IF Check-In (March 27th)

Happy Friday, All,

Below are is a high-level readout the WH IF Check-In call this evening:

(b) (5)

(b) (5)

For others that attended the WH meeting, please feel free to add anything else to the chain that you think the group would find useful. I hope everyone can enjoy at least a bit of time off this weekend!

Thanks!

Teresa

Teresa A. Croce, Ph.D. (she/her/hers)

Senior Advisor

Office of Policy, Legislation, and International Affairs

Office of the Commissioner

U.S. Food and Drug Administration

Mobile: (b) (6) Tel: 240-402-1281

teresa.croce@fda.hhs.gov



From: Yiannas, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93CDF56A41324683AB173699C441FEC8-FRANK.YIANN]
Sent: 5/27/2022 7:09:38 PM
To: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dcce89b861b673-JOS]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbbba07102b-MCMEEKINJ]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: Re: Availability Request - Infant Formula (IF) Weekend/Holiday Update

I can as well.

[Get Outlook for iOS](#)

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Friday, May 27, 2022 5:28:24 PM
To: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: Re: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Same here - thanks, Frank.

From: Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>
Sent: Friday, May 27, 2022 5:52:31 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: Availability Request - Infant Formula (IF) Weekend/Holiday Update

I can make these work as well.

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>

Sent: Friday, May 27, 2022 5:50 PM

To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>

Subject: RE: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Thanks, Frank. I can made these work.

Erica

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>

Sent: Friday, May 27, 2022 5:49 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>

Subject: RE: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Going straight to principals given the late in the day holiday Friday...

Saturday is confirmed for 1:30-2:00 PM – this time worked for all that I received responses for.

Based on the responses I've received...

Can we make 8:30-9:00 AM work on Sunday?

Can we make 2:30-3:00 PM work on Monday?

Placing holds now. If these times don't work let me know, otherwise accepting the calendar invite works!

Thank you,

frank

From: Olivarria, Frank

Sent: Friday, May 27, 2022 1:45 PM

Subject: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Importance: High

Good afternoon, Happy holiday Friday (with early dismissal I hear, for those who can... 😊) -

OC/OCOS is requesting weekend and holiday syncs on IF, 30 mins Sat-Monday. Please let me which of the below offerings work for your principal, including any preferences.

| Infant Formula (IF) | OPTION 1 | OPTION 2 | OPTION 3 | OPTION 4 | OPTION 5 | OPTION 6 | OPTION 7 | OPTION 8 | OPTION 9 |
|------------------------|-----------------|-------------|-------------|-------------|---------------|-------------|-------------|---------------|-------------|
| | Saturday, 5/28" | | | | Sunday, 5/29: | | | Monday, 5/30: | |

| Weekend/Holiday Update | 11:00-11:30 AM | 12:00-12:30 PM | 1:00-1:30 PM | 1:30-2:00 PM | 11:00-11:30 AM | 1:30-2:00 PM | 3:30-4:00 PM | 10:30-11:00 AM | 12:30-1:00 PM |
|--|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| Dr. Califf | <i>Preference Pending</i> | <i>Preference Pending</i> | <i>Preference Pending</i> | <i>Preference Pending</i> | <i>Preference Pending</i> | <i>Preference Pending</i> | <i>Preference Pending</i> | <i>Preference Pending</i> | <i>Preference Pending</i> |
| Julie Tierney (Frank for Susan) | | | | | | | | | |
| Dr. Woodcock (Jacque) | | | | | | | | | |
| Frank Yiannas (Larry) | | | | | | | | | |
| Andi Fristedt (Stephanie Fish) | | | | | | | | | |
| Erica Jefferson (Kristen/Lilliana?) | | | | | | | | | |
| Dr. Mayne (Landy for Natalie) | | | | | | | | | |
| Mark Raza (Deedee) | | | | | | | | | |
| Caitlin Boon (Melissa) | | | | | | | | | |
| Joshua Simms | | | | | | | | | |
| Judy McMeekin (Syrena) | | | | | | | | | |

Thank you!

Frank

Frank A. Olivarria

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



From: Mayne, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9E69ACD84A37469AA57466A957814563-SUSAN.MAYNE]
Sent: 5/27/2022 7:53:05 PM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; 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]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Boon, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dcce89b861b673-JOS]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbb07102b-MCMEEKINJ]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Colonius, Tristan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Col]
Subject: Re: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Yes can do

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From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, May 27, 2022 5:48:56 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>
Subject: RE: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Going straight to principals given the late in the day holiday Friday...

Saturday is confirmed for 1:30-2:00 PM – this time worked for all that I received responses for.

Based on the responses I've received...

Can we make 8:30-9:00 AM work on Sunday?

Can we make 2:30-3:00 PM work on Monday?

Placing holds now. If these times don't work let me know, otherwise accepting the calendar invite works!

Thank you,
frank

From: Olivarria, Frank

Sent: Friday, May 27, 2022 1:45 PM

Subject: Availability Request - Infant Formula (IF) Weekend/Holiday Update

Importance: High

Good afternoon, Happy holiday Friday (with early dismissal I hear, for those who can... 😊) -

OC/OCOS is requesting weekend and holiday syncs on IF, 30 mins Sat-Monday. Please let me which of the below offerings work for your principal, including any preferences.

| Infant Formula (IF) Weekend/Holiday Update | OPTION 1 | OPTION 2 | OPTION 3 | OPTION 4 | OPTION 5 | OPTION 6 | OPTION 7 | OPTION 8 | OPTION 9 |
|---|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| | Saturday, 5/28" | | | | Sunday, 5/29: | | | Monday, 5/30 | |
| | 11:00- 11:30 AM | 12:00- 12:30 PM | 1:00-1:30 PM | 1:30-2:00 PM | 11:00- 11:30 AM | 1:30-2:00 PM | 3:30-4:00 PM | 10:30- 11:00 AM | 12:30- 1:00 PM |
| Dr. Califf | Preference Pending | Preference Pending | Preference Pending | Preference Pending | Preference Pending | Preference Pending | Preference Pending | Preference Pending | Preference Pending |
| Julie Tierney (Frank for Susan) | | | | | | | | | |
| Dr. Woodcock (Jacque) | | | | | | | | | |
| Frank Yiannas (Larry) | | | | | | | | | |
| Andi Fristedt (Stephanie Fish) | | | | | | | | | |
| Erica Jefferson (Kristen/Lilliana?) | | | | | | | | | |
| Dr. Mayne (Landy for Natalie) | | | | | | | | | |
| Mark Raza (Deedee) | | | | | | | | | |
| Caitlin Boon (Melissa) | | | | | | | | | |
| Joshua Simms | | | | | | | | | |
| Judy McMeekin (Syrena) | | | | | | | | | |

Thank you!

Frank

Frank A. Olivarria

Management and Program Analyst

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 240-402-9882

Frank.Olivarria@fda.hhs.gov



