

**From:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

Varrone, Michael (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9306362f89804e94ab30bdf2d28ee0a6-Varrone, Mi <Michael.Varrone@hhs.gov>;

Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edef6-mark.raza.f (b)(6)

Edmonds, Amanda (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5cbda2dd035d4ab7bdca39b091c7ff66-amanda.edmo (b)(6)

Beckerman, Peter (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54fae5623914e20a6df020d109ccdd1-peter.becke (b)(6)

Kropa, Halley (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group

**To:** (FYDIBOHF23SPDLT)/cn=Recipients/cn=2782dc39858a4ead9e69101b602df6db-halley.espy (b)(6)

Vicente, Wendy (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3aa5224fb7184a7ba2e125d93726418f-wendy.vicen (b)(6)

Hutchinson, Shoshana (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54a41cc94644a6ea5ff0896e77f61d6-shoshana.hu (b)(6)

Dickinson, Elizabeth (FDA) (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0da45fb448674130a7431f614c72a8f0-elizabeth.d (b)(6)

Cohen, Leslie (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8834d040a68147fc968d599219ff98f1-leslie.cohe (b)(6)

Gorji, Perham (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=57ebf62fd8094c438409ffe4361627c8-perham.gorj (b)(6)

Singleton, Shannon (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group

**CC:** (FYDIBOHF23SPDLT)/cn=Recipients/cn=116a012b4393457194d92e2bf6f4a22d-shannon.sin (b)(6)

Allred, James (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cf6398e7c20448187de0e5fca28e9fb-james.allre (b)(6)

**Subject:** Re: Draft Appeals Court brief - Sandoz v. FDA

**Date:** 2022/09/22 12:03:36

**Priority:** Normal

**Type:** Note

This looks great. Thanks.

Samuel R. Bagenstos

General Counsel

Department of Health and Human Services

200 Independence Ave, SW

Washington, DC. 20201

(202) 690-7758

**From:** Cohen, Leslie (b)(6)

**Sent:** Wednesday, September 21, 2022 9:04:13 PM

**To:** Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>; Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Raza, Mark (FDA/OC) (b)(6) Edmonds, Amanda

(FDA/OC) (b)(6) Beckerman, Peter (FDA/OC)  
(b)(6) Kropa, Halley (FDA/OC) (b)(6) Vicente, Wendy  
(FDA/OC) (b)(6) Hutchinson, Shoshana (FDA/OC)  
(b)(6) Dickinson, Elizabeth (FDA) (FDA/OC)  
(b)(6)  
**Cc:** Gorji, Perham (FDA/OC) (b)(6) Singleton, Shannon (FDA/OC)  
(b)(6) Allred, James (FDA/OC) (b)(6)  
**Subject:** Draft Appeals Court brief - Sandoz v. FDA

Hi all,

Attached for your review is a draft responsive brief for filing in *Sandoz, Inc. v. Becerra*, No. 22-5202 (D.C. Cir.). The deadline for filing is this coming Friday, Sept. 23. We provided Civil Appellate extensive edits and comments this evening. The attached draft incorporates those changes without redlining, but we won't know until Friday what DOJ will accept. Please send us suggested edits and comments, if any, by close of business tomorrow if at all possible.

(b)(5)

Please let me know if you have any questions.

**Leslie Cohen**

*Associate Chief Counsel*

**FDA Office of the Chief Counsel**

**HHS OGC Food and Drug Division**

Tel: 301-796-0551

(b)(6)



✖ ✖ ✖ ✖ ✖



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Allred, James (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cf6398e7c20448187de0e5fca28e9fb-james.allre (b)(6)

Varrone, Michael (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9306362f89804e94ab30bdf2d28ee0a6-Varrone, Mi <Michael.Varrone@hhs.gov>;

Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edefb-mark.raza.f (b)(6)

Edmonds, Amanda (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5cbda2dd035d4ab7bdca39b091c7ff6f6-amanda.edmo <A(b)(6)

**Recipient:** Beckerman, Peter (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54fae5623914e20a6df020d109ccdd1-peter.becke (b)(6)

Kropa, Halley (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2782dc39858a4ead9e69101b602df6db-halley.espy (b)(6)

Vicente, Wendy (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3aa5224fb7184a7ba2e125d93726418f-wendy.vicen (b)(6)

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Cohen, Leslie (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8834d040a68147fc968d599219ff98f1-leslie.cohe (b)(6)

**Sent Date:** 2022/09/22 12:03:36

**From:** Bagenstos, Samuel (HHS/OGC) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AFA71EA876614421A32EEE5049C60E45-BAGENSTOS,>  
Edmonds, Amanda (b)(6)  
**To:** Varrone, Michael (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9306362f89804e94ab30bdf2d28ee0a6-Varrone, Mi <Michael.Varrone@hhs.gov>  
Hutchinson, Shoshana (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54a41cc94644a6ea5ff0896e77f61d6-shoshana.hu (b)(6)  
Taylor, Paige (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4d4996afe9942e8aadae54716e6ff9f-paige.taylo (b)(6)  
**CC:** Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25727dc5722145c28b23f442cccbece3-tracey.alle (b)(6)  
Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edef6-mark.raza.f (b)(6)

**Subject:** RE: just fyi re exhaustion argument

**Date:** 2023/01/10 14:39:00

**Priority:** Normal

**Type:** Note

Our Comstock and Subpart H/ANDA exhaustion arguments certainly fail under CADC's view. Mrs. Lincoln finds it a good opinion overall, though!

Samuel R. Bagenstos  
General Counsel  
Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201  
(202) 690-7758

**From:** Edmonds, Amanda (b)(6)  
**Sent:** Tuesday, January 10, 2023 2:27 PM  
**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>  
**Cc:** Hutchinson, Shoshana (FDA/OC) (b)(6) Taylor, Paige (FDA/OC) (b)(6)  
(b)(6) Allen, Tracey (FDA/OC) (b)(6) Raza, Mark (FDA/OC) (b)(6)  
**Subject:** FW: just fyi re exhaustion argument

Just wanted to make sure you saw this part of a decision we got today.

**From:** Hutchinson, Shoshana (b)(6)  
**Sent:** Tuesday, January 10, 2023 1:40 PM  
**To:** Edmonds, Amanda (b)(6) Taylor, Paige (b)(6)  
Allen, Tracey (b)(6)  
**Subject:** RE: just fyi re exhaustion argument



Here's James' summary of the court's exhaustion ruling, for more background:

(b)(5)

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**From:** Edmonds, Amanda (b)(6)

**Sent:** Tuesday, January 10, 2023 1:35 PM

**To:** Taylor, Paige (b)(6) Allen, Tracey (b)(6) Hutchinson, Shoshana (b)(6)

**Subject:** just fyi re exhaustion argument

(b)(5)

---

**From:** Unlu, Mustafa (b)(6)

**Sent:** Tuesday, January 10, 2023 11:08 AM

**To:** OC OCC Hatch-Waxman List (b)(6)

**Cc:** Edmonds, Amanda (b)(6) Chasan-Sloan, Deborah (FDA) (b)(6)

**Subject:** FW: [EXTERNAL] Sandoz - Favorable Decision

I wanted to share the good news with you that the D.C. Circuit ruled for FDA on the Aubagio matter. If you are wondering why I am still writing to this list, this is/was my last litigation matter as an OCC attorney. Though the court did not agree with us on the administrative exhaustion issue (the potential impact of that holding may be more broad than this particular matter), and though the opinion has some unfortunate language about NCE exclusivity expiring after 4 years, the end result is as good as we could have expected. The court (Judge Rao writing) dismissed Sandoz's arguments about how an impurity can be considered to be previously approved for NCE exclusivity purposes, either as an impurity, or as an active ingredient. It also confirmed our ministerial role with respect to patents under the Hatch-Waxman provisions.

Mustafa Ünlü  
Office of Therapeutic Biologics and Biosimilars  
Office of New Drugs  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

White Oak Bldg 22-1139  
10903 New Hampshire Ave.  
Silver Spring, MD 20903

E: (b)(6)

T: 301.796.3396

M: (b)(6)

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---

**From:** Hazel, Steven H. (CIV) <Steven.H.Hazel@usdoj.gov>

**Sent:** Tuesday, January 10, 2023 10:34 AM

**To:** Tenny, Daniel (CIV) <Daniel.Tenny@usdoj.gov>; Allred, James (b)(6) Cohen, Leslie (b)(6) Katzen, Noah T. <Noah.T.Katzen@usdoj.gov>; Wadden, Michael J. <Michael.J.Wadden@usdoj.gov>

**Cc:** Unlu, Mustafa (b)(6) Sitlani, Jay (b)(6)

**Subject:** [EXTERNAL] Sandoz - Favorable Decision

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.

Hi all,

(b)(5)

(b)(5)

Many thanks to everyone for all the great work that's helped achieve this outcome!  
Steven

---

**From:** Hazel, Steven H. (CIV)

**Sent:** Monday, November 7, 2022 1:49 PM

**To:** Tenny, Daniel (CIV) <Daniel.Tenny@usdoj.gov>; Allred, James (b)(6) Cohen, Leslie (b)(6) Katzen, Noah T. <Noah.T.Katzen@usdoj.gov>; Wadden, Michael J. <Michael.J.Wadden@usdoj.gov>; Lopez, Caroline D. (CIV) <Caroline.D.Lopez@usdoj.gov>; Padhi, Catherine M. (CIV) <Catherine.M.Padhi@usdoj.gov>; Hopen, David (CIV) <David.Hopen@usdoj.gov>; Neumeister, McKaye L. (CIV) <McKaye.L.Neumeister@usdoj.gov>; Starcher, Jack E. (CIV) <John.E.Starcher@usdoj.gov>

**Cc:** Unlu, Mustafa (b)(6) Sitlani, Jay (b)(6)

**Subject:** Sandoz - Oral Argument

Hi all,

(b)(5)

For those who didn't get a chance to listen to the live stream, a short recap is below and a recording of the full argument is available [here](#).

(b)(5)

We'll let you know as soon as we hear from the Court.

Thanks,  
Steven

---

**From:** Hazel, Steven H. (CIV)  
**Sent:** Friday, November 4, 2022 1:07 PM  
**To:** Tenny, Daniel (CIV) <Daniel.Tenny@usdoj.gov>; Allred, James (b)(6) Cohen, Leslie (b)(6) Katzen, Noah T. <Noah.T.Katzen@usdoj.gov>; Wadden, Michael J. <Michael.J.Wadden@usdoj.gov>; Lopez, Caroline D. (CIV) <Caroline.D.Lopez@usdoj.gov>; Padhi, Catherine M. (CIV) <Catherine.M.Padhi@usdoj.gov>; Hopen, David (CIV) <David.Hopen@usdoj.gov>  
**Cc:** Unlu, Mustafa (b)(6) Sitlani, Jay (b)(6)  
**Subject:** RE: Sandoz - External Moot

Thanks again for your help with this moot. For those who are interested, the argument will be live streamed at the link below.

[https://www.youtube.com/watch?v=C\\_Eb7QBy6zw](https://www.youtube.com/watch?v=C_Eb7QBy6zw)

-----Original Appointment-----

**From:** Hazel, Steven H. (CIV)  
**Sent:** Thursday, September 29, 2022 7:48 PM  
**To:** Hazel, Steven H. (CIV); Tenny, Daniel (CIV); Allred, James; Cohen, Leslie; Katzen, Noah T.; Wadden, Michael J.; Lopez, Caroline D. (CIV); Padhi, Catherine M. (CIV); Hopen, David (CIV)  
**Cc:** Unlu, Mustafa; Sitlani, Jay  
**Subject:** Sandoz - External Moot  
**When:** Friday, November 4, 2022 10:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** Microsoft Teams Meeting (see below)

Thanks for helping with this moot! I've updated the attachments to include Sandoz's reply brief. If there's anything else you want to take a look at, just let me know.

The DJ number is (b)(6)

---

## Microsoft Teams meeting

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Edmonds, Amanda (b)(6)

Varrone, Michael (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9306362f89804e94ab30bdf2d28ee0a6-Varrone, Mi <Michael.Varrone@hhs.gov>;

Hutchinson, Shoshana (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54a41cc94644a6ea5ff0896e77f61d6-shoshana.hu (b)(6)

**Recipient:** Taylor, Paige (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4d4996afe9942e8aadae54716e6ff9f-paige.taylo (b)(6)

Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25727dc5722145c28b23f442cccbece3-tracey.allen (b)(6)

Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edef6-mark.raza.f (b)(6)

**Sent Date:** 2023/01/10 14:40:01

**Delivered Date:** 2023/01/10 14:39:00

**From:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

Edmonds, Amanda (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5cbda2dd035d4ab7bdca39b091c7ff66-amanda.edmo  
(b)(6)

**To:** Backfield, Katlin (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7b8d19569d64700b154b303c3c20fc9-5a0e7824-52 <Katlin.Backfield@hhs.gov>;

Taylor, Paige (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4d4996afe9942e8aadae54716e6ff9f-paige.taylo  
(b)(6)

Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25727dc5722145c28b23f442cccbece3-tracey.alle  
(b)(6)

**CC:** Sreenath, Aravind (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b01fd3a70f704078a223a48feeed5fce-aravind.sre  
(b)(6)

Katz, Donna (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddccdba7aaf4eada3d7bbd509beda08-donna.katz.  
(b)(6)

**Subject:** Re: [EXTERNAL] RE: Revised draft

**Date:** 2023/04/26 11:16:42

**Priority:** Normal

**Type:** Note

I do not.

Samuel R. Bagenstos (he, him, his)

General Counsel

Department of Health and Human Services

200 Independence Ave, SW

Washington, DC. 20201

(202) 690-7758

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**From:** Taylor, Paige (b)(6)

**Sent:** Wednesday, April 26, 2023 10:58:32 AM

**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Edmonds, Amanda (FDA/OC) (b)(6) Backfield, Katlin (HHS/OGC) <Katlin.Backfield@hhs.gov>

**Cc:** Allen, Tracey (FDA/OC) (b)(6) Sreenath, Aravind (FDA/OC)

(b)(6) Katz, Donna (FDA/OC) (b)(6)

**Subject:** RE: [EXTERNAL] RE: Revised draft

Thanks Sam. Do you know whether DOJ is planning to circulate a "showstoppers only" type draft today?

Paige

---

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>  
**Sent:** Wednesday, April 26, 2023 8:44 AM  
**To:** Edmonds, Amanda (b)(6) Backfield, Katlin M (OS) <Katlin.Backfield@hhs.gov>  
**Cc:** Taylor, Paige (b)(6) Allen, Tracey (b)(6) Sreenath, Aravind (b)(6) Katz, Donna (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft

I am informed that the offending sentences have been removed.

Samuel R. Bagenstos (he, him, his)  
General Counsel  
Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201  
(202) 690-7758

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**From:** Edmonds, Amanda (b)(6)  
**Sent:** Tuesday, April 25, 2023 8:41 PM  
**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin (HHS/OGC) <Katlin.Backfield@hhs.gov>  
**Cc:** Taylor, Paige (FDA/OC) (b)(6) Allen, Tracey (FDA/OC) (b)(6) Sreenath, Aravind (FDA/OC) (b)(6) Katz, Donna (FDA/OC) (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft

(b)(5)



---

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>

**Sent:** Tuesday, April 25, 2023 8:29 PM

**To:** Edmonds, Amanda (b)(6) Backfield, Katlin M (OS)

<Katlin.Backfield@hhs.gov>

**Cc:** Taylor, Paige (b)(6) Allen, Tracey (b)(6) Sreenath, Aravind (b)(6) Katz, Donna (b)(6)

**Subject:** RE: [EXTERNAL] RE: Revised draft

I think you probably saw my email to Sarah just now. I'm willing to push them on this.

Samuel R. Bagenstos (he, him, his)  
General Counsel  
Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC. 20201  
(202) 690-7758

---

**From:** Edmonds, Amanda (b)(6)

**Sent:** Tuesday, April 25, 2023 8:20 PM

**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin (HHS/OGC) <Katlin.Backfield@hhs.gov>

**Cc:** Taylor, Paige (FDA/OC) (b)(6) Allen, Tracey (FDA/OC) (b)(6) Sreenath, Aravind (FDA/OC) (b)(6) Katz, Donna (FDA/OC) (b)(6)

**Subject:** RE: [EXTERNAL] RE: Revised draft

**Importance:** High

Sam and Katlin,

We believe this is one we ought to elevate—the main concern is not (b)(5)

To recap, the draft brief says: (b)(5)

(b)(5)

We asked that the language be deleted. We have two main concerns.

(b)(5)

(b)(5)

Let us know if it would be helpful to discuss this—we didn't want to go back to DOJ until we raised with you.

Thanks,

Amanda and the FDD team

---

**From:** Harrington, Sarah E. (CIV) <[Sarah.E.Harrington@usdoj.gov](mailto:Sarah.E.Harrington@usdoj.gov)>

**Sent:** Tuesday, April 25, 2023 6:40 PM

**To:** Taylor, Paige <[Paige.Taylor@fda.hhs.gov](mailto:Paige.Taylor@fda.hhs.gov)>; Barmore, Cynthia A. (CIV) <[Cynthia.A.Barmore@usdoj.gov](mailto:Cynthia.A.Barmore@usdoj.gov)>; Raab, Michael (CIV) <[Michael.Raab@usdoj.gov](mailto:Michael.Raab@usdoj.gov)>

**Cc:** Bagenstos, Samuel R (OS) <[Samuel.Bagenstos@hhs.gov](mailto:Samuel.Bagenstos@hhs.gov)>; Backfield, Katlin M (OS) <[Katlin.Backfield@hhs.gov](mailto:Katlin.Backfield@hhs.gov)>; Edmonds, Amanda (b)(6)

Tracey (b)(6) Sreenath, Aravind (b)(6)

Katz, Donna (b)(6)

**Subject:** [EXTERNAL] RE: Revised draft

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Paige,

(b)(5)

(b)(5)

(b)(5)

Please let me know ASAP. Thanks.

Sarah

Sarah E. Harrington (she/her)  
Deputy Assistant Attorney General  
Civil Division

(b)(6)

---

**From:** Taylor, Paige (b)(6)

**Sent:** Tuesday, April 25, 2023 1:03 PM

**To:** Harrington, Sarah E. (CIV) <Sarah.E.Harrington@usdoj.gov>

**Cc:** Bagenstos, Samuel R (OS) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin M (OS) <Katlin.Backfield@hhs.gov>; Edmonds, Amanda (b)(6) Allen, Tracey (b)(6)

Sreenath, Aravind (b)(6)  
Katz, Donna <Donna.Katz@fda.hhs.gov>

**Subject:** [EXTERNAL] Revised draft

Attached are FDA's comments on the revised draft. Sam and Katlin did not have an opportunity to review these proposed edits.

Please let us know if you have any questions about our comments.

Thanks much

Paige

Paige H. Taylor (she/her/hers)  
Senior Counsel  
Food and Drug Division, OGC  
White Oak Bldg 32, Rm 4380  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
301-796-8720 (office)  
301-847-8618 (fax)  
[paige.taylor@fda.hhs.gov](mailto:paige.taylor@fda.hhs.gov)

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Taylor, Paige (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4d4996afe9942e8aadae54716e6ff9f-paige.taylo (b)(6)

**Sent Date:** 2023/04/26 11:16:41

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Varrone, Michael (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9306362f89804e94ab30bdf2d28ee0a6-Varrone, Mi <Michael.Varrone@hhs.gov>;

Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edef6-mark.raza.f (b)(6)

**To:** Beckerman, Peter (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54fae5623914e20a6df020d109ccdd1-peter.becke (b)(6)

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Vicente, Wendy (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3aa5224fb7184a7ba2e125d93726418f-wendy.vicen (b)(6)

**CC:** Hutchinson, Shoshana (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54a41cc94644a6ea5ff0896e77f61d6-shoshana.hu (b)(6)

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Cohen, Leslie (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8834d040a68147fc968d599219ff98f1-leslie.cohe (b)(6)

**Subject:** Re: Sandoz v. Becerra DC Circuit Affirmance

**Date:** 2023/01/10 21:50:24

**Priority:** Normal

**Type:** Note

Thanks. I'll take the win.

Samuel R. Bagenstos

General Counsel

Department of Health and Human Services

200 Independence Ave, SW

Washington, DC. 20201

(202) 690-7758

**From:** Allred, James (b)(6)

**Sent:** Tuesday, January 10, 2023 9:40:13 PM

**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>; Raza, Mark (FDA/OC) (b)(6) Beckerman, Peter

(FDA/OC) (b)(6) Edmonds, Amanda (FDA/OC)

(b)(6)

**Cc:** Chasan-Sloan, Deborah (FDA) (FDA/OC) (b)(6) Dettelbach, Kim

(FDA/OC) (b)(6) Vicente, Wendy (FDA/OC) (b)(6)

Hutchinson, Shoshana (FDA/OC) (b)(6) Gorji, Perham (FDA/OC)

(b)(6) Singleton, Shannon (FDA/OC) (b)(6) Cohen,

Leslie (FDA/OC) (b)(6)

**Subject:** Sandoz v. Becerra DC Circuit Affirmance

Good Evening,

As you may have heard, earlier today the US Court of Appeals for the DC Circuit affirmed the district court's ruling in our favor in Sandoz v. Becerra, a case concerning recognition of New Chemical Entity (NCE) exclusivity for Sanofi's drug Aubagio. Leslie Cohen and I have been handling this matter for FDD. The opinion for a united panel authored by Judge Rao represents (b)(5)

(b)(5)

(b)(5) In addition, the opinion contained (b)(5)

(b)(5) A summary of important points follows,

and Leslie and I are available to provide further information.

In summary, this case concerned (b)(5)

(b)(5)

The district court ruled in FDA's favor because it held that the (b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Finally, the opinion contained a significant discussion of

(b)(5)

(b)(5)



(b)(5)

Thank you for your continued review and consideration of this matter.

James

James Allred  
Food & Drug Division, OGC/HHS  
Office of the Chief Counsel, FDA

(b)(6)

(O): 301-837-7618

(C): (b)(6) (preferred)

**Sender:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>  
Chasan-Sloan, Deborah (FDA) (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0111b554e2b24547b62f1c70e29340a9-deborah.cha (b)(6)  
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Hutchinson, Shoshana (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54a41cc94644a6ea5ff0896e77f61d6-shoshana.hu (b)(6)  
Gorji, Perham (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=57ebf62fd8094c438409ffe4361627c8-perham.gorj (b)(6)  
**Recipient:** Singleton, Shannon (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=116a012b4393457194d92e2bf6f4a22d-shannon.sin (b)(6)  
Cohen, Leslie (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8834d040a68147fc968d599219ff98f1-leslie.cohe (b)(6)  
Varrone, Michael (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9306362f89804e94ab30bdf2d28ee0a6-Varrone, Mi <Michael.Varrone@hhs.gov>;  
Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edefb-mark.raza.f (b)(6)  
Beckerman, Peter (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a54fae5623914e20a6df020d109ccdd1-peter.becke (b)(6)  
Edmonds, Amanda (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5cbda2dd035d4ab7bdca39b091c7ff66-amanda.edmo (b)(6)

Allred, James (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4cf6398e7c20448187de0e5fca28e9fb-james.allre  
(b)(6)

**Sent Date:** 2023/01/10 21:50:23

**Delivered Date:** 2023/01/10 21:50:24

**From:** Edmonds, Amanda (b)(6)

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**To:** Backfield, Katlin (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7b8d19569d64700b154b303c3c20fc9-5a0e7824-52 <Katlin.Backfield@hhs.gov>

Taylor, Paige (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4d4996afe9942e8aadae54716e6ff9f-paige.taylo (b)(6)

Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25727dc5722145c28b23f442cccbece3-tracey.allen (b)(6)

**CC:** Sreenath, Aravind (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b01fd3a70f704078a223a48feed5fce-aravind.sreenath (b)(6)

Katz, Donna (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddccdba7aaf4eada3d7bbd509beda08-donna.katz. (b)(6)

**Subject:** RE: [EXTERNAL] RE: Revised draft

**Date:** 2023/04/26 09:26:45

**Priority:** Normal

**Type:** Note

That's very helpful background. Thank you.

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>

**Sent:** Wednesday, April 26, 2023 9:22 AM

**To:** Edmonds, Amanda (b)(6) Backfield, Katlin M (OS) <Katlin.Backfield@hhs.gov>

**Cc:** Taylor, Paige (b)(6) Allen, Tracey (b)(6) Sreenath, Aravind (b)(6) Katz, Donna (b)(6)

**Subject:** RE: [EXTERNAL] RE: Revised draft

(b)(5)

(b)(5)

(b)(5)

Samuel R. Bagenstos (he, him, his)  
General Counsel  
Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201  
(202) 690-7758

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**From:** Edmonds, Amanda (b)(6)  
**Sent:** Wednesday, April 26, 2023 8:55 AM  
**To:** Backfield, Katlin (HHS/OGC) <Katlin.Backfield@hhs.gov>; Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>  
**Cc:** Taylor, Paige (FDA/OC) (b)(6) Allen, Tracey (FDA/OC) (b)(6) Sreenath, Aravind (FDA/OC) (b)(6) Katz, Donna (FDA/OC) (b)(6)  
**Subject:** Re: [EXTERNAL] RE: Revised draft

Hurrah! Thank you.

---

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>  
**Sent:** Wednesday, April 26, 2023 8:44:29 AM  
**To:** Edmonds, Amanda (b)(6) Backfield, Katlin M (OS) <Katlin.Backfield@hhs.gov>  
**Cc:** Taylor, Paige (b)(6) Allen, Tracey (b)(6) Sreenath, Aravind (b)(6) Katz, Donna (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft

I am informed that the offending sentences have been removed.

Samuel R. Bagenstos (he, him, his)  
General Counsel  
Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201  
(202) 690-7758

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**From:** Edmonds, Amanda (b)(6)  
**Sent:** Tuesday, April 25, 2023 8:41 PM  
**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin (HHS/OGC) <Katlin.Backfield@hhs.gov>

**Cc:** Taylor, Paige (FDA/OC) (b)(6) Allen, Tracey (FDA/OC)  
(b)(6) Sreenath, Aravind (FDA/OC) (b)(6) Katz,  
Donna (FDA/OC) (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft

Awesome, thanks so much. It's so hard to see why the statement (b)(5)

(b)(5)

---

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>  
**Sent:** Tuesday, April 25, 2023 8:29 PM  
**To:** Edmonds, Amanda (b)(6) Backfield, Katlin M (OS)  
<Katlin.Backfield@hhs.gov>  
**Cc:** Taylor, Paige (b)(6) Allen, Tracey (b)(6) Sreenath,  
Aravind (b)(6) Katz, Donna (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft

I think you probably saw my email to Sarah just now. I'm willing to push them on this.

Samuel R. Bagenstos (he, him, his)  
General Counsel  
Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC. 20201  
(202) 690-7758

---

**From:** Edmonds, Amanda (b)(6)  
**Sent:** Tuesday, April 25, 2023 8:20 PM  
**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin (HHS/OGC)  
<Katlin.Backfield@hhs.gov>  
**Cc:** Taylor, Paige (FDA/OC) (b)(6) Allen, Tracey (FDA/OC)  
(b)(6) Sreenath, Aravind (FDA/OC) (b)(6) Katz,  
Donna (FDA/OC) (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft  
**Importance:** High

Sam and Katlin,

We believe this is one we ought to elevate—the main concern is not (b)(5)

To recap, the draft brief says: (b)(5)

(b)(5)

(b)(5)

We asked that the language be deleted. We have two main concerns.

(b)(5)

Let us know if it would be helpful to discuss this—we didn't want to go back to DOJ until we raised with you.

Thanks,



Amanda and the FDD team

---

**From:** Harrington, Sarah E. (CIV) <Sarah.E.Harrington@usdoj.gov>  
**Sent:** Tuesday, April 25, 2023 6:40 PM  
**To:** Taylor, Paige (b)(6) Barmore, Cynthia A. (CIV) <Cynthia.A.Barmore@usdoj.gov>; Raab, Michael (CIV) <Michael.Raab@usdoj.gov>  
**Cc:** Bagenstos, Samuel R (OS) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin M (OS) <Katlin.Backfield@hhs.gov>; Edmonds, Amanda (b)(6) Allen, Tracey (b)(6) Sreenath, Aravind (b)(6) Katz, Donna (b)(6)  
**Subject:** [EXTERNAL] RE: Revised draft

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Paige,

(b)(5)

(b)(5)

Please let me know ASAP. Thanks.

Sarah

---

Sarah E. Harrington (she/her)  
Deputy Assistant Attorney General  
Civil Division

(b)(6)

**From:** Taylor, Paige (b)(6)  
**Sent:** Tuesday, April 25, 2023 1:03 PM  
**To:** Harrington, Sarah E. (CIV) <Sarah.E.Harrington@usdoj.gov>  
**Cc:** Bagenstos, Samuel R (OS) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin M (OS) <Katlin.Backfield@hhs.gov>; Edmonds, Amanda (b)(6) Allen, Tracey (b)(6) Sreenath, Aravind (b)(6) Katz, Donna (b)(6)  
**Subject:** [EXTERNAL] Revised draft

Attached are FDA's comments on the revised draft. Sam and Katlin did not have an opportunity to review these proposed edits.

Please let us know if you have any questions about our comments.

Thanks much

Paige

Paige H. Taylor (she/her/hers)  
Senior Counsel  
Food and Drug Division, OGC  
White Oak Bldg 32, Rm 4380  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
301-796-8720 (office)  
301-847-8618 (fax)  
(b)(6)

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Katz, Donna (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
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(b)(6)

**Sent Date:** 2023/04/26 09:26:26

**Delivered Date:** 2023/04/26 09:26:45

**From:** Varrone, Michael (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9306362F89804E94AB30BDF2D28EE0A6-VARRONE, MI <Michael.Varrone@hhs.gov>

**To:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

**Subject:** RE: Sandoz v. Becerra: Draft Joint Status Report

**Date:** 2022/06/28 16:06:10

**Priority:** Normal

**Type:** Note

Thanks. Nothing notable here.

---

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>

**Sent:** Tuesday, June 28, 2022 4:03 PM

**To:** Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>

**Subject:** Re: Sandoz v. Becerra: Draft Joint Status Report

I don't need to review a JSR unless you tell me there's something notable about it.

Samuel R. Bagenstos  
General Counsel  
Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC. 20201  
(202) 690-7758

---

**From:** Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>

**Sent:** Tuesday, June 28, 2022 4:01:25 PM

**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>

**Subject:** FW: Sandoz v. Becerra: Draft Joint Status Report

Sam – I presume you do not want to review this joint status report that is **due tomorrow**, but please let me know if you do (FWIW, it looks fine to me).

---

**From:** Allred, James (b)(6)

**Sent:** Tuesday, June 28, 2022 3:51 PM

**To:** Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>

**Cc:** Raza, Mark (FDA/OC) (b)(6) Dickinson, Elizabeth (FDA) (FDA/OC)

(b)(6) Beckerman, Peter (FDA/OC) (b)(6)

Edmonds, Amanda (FDA/OC) (b)(6) Vicente, Wendy (FDA/OC)

(b)(6) Gorji, Perham (FDA/OC) (b)(6) Hutchinson,

Shoshana (FDA/OC) (b)(6) Singleton, Shannon (FDA/OC)

(b)(6) Cohen, Leslie (FDA/OC) (b)(6)

**Subject:** Sandoz v. Becerra: Draft Joint Status Report

Mike,

I have attached a proposed Joint Status Report in the case of Sandoz v. FDA. This case is an APA challenge to FDA's award of five-year New Chemical Entity (NCE) exclusivity to Sanofi's drug Aubagio,

(b)(5)

(b)(5)

The case was fully briefed as of August 2021 and is awaiting oral argument or decision in the district court for the District of Columbia.

Last week, the Court issued a Minute Order asking the parties to file a Joint Status Report within seven days answering the factual question of whether any generics referencing Sanofi's Aubagio are being marketed. The parties have conferred and drafted the attached JSR. This JSR aims simply to (b)(5)

(b)(5)

We are providing the draft to you in case you or Sam want to review. Unfortunately, because of the short timeframe ordered by the court, the deadline to file is tomorrow (June 29).

Please let Leslie and me know if we can answer any questions or otherwise assist your review. We appreciate it.

James

James Allred  
Food & Drug Division, OGC/HHS  
Office of the Chief Counsel, FDA  
(b)(6)  
(O): 301-837-7618  
(C): 240-463-3958 (preferred)

**Sender:** Varrone, Michael (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9306362F89804E94AB30BDF2D28EE0A6-VARRONE, MI <Michael.Varrone@hhs.gov>

**Recipient:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

**Sent Date:** 2022/06/28 16:06:09

**Delivered Date:** 2022/06/28 16:06:10

**From:** Varrone, Michael (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9306362F89804E94AB30BDF2D28EE0A6-VARRONE, MI <Michael.Varrone@hhs.gov>

**To:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

**Subject:** RE: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/25 BY 4:00PM

**Date:** 2022/07/25 15:25:38

**Priority:** Normal

**Type:** Note

Ok. Thank you!

---

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>  
**Sent:** Monday, July 25, 2022 3:24 PM  
**To:** Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>  
**Subject:** RE: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/25 BY 4:00PM

I think I saw the draft guidance when I was at OMB. You may certainly clear. Thanks!

Samuel R. Bagenstos  
General Counsel  
Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201  
(202) 690-7758

---

**From:** Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>  
**Sent:** Monday, July 25, 2022 3:18 PM  
**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>  
**Subject:** FW: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/25 BY 4:00PM  
**Importance:** High

Sam,

Attached for review **by 6 pm today** is a guidance for industry entitled "Policy Regarding N-acetyl-L-cysteine: Guidance for Industry." Currently, N-acetyl-L-cysteine (NAC) is excluded from the definition of a "dietary supplement" because FDA approved NAC as a new drug on September 14, 1963, and the agency is not aware of any evidence NAC was marketed as a dietary supplement or as a food before that date. The guidance explains FDA's intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain NAC and are labeled as dietary supplements until either:

- FDA completes a notice-and-comment rulemaking to allow the use of NAC in or as a dietary supplement; or
- FDA denies the Natural Products Association's (NPA) citizen petition request for rulemaking.

NPA has sued FDA regarding whether NAC is excluded from the FD&C Act's definition of "dietary supplement." The lawsuit alleges, among other things, that certain statements by FDA regarding the status of NAC caused a major online retailer to remove NAC-containing products from its platform. FDA's goal is to issue this final guidance as soon as possible, as part of its litigation response strategy. NPA wants to see the final guidance before it decides whether to dismiss its lawsuit. A joint status report is due in the lawsuit on August 10, 2022.

The guidance finalizes, without substantive changes, a draft that FDA issued in April 2022. I have reviewed the guidance and do not have any comments. Please let me know if you would like to look at it. If you do, I would start with the backgrounder.

---

**From:** OS OGC-IO ControlDesk (HHS/OS/OGC) <[ControlDesk.OGCIO@hhs.gov](mailto:ControlDesk.OGCIO@hhs.gov)>  
**Sent:** Friday, July 22, 2022 11:19 AM  
**To:** Varrone, Michael (HHS/OGC) <[Michael.Varrone@hhs.gov](mailto:Michael.Varrone@hhs.gov)>  
**Cc:** OS OGC-IO ControlDesk (HHS/OS/OGC) <[ControlDesk.OGCIO@hhs.gov](mailto:ControlDesk.OGCIO@hhs.gov)>  
**Subject:** FW: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/25 BY 4:00PM  
**Importance:** High

Hi Mike,

Please see the updated attachments for your review and approval. DUE 7/25 BY 4:00PM

Respectfully,

Rochelle Ross  
U.S. Department of Health and Human Services  
Office of the General Counsel  
200 Independence Avenue, S.W., Room 737F.12  
Washington, DC 20201  
(202)690-5558, Office  
(b)(6) Work Cell  
[Rochelle.Ross@hhs.gov](mailto:Rochelle.Ross@hhs.gov)

---

**From:** Nunes, Bianca (b)(6)  
**Sent:** Friday, July 22, 2022 11:01 AM  
**To:** OS OGC-IO ControlDesk (HHS/OS/OGC) <[ControlDesk.OGCIO@hhs.gov](mailto:ControlDesk.OGCIO@hhs.gov)>; FDA OGC FDD Control (b)(6)  
**Cc:** Kropa, Halley (FDA/OC) (b)(6); Beckerman, Peter (FDA/OC) (b)(6)  
**Subject:** RE: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM- Return by 1:00pm

FDD has no comments on the backgrounder.

Reviewing attorney: Bianca Nunes  
Supervising attorney: Halley Kropa



Thanks very much,  
Bianca

Bianca Nunes  
Attorney  
Office of the Chief Counsel, FDA  
Food & Drug Division, OGC/HHS  
301-796-1717

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**From:** OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OCGIO@hhs.gov>  
**Sent:** Friday, July 22, 2022 10:49 AM  
**To:** FDA OGC FDD Control (b)(6)  
**Cc:** OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OCGIO@hhs.gov>; Nunes, Bianca (b)(6)  
**Subject:** RE: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM- Return by 1:00pm  
**Importance:** High

Good morning,

Please see the attached "backgrounder" for reviewer reference, as it was missing from the original package. The attached was being finalized but FDA wanted to get the documents out ASAP given the litigation and timing constraints. Please review and return by **1:00pm** please.

Respectfully,

Rochelle Ross  
U.S. Department of Health and Human Services  
Office of the General Counsel  
200 Independence Avenue, S.W., Room 737F.12  
Washington, DC 20201  
(202)690-5558, Office  
(b)(6) Work Cell  
[Rochelle.Ross@hhs.gov](mailto:Rochelle.Ross@hhs.gov)

---

**From:** Nunes, Bianca (b)(6)  
**Sent:** Friday, July 22, 2022 7:42 AM  
**To:** OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OCGIO@hhs.gov>  
**Cc:** FDA OGC FDD Control (b)(6) OC OCC Legal Requests-Foods Mailbox (b)(6)  
(b)(6) Kropa, Halley (FDA/OC) (b)(6)  
Beckerman, Peter (FDA/OC) (b)(6) Taylor, Paige (FDA/OC)

(b)(6)

**Subject:** FW: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM

FDD clears the guidance without comment.

Reviewing attorney: Bianca Nunes  
Supervising attorney: Halley Kropa

Best,  
Bianca

Bianca Nunes  
Attorney  
Office of the Chief Counsel, FDA  
Food & Drug Division, OGC/HHS  
301-796-1717

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**From:** OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OCGIO@hhs.gov>  
**Sent:** Thursday, July 21, 2022 5:59 PM  
**To:** FDA OGC FDD Control (b)(6)  
**Cc:** OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OCGIO@hhs.gov>  
**Subject:** \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM  
**Importance:** High

**\*EXPEDITED\* NAC Enforcement Discretion - Final Guidance  
DUE 7/22 BY 4:00PM**

Respectfully,

Rochelle Ross  
U.S. Department of Health and Human Services  
Office of the General Counsel  
200 Independence Avenue, S.W., Room 737F.12  
Washington, DC 20201  
(202)690-5558, Office  
(b)(6) Work Cell  
[Rochelle.Ross@hhs.gov](mailto:Rochelle.Ross@hhs.gov)

**Sender:** Varrone, Michael (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9306362F89804E94AB30BDF2D28EE0A6-VARRONE, MI <Michael.Varrone@hhs.gov>

**Recipient:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

**Sent Date:** 2022/07/25 15:25:37

**Delivered Date:** 2022/07/25 15:25:38

**From:** Taylor, Paige (b)(6)

Edmonds, Amanda (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5cbda2dd035d4ab7bdca39b091c7ff66-amanda.edmo  
(b)(6)

**To:** Backfield, Katlin (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e7b8d19569d64700b154b303c3c20fc9-5a0e7824-52  
<Katlin.Backfield@hhs.gov>;  
Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos,  
<Samuel.Bagenstos@hhs.gov>

Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=25727dc5722145c28b23f442cccbece3-tracey.all  
(b)(6)

**CC:** Sreenath, Aravind (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b01fd3a70f704078a223a48feed5fce-aravind.sre  
(b)(6)

Katz, Donna (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddccdba7aaf4eada3d7bbd509beda08-donna.katz.  
(b)(6)

**Subject:** Re: [EXTERNAL] RE: Revised draft

**Date:** 2023/04/25 20:45:53

**Priority:** Normal

**Type:** Note

Thank you!

Get Outlook for iOS

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>

**Sent:** Tuesday, April 25, 2023 8:44:23 PM

**To:** Edmonds, Amanda (b)(6) Backfield, Katlin M (OS)  
<Katlin.Backfield@hhs.gov>

**Cc:** Taylor, Paige (b)(6) Allen, Tracey (b)(6) Sreenath,  
Aravind (b)(6) Katz, Donna (b)(6)

**Subject:** RE: [EXTERNAL] RE: Revised draft

I got a little backstory from Sarah. She's going to try to shut this down with OSG. If that doesn't work, we'll meet tomorrow.

Samuel R. Bagenstos (he, him, his)  
General Counsel  
Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC. 20201  
(202) 690-7758

**From:** Edmonds, Amanda (b)(6)

**Sent:** Tuesday, April 25, 2023 8:41 PM

**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin (HHS/OGC)  
<Katlin.Backfield@hhs.gov>

**Cc:** Taylor, Paige (FDA/OC) (b)(6) Allen, Tracey (FDA/OC)

(b)(6) Sreenath, Aravind (FDA/OC) (b)(6) Katz,  
Donna (FDA/OC) (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft

Awesome, thanks so much. It's so hard to see why the statement (b)(5)

(b)(5)

---

**From:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>  
**Sent:** Tuesday, April 25, 2023 8:29 PM  
**To:** Edmonds, Amanda (b)(6) Backfield, Katlin M (OS)  
<Katlin.Backfield@hhs.gov>  
**Cc:** Taylor, Paige (b)(6) Allen, Tracey (b)(6) Sreenath,  
Aravind (b)(6) Katz, Donna (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft

I think you probably saw my email to Sarah just now. I'm willing to push them on this.

Samuel R. Bagenstos (he, him, his)  
General Counsel  
Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC. 20201  
(202) 690-7758

---

**From:** Edmonds, Amanda (b)(6)  
**Sent:** Tuesday, April 25, 2023 8:20 PM  
**To:** Bagenstos, Samuel (HHS/OGC) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin (HHS/OGC)  
<Katlin.Backfield@hhs.gov>  
**Cc:** Taylor, Paige (FDA/OC) (b)(6) Allen, Tracey (FDA/OC)  
(b)(6) Sreenath, Aravind (FDA/OC) (b)(6) Katz,  
Donna (FDA/OC) (b)(6)  
**Subject:** RE: [EXTERNAL] RE: Revised draft  
**Importance:** High

Sam and Katlin,

We believe this is one we ought to elevate—the main concern is not (b)(5)

To recap, the draft brief says: (b)(5)

(b)(5)

(b)(5)

We asked that the language be deleted. We have two main concerns.

(b)(5)

Let us know if it would be helpful to discuss this—we didn't want to go back to DOJ until we raised with you.

Thanks,

Amanda and the FDD team

---

**From:** Harrington, Sarah E. (CIV) <Sarah.E.Harrington@usdoj.gov>

**Sent:** Tuesday, April 25, 2023 6:40 PM

**To:** Taylor, Paige (b)(6) Barmore, Cynthia A. (CIV)  
<Cynthia.A.Barmore@usdoj.gov>; Raab, Michael (CIV) <Michael.Raab@usdoj.gov>

**Cc:** Bagenstos, Samuel R (OS) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin M (OS)  
<Katlin.Backfield@hhs.gov>; Edmonds, Amanda (b)(6) Allen,  
Tracey (b)(6) Sreenath, Aravind (b)(6)  
Katz, Donna (b)(6)

**Subject:** [EXTERNAL] RE: Revised draft

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.

Paige,

(b)(5)

Sarah

---

Sarah E. Harrington (she/her)  
Deputy Assistant Attorney General  
Civil Division  
(202) 598-3883

---

**From:** Taylor, Paige (b)(6)

**Sent:** Tuesday, April 25, 2023 1:03 PM

**To:** Harrington, Sarah E. (CIV) <Sarah.E.Harrington@usdoj.gov>  
**Cc:** Bagenstos, Samuel R (OS) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin M (OS) <Katlin.Backfield@hhs.gov>; Edmonds, Amanda (b)(6) Allen, Tracey (b)(6) Sreenath, Aravind (b)(6) Katz, Donna (b)(6)  
**Subject:** [EXTERNAL] Revised draft

Attached are FDA's comments on the revised draft. Sam and Katlin did not have an opportunity to review these proposed edits.

Please let us know if you have any questions about our comments.

Thanks much

Paige

Paige H. Taylor (she/her/hers)  
Senior Counsel  
Food and Drug Division, OGC  
White Oak Bldg 32, Rm 4380  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
301-796-8720 (office)  
301-847-8618 (fax)  
(b)(6)

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**Sender:** Taylor, Paige (b)(6)  
Edmonds, Amanda (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5cbda2dd035d4ab7bdca39b091c7ff66-amanda.edmo (b)(6)  
Backfield, Katlin (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7b8d19569d64700b154b303c3c20fc9-5a0e7824-52 <Katlin.Backfield@hhs.gov>;  
**Recipient:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>;  
Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25727dc5722145c28b23f442cccbece3-tracey.alle (b)(6)  
Sreenath, Aravind (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b01fd3a70f704078a223a48feed5fce-aravind.sre (b)(6)  
Katz, Donna (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddccdba7aaf4eada3d7bbd509beda08-donna.katz.  
(b)(6)

**Sent Date:** 2023/04/25 20:45:24

**Delivered Date:** 2023/04/25 20:45:53

**From:** Varrone, Michael (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9306362F89804E94AB30BDF2D28EE0A6-VARRONE, MI <Michael.Varrone@hhs.gov>

**To:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

**Subject:** FW: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/25 BY 4:00PM

**Date:** 2022/07/25 15:18:40

**Importance:** High

**Priority:** Urgent

**Type:** Note

Sam,

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- FDA denies the Natural Products Association's (NPA) citizen petition request for rulemaking.

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**Sent:** Friday, July 22, 2022 11:19 AM

**To:** Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>

**Cc:** OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>

**Subject:** FW: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/25 BY 4:00PM

**Importance:** High

Hi Mike,

Please see the updated attachments for your review and approval. DUE 7/25 BY 4:00PM

Respectfully,

Rochelle Ross  
U.S. Department of Health and Human Services  
Office of the General Counsel  
200 Independence Avenue, S.W., Room 737F.12  
Washington, DC 20201  
(202)690-5558, Office  
(202)731-8760, Work Cell  
[Rochelle.Ross@hhs.gov](mailto:Rochelle.Ross@hhs.gov)

---

**From:** Nunes, Bianca (b)(6)  
**Sent:** Friday, July 22, 2022 11:01 AM  
**To:** OS OGC-IO ControlDesk (HHS/OS/OGC) <[ControlDesk.OCGIO@hhs.gov](mailto:ControlDesk.OCGIO@hhs.gov)>; FDA OGC FDD Control (b)(6)  
**Cc:** Kropa, Halley (FDA/OC) (b)(6); Beckerman, Peter (FDA/OC) (b)(6)  
**Subject:** RE: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM- Return by 1:00pm

FDD has no comments on the backgrounder.

Reviewing attorney: Bianca Nunes  
Supervising attorney: Halley Kropa

Thanks very much,  
Bianca

Bianca Nunes  
Attorney  
Office of the Chief Counsel, FDA  
Food & Drug Division, OGC/HHS  
301-796-1717

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**Cc:** OS OGC-IO ControlDesk (HHS/OS/OGC) <[ControlDesk.OCGIO@hhs.gov](mailto:ControlDesk.OCGIO@hhs.gov)>; Nunes, Bianca (b)(6)

**Subject:** RE: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM- Return by 1:00pm  
**Importance:** High

Good morning,

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Respectfully,

Rochelle Ross  
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Office of the General Counsel  
200 Independence Avenue, S.W., Room 737F.12  
Washington, DC 20201  
(202)690-5558, Office  
(202)731-8760, Work Cell  
[Rochelle.Ross@hhs.gov](mailto:Rochelle.Ross@hhs.gov)

---

**From:** Nunes, Bianca (b)(6)  
**Sent:** Friday, July 22, 2022 7:42 AM  
**To:** OS OGC-IO ControlDesk (HHS/OS/OGC) <[ControlDesk.OCICIO@hhs.gov](mailto:ControlDesk.OCICIO@hhs.gov)>  
**Cc:** FDA OGC FDD Control (b)(6) OC OCC Legal Requests-Foods Mailbox (b)(6) Kropa, Halley (FDA/OC) (b)(6) Beckerman, Peter (FDA/OC) (b)(6) Taylor, Paige (FDA/OC) <[Paige.Taylor@fda.hhs.gov](mailto:Paige.Taylor@fda.hhs.gov)>  
**Subject:** FW: \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM

FDD clears the guidance without comment.

Reviewing attorney: Bianca Nunes  
Supervising attorney: Halley Kropa

Best,  
Bianca

Bianca Nunes  
Attorney  
Office of the Chief Counsel, FDA  
Food & Drug Division, OGC/HHS  
301-796-1717

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**From:** OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>  
**Sent:** Thursday, July 21, 2022 5:59 PM  
**To:** FDA OGC FDD Control (b)(6)  
**Cc:** OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>  
**Subject:** \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM  
**Importance:** High

**\*EXPEDITED\* NAC Enforcement Discretion - Final Guidance  
DUE 7/22 BY 4:00PM**

Respectfully,

Rochelle Ross  
U.S. Department of Health and Human Services  
Office of the General Counsel  
200 Independence Avenue, S.W., Room 737F.12  
Washington, DC 20201  
(202)690-5558, Office  
(202)731-8760, Work Cell  
[Rochelle.Ross@hhs.gov](mailto:Rochelle.Ross@hhs.gov)

**Sender:** Varrone, Michael (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9306362F89804E94AB30BDF2D28EE0A6-VARRONE, MI <Michael.Varrone@hhs.gov>  
**Recipient:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>  
**Sent Date:** 2022/07/25 15:18:07  
**Delivered Date:** 2022/07/25 15:18:40  
**From:** OS OGC-IO ControlDesk (HHS/OS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C9F99A0B2364CB5BD1B739DB7851E43-CONTROLDESK <ControlDesk.OGCIO@hhs.gov>  
**To:** FDA OGC FDD Control (b)(6)  
**CC:** OS OGC-IO ControlDesk (HHS/OS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c9f99a0b2364cb5bd1b739db7851e43-controldesk <ControlDesk.OGCIO@hhs.gov>  
**Subject:** \*EXPEDITED\* TRACS NO. 22-16294 % DUE 7/22 BY 4:00PM  
**Date:** 2022/07/21 17:59:00  
**Importance:** High  
**Priority:** Urgent  
**Type:** Note

**\*EXPEDITED\*** NAC Enforcement Discretion - Final Guidance  
**DUE 7/22 BY 4:00PM**

Respectfully,

Rochelle Ross  
U.S. Department of Health and Human Services  
Office of the General Counsel  
200 Independence Avenue, S.W., Room 737F.12  
Washington, DC 20201  
(202)690-5558, Office  
(b)(6) Work Cell  
[Rochelle.Ross@hhs.gov](mailto:Rochelle.Ross@hhs.gov)

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**Recipient:** FDA OGC FDD Control (b)(6)  
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**Sent Date:** 2022/07/21 17:59:23

**Delivered Date:** 2022/07/21 17:59:00

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Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

**Subject:** FW: Sandoz v. Becerra: Summary Judgment In Favor of FDA

**Date:** 2022/07/26 09:42:40

**Priority:** Normal

**Type:** Note

Hi Sam. See the email below from FDD about a good result in a challenge to FDA's award of new chemical entity exclusivity to Sanofi's drug, Aubagio. Interestingly, the court avoided any citation to *Chevron* despite both parties briefing it. The opinion is attached.

Mike

**From:** Allred, James (b)(6)

**Sent:** Friday, July 22, 2022 5:34 PM

**To:** Varrone, Michael (HHS/OGC) <Michael.Varrone@hhs.gov>; Raza, Mark (FDA/OC)

(b)(6) Dickinson, Elizabeth (FDA) (FDA/OC) (b)(6)

Beckerman, Peter (FDA/OC) (b)(6)

**Cc:** Edmonds, Amanda (FDA/OC) (b)(6) Vicente, Wendy (FDA/OC)

(b)(6) Gorji, Perham (FDA/OC) (b)(6) Hutchinson,

Shoshana (FDA/OC) (b)(6) Singleton, Shannon (FDA/OC)

(b)(6) Cohen, Leslie (FDA/OC) (b)(6)

**Subject:** Sandoz v. Becerra: Summary Judgment In Favor of FDA

Good Afternoon and Happy Friday,

I'm writing to share a positive result in a Hatch-Waxman litigation matter that has been pending for nearly a year. In Sandoz v. Becerra, the US District Court for the District of Columbia ruled in our favor on all counts and granted our motion for summary judgment this afternoon. I have attached the opinion.

In this case, Sandoz was challenging FDA's award of new chemical entity exclusivity to Sanofi's drug Aubagio. (b)(5)

(b)(5)

(b)(5)

Finally, in light of recent legal developments, I want to emphasize (b)(5)

(b)(5)

Finally, while I am the one writing on both of our behalf, credit is due to Leslie's brilliant strategizing and skillful craftwork in preparing these arguments and briefs. The court found our arguments and examples persuasive, and they appear throughout the opinion.

This appears to be an opinion that (b)(5)

(b)(5)

James

James Allred  
Food & Drug Division, OGC/HHS  
Office of the Chief Counsel, FDA

(b)(6)

(O): 301-837-7618

(C): (b)(6) (preferred)

**Sender:** Varrone, Michael (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9306362F89804E94AB30BDF2D28EE0A6-VARRONE, MI <Michael.Varrone@hhs.gov>

**Recipient:** Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>

**Sent Date:** 2022/07/26 09:42:22

**Delivered Date:** 2022/07/26 09:42:40



**From:** Edmonds, Amanda (b)(6)

Bagenstos, Samuel (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afa71ea876614421a32eee5049c60e45-Bagenstos, <Samuel.Bagenstos@hhs.gov>;

**To:** Backfield, Katlin (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7b8d19569d64700b154b303c3c20fc9-5a0e7824-52 <Katlin.Backfield@hhs.gov>

Taylor, Paige (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4d4996afe9942e8aadae54716e6ff9f-paige.taylor (b)(6)

Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25727dc5722145c28b23f442cccbece3-tracey.allen (b)(6)

**CC:** Sreenath, Aravind (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b01fd3a70f704078a223a48feeed5fce-aravind.sreenath (b)(6)

Katz, Donna (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddccdba7aaf4eada3d7bbd509beda08-donna.katz. (b)(6)

**Subject:** RE: [EXTERNAL] RE: Revised draft

**Date:** 2023/04/25 20:22:51

**Importance:** High

**Priority:** Urgent

**Type:** Note

Sam and Katlin,

We believe this is one we ought to elevate—the main concern is not (b)(5)

To recap, the draft brief says: (b)(5)

(b)(5)

We asked that the language be deleted. We have two main concerns.

(b)(5)

(b)(5)

Let us know if it would be helpful to discuss this—we didn't want to go back to DOJ until we raised with you.

Thanks,

Amanda and the FDD team

---

**From:** Harrington, Sarah E. (CIV) <Sarah.E.Harrington@usdoj.gov>

**Sent:** Tuesday, April 25, 2023 6:40 PM

**To:** Taylor, Paige (b)(6) Barmore, Cynthia A. (CIV)  
<Cynthia.A.Barmore@usdoj.gov>; Raab, Michael (CIV) <Michael.Raab@usdoj.gov>

**Cc:** Bagenstos, Samuel R (OS) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin M (OS)  
<Katlin.Backfield@hhs.gov>; Edmonds, Amanda (b)(6) Allen,

Tracey (b)(6) Sreenath, Aravind (b)(6)

Katz, Donna (b)(6)

**Subject:** [EXTERNAL] RE: Revised draft

**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.

Paige,

(b)(5)

(b)(5)

Please let me know ASAP. Thanks.

Sarah

Sarah E. Harrington (she/her)  
Deputy Assistant Attorney General  
Civil Division

(b)(6)

**From:** Taylor, Paige (b)(6)  
**Sent:** Tuesday, April 25, 2023 1:03 PM  
**To:** Harrington, Sarah E. (CIV) <Sarah.E.Harrington@usdoj.gov>  
**Cc:** Bagenstos, Samuel R (OS) <Samuel.Bagenstos@hhs.gov>; Backfield, Katlin M (OS) <Katlin.Backfield@hhs.gov>; Edmonds, Amanda (b)(6) Allen, Tracey (b)(6) Sreenath, Aravind (b)(6) Katz, Donna (b)(6)  
**Subject:** [EXTERNAL] Revised draft

Attached are FDA's comments on the revised draft. Sam and Katlin did not have an opportunity to review these proposed edits.

Please let us know if you have any questions about our comments.

Thanks much

Paige

Paige H. Taylor (she/her/hers)  
Senior Counsel  
Food and Drug Division, OGC  
White Oak Bldg 32, Rm 4380  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
301-796-8720 (office)  
301-847-8618 (fax)

(b)(6)

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(b)(6)

**Sent Date:** 2023/04/25 20:20:23

**Delivered Date:** 2023/04/25 20:22:51

**From:** Edmonds, Amanda (b)(6)

Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edef6-mark.raza.f  
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**To:**

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Gerton, Jennifer (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
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Vicente, Wendy (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
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Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=25727dc5722145c28b23f442cccbece3-tracey.alle  
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Rawson, William (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d5627561e72c45fe8ade284d12df24f9-91a748c3-84  
(b)(6)  
Naik, Priya (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bae843af7b9497987c24680451e954b-priya.naik.  
(b)(6)

**Subject:** for the files--from Don Beers re (b)(5) of ANDAs

**Date:** 2023/04/25 17:48:00

**Type:** Note

An excellent email on the process CDER has followed for (b)(5) Not that this process

(b)(5)

**From:** Edmonds, Amanda

**Sent:** Friday, May 21, 2021 4:05 PM

**To:** Dettelbach, Kim (b)(6) Brandel, Abigail (b)(6)

Chasan-Sloan, Deborah (FDA) (b)(6)

**Subject:** FW: (b)(5)

(b)(5)

Another helpful email from Don for the files, re (b)(5) I remembered most of this but it is helpful to have it laid out in the email.

**From:** Beers, Donald (b)(6)

**Sent:** Friday, May 21, 2021 4:02 PM

**To:** Naik, Priya (b)(6)

**Cc:** Edmonds, Amanda (b)(6)

**Subject:** FW: (b)(5)

(b)(5)

Priya,

Amanda and Kim have asked me to bring you in on this example of a (b)(5)

(b)(5)

(b)(5)

Amanda requested that we include her when I brief you about (b)(5) generally and I have picked what looks like the next spot that is open on our three calendars for that next Wednesday at 1.

Don

**From:** Furness, Melissa (b)(6)

**Sent:** Thursday, May 20, 2021 11:42 AM

**To:** Beers, Donald (b)(6)

**Cc:** Graham, Laurie (b)(6) Ciurca, Lauren (b)(6)

**Subject:** RE: (b)(5)

(b)(5)

Hi Don,

Happy Thursday!

Please find the telecon script for (b)(5) attached for your review and comment. Please let me know if you have any questions or concerns.

Thanks much and have a great day!

Best,

Melissa

---

**From:** Beers, Donald (b)(6)  
**Sent:** Thursday, May 13, 2021 3:18 PM  
**To:** Furness, Melissa (b)(6)  
**Cc:** Graham, Laurie (b)(6); Ciurca, Lauren (b)(6)  
**Subject:** RE: (b)(5)

Thanks. If you have a sense that the applicant will fight about this, please let me know.

---

**From:** Furness, Melissa (b)(6)  
**Sent:** Thursday, May 13, 2021 3:12 PM  
**To:** Beers, Donald (b)(6)  
**Cc:** Graham, Laurie (b)(6); Ciurca, Lauren (b)(6)  
**Subject:** RE: (b)(5)

Thanks much, Don. We are in the process of drafting a telecon script. Once this is completed, we will plan to send to you for feedback. After the telecon, we will then draft a letter to the applicant that summarizes the discussion that occurred. Please let me know if you have any additional questions.

Thanks again!

Best,

Melissa

---

**From:** Beers, Donald (b)(6)  
**Sent:** Thursday, May 13, 2021 3:09 PM  
**To:** Furness, Melissa (b)(6)  
**Cc:** Graham, Laurie (b)(6); Ciurca, Lauren (b)(6)  
**Subject:** RE: (b)(5)

Melissa,

I have made a couple of suggested edits in the attached. Are you planning to proceed with a call and letter to the applicant?

Don

**From:** Furness, Melissa (b)(6)

**Sent:** Tuesday, May 11, 2021 2:01 PM

**To:** Beers, Donald (b)(6)

**Cc:** Graham, Laurie (b)(6); Ciurca, Lauren (b)(6)

**Subject:** (b)(5)

Hi Don,

I hope that this message finds you doing well.

(b)(5)

Thanks much as always for your time and guidance and I hope that you have a wonderful remainder of the week!

Best,

Melissa

## Melissa Hancock Furness

Policy Lead

CDER/OPQ/OPPQ/DIPAP

240-402-8912

**Sender:** Edmonds, Amanda (b)(6)

Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edef6-mark.raza.f

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Beardsley, Sara (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=104e625794584c708b00ba9a0317c77d-sara.beards



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(b)(6)

Taylor, Paige (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
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Allen, Tracey (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
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Rawson, William (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d5627561e72c45fe8ade284d12df24f9-91a748c3-84

(b)(6)

Naik, Priya (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bae843af7b9497987c24680451e954b-priya.naik.

(b)(6)

**Sent Date:** 2023/04/25 17:48:00

**From:** Cha, Stephen (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23E67977D77947D69BAF2ACE846821A8-CHA, STEPHE>  
Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>;  
Tierney, Julia (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group  
**To:** (FYDIBOHF23SPDLT)/cn=Recipients/cn=367e11c5deec4593ac4dc9b66d0a2e15-julia.tiern (b)(6)  
Miller - Tolbert, Kimberly (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae7fdbbb6735470bab1203afb08f5b7d-Miller - To <Kimberly.Miller-tolbert@hhs.gov>  
**Subject:** RE: [EXTERNAL] Infuvite and TPN | Request to release product  
**Date:** 2023/02/23 13:59:00  
**Priority:** Normal  
**Type:** Note

Nope. I wonder if the ASPR team might have been talking to them?

---

**From:** Despres, Sarah (HHS/IOS) <Sarah.Despres@hhs.gov>  
**Sent:** Thursday, February 23, 2023 1:58 PM  
**To:** Tierney, Julia (FDA/OC) (b)(6) Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Miller - Tolbert, Kimberly (OS/IOS) <Kimberly.Miller-tolbert@hhs.gov>  
**Subject:** RE: [EXTERNAL] Infuvite and TPN | Request to release product

NOT IT! Adding @Miller - Tolbert, Kimberly (OS/IOS) in case she has any insights.

---

**From:** Tierney, Julia (b)(6)  
**Sent:** Thursday, February 23, 2023 1:45 PM  
**To:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Despres, Sarah (HHS/IOS) <Sarah.Despres@hhs.gov>  
**Subject:** FW: [EXTERNAL] Infuvite and TPN | Request to release product

Is it possible this is referencing a call with HHS? No one on the to line was on a call with them yesterday.

---

**From:** Marston, Hilary (b)(6)  
**Sent:** Thursday, February 23, 2023 11:06 AM  
**To:** Courtney, Brooke (b)(6) Tierney, Julia (b)(6)  
**Cc:** Cristinzio, Dayle (b)(6) Jarman-Miller, Hannah <Hannah.Jarman-(b)(6)>  
**Subject:** Fwd: [EXTERNAL] Infuvite and TPN | Request to release product

I wasn't on this call but want to make sure this is triaged correctly. Brooke to whom should we send for follow up?

Get Outlook for IOS

**From:** Terri Wilson <Terri.Wilson@childrenshospitals.org>

**Sent:** Thursday, February 23, 2023 12:36:03 PM

**To:** Marston, Hilary (b)(6) Califf, Robert (b)(6) Cristinzio, Dayle (b)(6)

**Cc:** Natalie Torentinos <Natalie.Torentinos@childrenshospitals.org>; Aimee Ossman <Aimee.Ossman@childrenshospitals.org>

**Subject:** [EXTERNAL] Infuvite and TPN | Request to release product

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.

Thank you for taking time today to hear about the *Infuvite* shortage and how it's impacting pediatric hospitals. We appreciate the continued support FDA has shown for children's hospitals and the patients they serve.

Pediatric hospitals have been dealing with ongoing shortages and backorders on many products required to provide Total Parenteral Nutrition (TPN) for children and neonates. Children's hospitals compound more TPN than their adult counterparts, and neonates and critically ill children have unique nutritional needs that require more precise feeding, and have metabolic needs that are greater than they will be any other time in their lives.

*Infuvite* (Baxter), is produced by Sandoz, and is currently out of stock in US (and Canadian) distributors, and in critically short supply (due to long standing allocation system) in hospitals across the US, including Children's Hospitals. We understand this shortage is a direct result of a lack of supply of the reagent needed to test B12 potency in final formulations.

We also understand the following:

- Sandoz has continued production in hopes of attaining the needed reagent.
- *Infuvite* supply currently being held exceeds all backorders, and once released will adequately support patient care.
- Sandoz has not found a batch to be "out of B12 specs" during the time (~10 years) they have produced this product.
- The approved reagent (produced by BD) is not anticipated to be available until mid April at the earliest.
- Sandoz is seeking acquisition of an alternate testing reagent, which could possibly be available in mid March, and potentially validated and able to be used by the end of March, or early April.

Despite allocation to protect hospitals from shortage, as well as urgent response to critical hospital specific shortages, more supply is required. For this product we are asking FDA to release the supply currently awaiting B12 spec validation. This will be most impactful and most supportive for our patients who need *Infuvite* to sustain growth.

Please do not hesitate to reach out with questions, concerns or follow up needs, and thank you for collaborating with us to mitigate these ongoing shortages.

Be well,

**TERRI LYLE WILSON**

Director, Pharmacy – Supply Chain Services

**CHILDREN'S HOSPITAL ASSOCIATION**

16011 College Blvd. • Suite 250 • Lenexa, KS 66219

**direct** (913) 981-4110

**mobile** (b)(6)

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**Sender:** Cha, Stephen (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23E67977D77947D69BAF2ACE846821A8-CHA, STEPHE>

Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>;

**Recipient:** Tierney, Julia (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=367e11c5deec4593ac4dc9b66d0a2e15-julia.tiern (b)(6)

Miller - Tolbert, Kimberly (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae7fdbbb6735470bab1203afb08f5b7d-Miller - To <Kimberly.Miller-tolbert@hhs.gov>

**Sent Date:** 2023/02/23 13:59:52

**Delivered Date:** 2023/02/23 13:59:00

**From:** Ezernack, Paige (OS/ASPR/SPPR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0174777A449342BB811D7EEFB0A92EEC-ROGERS, PAI <Paige.Ezernack@hhs.gov>

Buckner, Rebecca J (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e04ae770cbb41ee967dda356e864d29-rebecca.buc (b)(6)

**To:** Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe <Stephen.Cha@hhs.gov>; Alvarez, Kathryn (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3592e08a712042b59a76b9c31dc80a86-Alvarez, Ka <Kathryn.Alvarez@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7014813c9a244f839e5c01fdaad79179-Bratcher-Bo <nikki.bratcherbowman@hhs.gov>

**CC:** Sprow, Kyle (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8fe7feb5946a480d97d705d5c56c60a0-Spro, Kyle <Kyle.Spro@hhs.gov>; Newkirk, Ryan (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f854265b73f74088976a273d367731b1-ryan.newkir (b)(6)

**Subject:** RE: Follow-Up Meeting This Evening

**Date:** 2022/09/11 18:23:15

**Priority:** Normal

**Type:** Note

That's great news, Rebecca! I will follow up on this thread as soon as we connect with AAK tomorrow. Appreciate the update!

Thank you,  
Paige

**L. Paige Ezernack**  
Chief, DPA-ERA  
HHS/ASPR

---

**From:** Buckner, Rebecca J (b)(6)

**Sent:** Sunday, September 11, 2022 6:17 PM

**To:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>

**Cc:** Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Spro@hhs.gov>; Newkirk, Ryan (FDA/CFSAN) (b)(6)

**Subject:** RE: Follow-Up Meeting This Evening

Hi all, just had a quick chat with Reckitt and AAK has promised to supply 13 trucks out of 17 this week, which is up from the 9 they were promising at the beginning of the weekend. Frank is interested in getting them all 17 or getting a better understanding of what the issue is. Please keep Ryan and me in

the loop on additional conversations with AAK tomorrow so we can keep leadership looped in as needed. Thanks so much for your help with this!!

---

**From:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>  
**Sent:** Sunday, September 11, 2022 5:56 PM  
**To:** Buckner, Rebecca J (b)(6) Ezernack, Paige (OS) <Paige.Ezernack@hhs.gov>; Alvarez, Kathryn (OS) <Kathryn.Alvarez@hhs.gov>; Bratcher-Bowman, Nikki (OS) <nikki.bratcherbowman@hhs.gov>  
**Cc:** Sprow, Kyle (OS) <Kyle.Spro@hhs.gov>  
**Subject:** RE: Follow-Up Meeting This Evening

Ok—in that case, I will pass on the call but will monitor email here and happy to chat later tonight if you all think helpful/necessary.

---

**From:** Buckner, Rebecca J (b)(6)  
**Sent:** Sunday, September 11, 2022 5:50 PM  
**To:** Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>; Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>  
**Cc:** Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Spro@hhs.gov>  
**Subject:** RE: Follow-Up Meeting This Evening

Thanks! Kyle and I touched base Fri evening and he indicated the same as below. I am guessing that Reckitt may have heard something over the weekend, otherwise I'm not sure why they want a call this evening. But they may just want to check in again to stress their concerns. Happy to fill you all in via email after the call.

---

**From:** Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>  
**Sent:** Sunday, September 11, 2022 5:44 PM  
**To:** Alvarez, Kathryn (OS) <Kathryn.Alvarez@hhs.gov>; Cha, Stephen S (OS) <Stephen.Cha@hhs.gov>; Bratcher-Bowman, Nikki (OS) <nikki.bratcherbowman@hhs.gov>; Buckner, Rebecca J (b)(6)  
**Cc:** Sprow, Kyle (OS) <Kyle.Spro@hhs.gov>  
**Subject:** RE: Follow-Up Meeting This Evening

All –

Kyle is off through Tuesday and I'm not home right now. I can provide additional background:

During meetings on Wednesday and Thursday of this week, Reckitt confirmed they had no further concerns about Fat Blend supplied by AAK and had line of sight on upcoming deliveries however, we received a call from Reckitt Thursday night in which they flagged “new concerns” with AAK. Highlights from that conversation with Reckitt:

- Over the past several weeks, AAK was having challenges meeting Reckitt (and other IF) requirements for Fat Blend

- This was because AAK's subtier supplier (from overseas) supplied AAK with coconut oil that was "out of spec"
- This required additional processing by AAK before they could conduct the standard blending.
- For the last several weeks, AAK was supplying about 50% of Reckitt's requirements (~8 tankers per week vs. 15 tankers per week)
- AAK informed us and Reckitt they had line of sight on "new" coconut oil from their supplier that was in-spec and that was set to arrive at AAK's facility around late August/early September.
- According to Reckitt, AAK "promised" 15 tankers/week starting around September 6<sup>th</sup> and that has now been pushed out to September 19<sup>th</sup>
  - Note: Reckitt's new fat blend supplier is set to come online in late September.
- Per Reckitt, the 8 tanker quantity is impacting Reckitt's production by 50% (basically one of their two lines is shutdown).
  - Reckitt did note that AAK had some equipment failures in late august/early September, but, according to Reckitt, those have been solved.

We reached out to AAK Friday to better understand the situation from their perspective. AAK acknowledged some challenges meeting Reckitt's requirements based on the above information however they are "re-running their production and delivery schedules to ultimately see what they would be providing Reckitt over the next several days." We anticipate follow-up from AAK tomorrow but will reach back out if we don't have a response by late afternoon.

Hope this helps!  
Paige

**L. Paige Ezernack**  
Chief, DPA-ERA  
HHS/ASPR

---

**From:** Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>  
**Sent:** Sunday, September 11, 2022 4:43 PM  
**To:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Spro@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; Buckner, Rebecca J (FDA/CFSAN) <(b)(6)>  
**Subject:** Re: Follow-Up Meeting This Evening

+ Nikki too

---

**From:** Buckner, Rebecca J <(b)(6)>  
**Sent:** Sunday, September 11, 2022 4:34:53 PM  
**To:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>; Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Spro@hhs.gov>  
**Subject:** RE: Follow-Up Meeting This Evening



Kyle was on the call on Fri. Reckitt continues to have trouble sourcing fat blend and, as of Fri, was not getting shipments it was expecting this weekend and was told they wouldn't be getting full shipments until 9/19. Kyle has been in contact with AAK, the fat blend supplier, about prioritizing shipments to Reckitt. I am going to set a call for 6pm tonight. Join if you like or I can fill you in later. Thanks, Rebecca

---

**From:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>  
**Sent:** Sunday, September 11, 2022 4:04 PM  
**To:** Ezernack, Paige (OS) <Paige.Ezernack@hhs.gov>; Alvarez, Kathryn (OS) <Kathryn.Alvarez@hhs.gov>; Sprow, Kyle (OS) <Kyle.Spro@hhs.gov>  
**Cc:** Buckner, Rebecca J (b)(6)  
**Subject:** FW: Follow-Up Meeting This Evening

Can loop the ASPR team in directly, but any info on this?

---

**From:** Erickson, Audrae <Audrae.Erickson@reckitt.com>  
**Sent:** Sunday, September 11, 2022 1:22 PM  
**To:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Yiannas, Frank (FDA/OC)  
(b)(6) Buckner, Rebecca J (FDA/CFSAN) (b)(6)  
**Cc:** Newkirk, Ryan (FDA/CFSAN) (b)(6) Sprow, Kyle (OS/ASPR/SPPR)  
<Kyle.Spro@hhs.gov>  
**Subject:** Follow-Up Meeting This Evening

Dear Stephen, Frank, Rebecca &HHS/FDA team,

We would like to respectfully request a follow up meeting this evening, if possible, concerning the topic we discussed late Friday afternoon. Attendees will be:

Robert Cleveland, SVP Nutrition, N. America &Europe  
Alex Grillet, SVP Supply, Nutrition  
Art Pike, Global Manufacturing Footprint Director  
Audrae Erickson, VP Global External &Public Affairs

Please let us know if you would be available to meet this evening at 6:00pm or 8:30pm, both Eastern times. Thank you for sending a Zoom invite for your preferred time for the call.

Kind regards,

Audrae





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Buckner, Rebecca J (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e04ae770cbb41ee967dda356e864d29-rebecca.buc (b)(6)

Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe <Stephen.Cha@hhs.gov>;

Alvarez, Kathryn (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3592e08a712042b59a76b9c31dc80a86-Alvarez, Ka <Kathryn.Alvarez@hhs.gov>;

**Recipient:** Bratcher-Bowman, Nikki (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7014813c9a244f839e5c01fdaad79179-Bratcher-Bo <nikki.bratcherbowman@hhs.gov>;

Sprow, Kyle (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8fe7feb5946a480d97d705d5c56c60a0-Sprow, Kyle <Kyle.Sprow@hhs.gov>;

Newkirk, Ryan (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f854265b73f74088976a273d367731b1-ryan.newkir (b)(6)

**Sent Date:** 2022/09/11 18:23:12

**Delivered Date:** 2022/09/11 18:23:15

|                  |   |
|------------------|---|
| <b>From:</b>     | Bratcher-Bowman, Nikki (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7014813C9A244F839E5C01FDAAD79179-BRATCHER-BO <nikki.bratcherbowman@hhs.gov>   |
| <b>To:</b>       | Ezernack, Paige (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0174777a449342bb811d7eefb0a92eec-Rogers, Pai <Paige.Ezernack@hhs.gov>;<br>Buckner, Rebecca J (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e04ae770cbb41ee967dda356e864d29-rebecca.buc (b)(6)   |
| <b>CC:</b>       | Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe <Stephen.Cha@hhs.gov>;<br>Alvarez, Kathryn (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3592e08a712042b59a76b9c31dc80a86-Alvarez, Ka <Kathryn.Alvarez@hhs.gov>;<br>Sprow, Kyle (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8fe7feb5946a480d97d705d5c56c60a0-Spro, Kyle <Kyle.Spro@hhs.gov>;<br>Newkirk, Ryan (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f854265b73f74088976a273d367731b1-ryan.newkir (b)(6) |
| <b>Subject:</b>  | RE: Follow-Up Meeting This Evening  |
| <b>Date:</b>     | 2022/09/15 10:10:59   |
| <b>Priority:</b> | Normal  |
| <b>Type:</b>     | Note  |

Good news indeed! Really appreciate the team's discussions with AAK.

Nikki

---

**From:** Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>  
**Sent:** Thursday, September 15, 2022 10:07 AM  
**To:** Buckner, Rebecca J (FDA/CFSAN) (b)(6) Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>  
**Cc:** Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Spro@hhs.gov>; Newkirk, Ryan (FDA/CFSAN) (b)(6)  
**Subject:** RE: Follow-Up Meeting This Evening

All –

Wanted to share some fantastic news - AAK has increased deliveries to Reckitt from 14 to 17 trucks/week for fat blend. This meets Reckitt's full requirement so this is one constraint that has cleared.

Best,  
Paige

**L. Paige Ezernack**  
Chief, DPA-ERA

HHS/ASPR

---

**From:** Buckner, Rebecca J (b)(6)  
**Sent:** Monday, September 12, 2022 3:40 PM  
**To:** Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>  
**Cc:** Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Sprow@hhs.gov>; Newkirk, Ryan (FDA/CFSAN) (b)(6)  
**Subject:** RE: Follow-Up Meeting This Evening

Great news – thanks so much for your help on this! Please keep us posted if there is additional follow up.

---

**From:** Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>  
**Sent:** Monday, September 12, 2022 10:16 AM  
**To:** Bratcher-Bowman, Nikki (OS) <nikki.bratcherbowman@hhs.gov>; Cha, Stephen S (OS) <Stephen.Cha@hhs.gov>; Buckner, Rebecca J (b)(6) Alvarez, Kathryn (OS) <Kathryn.Alvarez@hhs.gov>  
**Cc:** Sprow, Kyle (OS) <Kyle.Sprow@hhs.gov>  
**Subject:** RE: Follow-Up Meeting This Evening

Good morning,

AAK provided an in-depth response to our request for information. Highlights here and full summary below.

- AAK will provide 13 loads this week as communicated by Reckitt.
- They now have shipments of new raw material that cuts out the additional processing step saving production time.
- Production lines are up and running at full speed which may enable AAK to provide 100% or more of Reckitt's requirement. They are also looking for process improvements that might shave off some production time.

It appears that Reckitt's deliveries will increase from 50% to 76% of full order this week and likely continue to improve. We will closely monitor to validate.

v/r  
Paige

Per AAK:

*First all the vessel carrying our infant grade coconut oil docked on the 3rd and was ready to use by the 5th. Unfortunately on the 6th one of our deodorizers went down and needed some unplanned maintenance. This put our schedule behind as it did not come back up until the 8th. This was unfortunate as we had consumed all of our excess inventory of in-process and finished goods which then had to be replenished. In addition each step of production requires a finite amount of time for highly specialized testing before the product can be advanced to the next step. As discussed with RB during a recent face-*

*to-face meeting that with extraordinary heavy demand a complex vegetable oil refinery like ours could experience unplanned maintenance events like this, especially when running hard!*

*I am happy to say that we believe we are back to the inventory levels that will allow us to deliver to target volumes, or possibly even beyond.*

- Tanks with off-spec product have been resolved and are now available to support of production*
- A new lot of lower contaminant raw material has arrived – removing an extra processing step*
- We are validating a process improvement that could deliver a 20% cycle time reduction on our most limiting process*
- We isolated and fixed a very difficult problem with our deodorizer unit that caused 4 days of unexpected downtime on 50% of our plant's capacity. It is now back up to full speed.*

*As for next week we have 13 loads accepted on our schedule, we are verifying with our CS how many more were requested, and if we can do more we will let RB know immediately.*

---

**From:** Bratcher-Bowman, Nikki (OS/ASPR/IO) <[nikki.bratcherbowman@hhs.gov](mailto:nikki.bratcherbowman@hhs.gov)>

**Sent:** Sunday, September 11, 2022 7:58 PM

**To:** Cha, Stephen (HHS/IOS) <[Stephen.Cha@hhs.gov](mailto:Stephen.Cha@hhs.gov)>; Buckner, Rebecca J (FDA/CFSAN)

(b)(6) Ezernack, Paige (OS/ASPR/SPPR) <[Paige.Ezernack@hhs.gov](mailto:Paige.Ezernack@hhs.gov)>; Alvarez, Kathryn (OS/ASPR/IO) <[Kathryn.Alvarez@hhs.gov](mailto:Kathryn.Alvarez@hhs.gov)>

**Cc:** Sprow, Kyle (OS/ASPR/SPPR) <[Kyle.Sprow@hhs.gov](mailto:Kyle.Sprow@hhs.gov)>

**Subject:** Re: Follow-Up Meeting This Evening

Thanks Paige. I agree with Stephen and will stay tuned for additional updates following discussions with AAK tomorrow.

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**From:** Cha, Stephen (HHS/IOS) <[Stephen.Cha@hhs.gov](mailto:Stephen.Cha@hhs.gov)>

**Sent:** Sunday, September 11, 2022 5:55 PM

**To:** Buckner, Rebecca J (FDA/CFSAN) (b)(6) Ezernack, Paige (OS/ASPR/SPPR) <[Paige.Ezernack@hhs.gov](mailto:Paige.Ezernack@hhs.gov)>; Alvarez, Kathryn (OS/ASPR/IO) <[Kathryn.Alvarez@hhs.gov](mailto:Kathryn.Alvarez@hhs.gov)>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <[nikki.bratcherbowman@hhs.gov](mailto:nikki.bratcherbowman@hhs.gov)>

**Cc:** Sprow, Kyle (OS/ASPR/SPPR) <[Kyle.Sprow@hhs.gov](mailto:Kyle.Sprow@hhs.gov)>

**Subject:** RE: Follow-Up Meeting This Evening

Ok—in that case, I will pass on the call but will monitor email here and happy to chat later tonight if you all think helpful/necessary.

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**From:** Buckner, Rebecca J (b)(6)

**Sent:** Sunday, September 11, 2022 5:50 PM

**To:** Ezernack, Paige (OS/ASPR/SPPR) <[Paige.Ezernack@hhs.gov](mailto:Paige.Ezernack@hhs.gov)>; Alvarez, Kathryn (OS/ASPR/IO) <[Kathryn.Alvarez@hhs.gov](mailto:Kathryn.Alvarez@hhs.gov)>; Cha, Stephen (HHS/IOS) <[Stephen.Cha@hhs.gov](mailto:Stephen.Cha@hhs.gov)>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <[nikki.bratcherbowman@hhs.gov](mailto:nikki.bratcherbowman@hhs.gov)>

**Cc:** Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Spro@hhs.gov>

**Subject:** RE: Follow-Up Meeting This Evening

Thanks! Kyle and I touched base Fri evening and he indicated the same as below. I am guessing that Reckitt may have heard something over the weekend, otherwise I'm not sure why they want a call this evening. But they may just want to check in again to stress their concerns. Happy to fill you all in via email after the call.

**From:** Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>

**Sent:** Sunday, September 11, 2022 5:44 PM

**To:** Alvarez, Kathryn (OS) <Kathryn.Alvarez@hhs.gov>; Cha, Stephen S (OS) <Stephen.Cha@hhs.gov>;

Bratcher-Bowman, Nikki (OS) <nikki.bratcherbowman@hhs.gov>; Buckner, Rebecca J

(b)(6)

**Cc:** Sprow, Kyle (OS) <Kyle.Spro@hhs.gov>

**Subject:** RE: Follow-Up Meeting This Evening

All –

Kyle is off through Tuesday and I'm not home right now. I can provide additional background:

During meetings on Wednesday and Thursday of this week, Reckitt confirmed they had no further concerns about Fat Blend supplied by AAK and had line of sight on upcoming deliveries however, we received a call from Reckitt Thursday night in which they flagged "new concerns" with AAK. Highlights from that conversation with Reckitt:

- Over the past several weeks, AAK was having challenges meeting Reckitt (and other IF) requirements for Fat Blend
- This was because AAK's subtier supplier (from overseas) supplied AAK with coconut oil that was "out of spec"
- This required additional processing by AAK before they could conduct the standard blending.
- For the last several weeks, AAK was supplying about 50% of Reckitt's requirements (~8 tankers per week vs. 15 tankers per week)
- AAK informed us and Reckitt they had line of sight on "new" coconut oil from their supplier that was in-spec and that was set to arrive at AAK's facility around late August/early September.
- According to Reckitt, AAK "promised" 15 tankers/week starting around September 6<sup>th</sup> and that has now been pushed out to September 19<sup>th</sup>
  - Note: Reckitt's new fat blend supplier is set to come online in late September.
- Per Reckitt, the 8 tanker quantity is impacting Reckitt's production by 50% (basically one of their two lines is shutdown).
  - Reckitt did note that AAK had some equipment failures in late august/early September, but, according to Reckitt, those have been solved.

We reached out to AAK Friday to better understand the situation from their perspective. AAK acknowledged some challenges meeting Reckitt's requirements based on the above information however they are "re-running their production and delivery schedules to ultimately see what they would be providing Reckitt over the next several days." We anticipate follow-up from AAK tomorrow but will reach back out if we don't have a response by late afternoon.

Hope this helps!  
Paige

**L. Paige Ezernack**  
Chief, DPA-ERA  
HHS/ASPR

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**From:** Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>  
**Sent:** Sunday, September 11, 2022 4:43 PM  
**To:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Spro@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; Buckner, Rebecca J (FDA/CFSAN) (b)(6)  
**Subject:** Re: Follow-Up Meeting This Evening

+ Nikki too

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**From:** Buckner, Rebecca J (b)(6)  
**Sent:** Sunday, September 11, 2022 4:34:53 PM  
**To:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Alvarez, Kathryn (OS/ASPR/IO) <Kathryn.Alvarez@hhs.gov>; Sprow, Kyle (OS/ASPR/SPPR) <Kyle.Spro@hhs.gov>  
**Subject:** RE: Follow-Up Meeting This Evening

Kyle was on the call on Fri. Reckitt continues to have trouble sourcing fat blend and, as of Fri, was not getting shipments it was expecting this weekend and was told they wouldn't be getting full shipments until 9/19. Kyle has been in contact with AAK, the fat blend supplier, about prioritizing shipments to Reckitt. I am going to set a call for 6pm tonight. Join if you like or I can fill you in later. Thanks, Rebecca

---

**From:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>  
**Sent:** Sunday, September 11, 2022 4:04 PM  
**To:** Ezernack, Paige (OS) <Paige.Ezernack@hhs.gov>; Alvarez, Kathryn (OS) <Kathryn.Alvarez@hhs.gov>; Sprow, Kyle (OS) <Kyle.Spro@hhs.gov>  
**Cc:** Buckner, Rebecca J (b)(6)  
**Subject:** FW: Follow-Up Meeting This Evening

Can loop the ASPR team in directly, but any info on this?

---

**From:** Erickson, Audrae <Audrae.Erickson@reckitt.com>  
**Sent:** Sunday, September 11, 2022 1:22 PM  
**To:** Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Yiannas, Frank (FDA/OC) (b)(6) Buckner, Rebecca J (FDA/CFSAN) (b)(6)  
**Cc:** Newkirk, Ryan (FDA/CFSAN) (b)(6) Sprow, Kyle (OS/ASPR/SPPR)



<Kyle.Sproaw@hhs.gov>

**Subject:** Follow-Up Meeting This Evening

Dear Stephen, Frank, Rebecca &HHS/FDA team,

We would like to respectfully request a follow up meeting this evening, if possible, concerning the topic we discussed late Friday afternoon. Attendees will be:

Robert Cleveland, SVP Nutrition, N. America &Europe

Alex Grillet, SVP Supply, Nutrition

Art Pike, Global Manufacturing Footprint Director

Audrae Erickson, VP Global External &Public Affairs

Please let us know if you would be available to meet this evening at 6:00pm or 8:30pm, both Eastern times. Thank you for sending a Zoom invite for your preferred time for the call.

Kind regards,

Audrae



□ □ □ □

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Ezernack, Paige (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0174777a449342bb811d7eefb0a92eec-Rogers, Pai <Paige.Ezernack@hhs.gov>;

**Recipient:** Buckner, Rebecca J (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e04ae770cbb41ee967dda356e864d29-rebecca.buc (b)(6)

Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe

<Stephen.Cha@hhs.gov>;  
Alvarez, Kathryn (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3592e08a712042b59a76b9c31dc80a86-Alvarez, Ka  
<Kathryn.Alvarez@hhs.gov>;  
Sprow, Kyle (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8fe7feb5946a480d97d705d5c56c60a0-Spro, Kyle  
<Kyle.Spro@hhs.gov>;  
Newkirk, Ryan (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group  
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(b)(6)

**Sent Date:** 2022/09/15 10:10:57

**Delivered Date:** 2022/09/15 10:10:59



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|------------------|--|
| <b>From:</b>     | Fristedt, Andi (b)(6)  |
| <b>To:</b>       | Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>;<br>Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe <Stephen.Cha@hhs.gov>;<br>Barclay, Lisa (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=872be990f41a4c7aaef491129db0ab89-Barclay, Li <Lisa.Barclay@hhs.gov>;<br>Seshasai, Karuna (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f18c182cd9f74851af73f94ba2dff06-Seshasai, K <Karuna.Seshasai@hhs.gov> |
| <b>Subject:</b>  | N-acetyl-L-cysteine Update   |
| <b>Date:</b>     | 2022/03/28 20:40:46  |
| <b>Priority:</b> | Normal   |
| <b>Type:</b>     | Note   |

Hi All,

As promised, I wanted to follow-up on our discussion earlier today related to the CP response and draft enforcement discretion guidance regarding N-acetyl-L-cysteine (NAC). I'm looping in both Karuna (per your advice, Sarah) and Lisa (Lisa, much of this background will look familiar from what OCC prepared for you). There were a number of good questions Sarah had that I will loop back on, but in the meantime I wanted to provide you background information on both the intent of the guidance, as well as our response to the citizen petition that we intend to issue on March 31<sup>st</sup>. As you know, the CP response is tied to the guidance so I'm providing background here on both.

As a reminder, FDA's position on NAC's exclusion from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act has been the subject of congressional and industry interest, and one of the petitioners (NPA) has sued FDA over our position on NAC. The petitions raise a number of statutory interpretation arguments regarding 201(ff)(3)(B) and our response to the citizen petition will be the first time FDA expressly addresses these issues.

### Background

Under section 201(ff)(3)(B) of the FD&C Act, added by the Dietary Supplement Health and Education Act of 1994 (DSHEA), the term "dietary supplement" excludes:

- (i) an article that is approved as a new drug under section 505 [of the FD&C Act], certified as an antibiotic under section 507 [of the FD&C Act], or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or
- (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

FDA's longstanding position has been that NAC is excluded from the dietary supplement definition under section 201(ff)(3)(B)(i) because it was approved as a new drug in 1963, well before it was marketed as a dietary supplement or as a food. However, it appears that industry was largely unaware of this position until FDA noted it in several warning letters issued in July 2020 to firms unlawfully selling products intended for treatment or prevention of hangovers. Although FDA had stated this position publicly a decade earlier in a New Dietary Ingredient Notification response, industry characterized the July 2020 warning letters as a "sudden policy change." The issue received even more attention, including congressional interest, after Amazon removed NAC products from its platform in the spring of 2021. Currently, FDA is not taking any regulatory or enforcement action against NAC products labeled as dietary supplements. FDA has determined that NAC is excluded from the dietary supplement definition under section 201(ff)(3)(B)(i) because NAC was approved as a new drug before it was marketed as a dietary supplement or as a food.

Two trade associations – the Council for Responsible Nutrition (CRN) and the Natural Products Association (NPA) – have submitted citizen petitions regarding N-acetyl-L-cysteine (NAC). Both petitions request FDA to reverse our position that products containing NAC are excluded from the definition of dietary supplement. The NPA petition also requested, in the alternative, that FDA issue a rule to permit the use of NAC in dietary supplements. FDA expects to issue a joint final response on March 31, 2022 to the citizen petitions from NPA and CRN, confirming NAC's exclusion from the dietary supplement definition. The CP response also hints that we're considering exercising enforcement discretion for certain NAC products labeled as dietary supplements. In the CP response and in the draft guidance, we explain that we have not yet reached a final decision on this request and that we are considering initiating rulemaking under section 201(ff)(3)(B) to permit the use of NAC in or as a dietary supplement.

#### **The Petitions and FDA's Draft Response**

As noted above, the two petitions are from dietary supplement trade associations and both ask FDA to reverse its position on NAC, arguing, among other things, that the agency is misinterpreting section 201(ff)(3)(B)(i) by applying it to a drug that was approved before the enactment of DSHEA and for a route of administration (inhalation) that is different from that of a dietary supplement (ingestion).

Our response denies this request, drawing from the statutory language, legislative history, and case law to support FDA's position that:

- Section 201(ff)(3)(B) does not provide an exception for drugs that were approved prior to DSHEA, drugs that were authorized for investigation prior to DSHEA, or dietary supplements or foods that were marketed as such prior to DSHEA. This interpretation doesn't give the provision "retroactive effect," as the petitioners' claim; and
- Two products can contain the same "article" under section 201(ff)(3)(B) even if they have a different route of administration. Under case law interpreting this provision, either an entire product or a product component (e.g., an active ingredient) may be "an article that is approved as a new drug" or "an article authorized for investigation as a new drug" for purposes of 201(ff)(3)(B). The legislative history also supports this interpretation, as Senator Hatch (a sponsor of DSHEA) mentioned an injected drug (taxol) as an example of the impetus for 201(ff)(3)(B).

One of the petitions also asks FDA "in the alternative, to recommend and support to the Secretary of HHS, that they issue[] a regulation, after notice and comment, finding that NAC, would be lawful under

the [FD&C Act].” Our response says we have not yet reached a decision on this rulemaking request. We also note the following about our ongoing review of this request:

- • Our review thus far has not identified safety concerns with respect to the use of NAC in or as a dietary supplement;

(b)(5)

- • In light of the absence of safety concerns based on our review thus far, among other factors, we think it appropriate to consider exercising enforcement discretion for products marketed as dietary supplements that contain NAC if such products would be lawfully marketed dietary supplements if NAC were not excluded from the definition of dietary supplement, and we intend to issue guidance on this topic.

#### Additional Considerations

(b)(5)

#### Draft Guidance

As we have discussed, FDA would like to issue draft guidance soon after the CP response stating our intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain NAC and are labeled as dietary supplements. The enforcement discretion policy would apply to products that would be lawfully marketed dietary supplements if NAC were not excluded from the definition of “dietary supplement” and that are not otherwise in violation of the FD&C Act.

The reason for FDA’s request to waive review is because FDA would like to issue the draft guidance as soon as possible after the CP response, including because the release of the draft guidance and our

response to two citizen petitions about NAC (b)(5)

(b)(5)

Additional Considerations

(b)(5)

Please let us know if you have additional questions or concerns and we would be happy to track those down.

Many thanks,  
Andi

**Sender:** Fristedt, Andi (b)(6)

Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>;  
Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe <Stephen.Cha@hhs.gov>;  
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Seshasai, Karuna (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f18c182cd9f74851af73f94ba2dff06-Seshasai, K <Karuna.Seshasai@hhs.gov>

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