

(b)(4)

**From:** Rooney, Debra K  
**To:** Lotze, Andrea  
**Cc:** Assar, Carrie  
**Subject:** [EXTERNAL] RE: (b)(4)  
**Date:** Tuesday, March 1, 2022 7:52:02 AM  
**Attachments:** image001.jpg

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**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.

Good morning Andrea. 5:30 AM? I think you beat the roosters this morning!  
Thank you for the response. I'll take the information back to the group. No additional questions at this time.  
Hope the rest of your day goes well!

Sincerely,

Debbie

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	<b>Debra K Rooney Phd</b> Associate Director Regulatory Affairs Pediatrics US	Abbott Nutrition Dept 104070, RP3-2 3300 Stelzer Road Columbus, OH 43219-3034	O: +1 614-624-3884 F: +1 614-727-3884 <a href="mailto:debra.rooney@abbott.com">debra.rooney@abbott.com</a>
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**From:** Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>  
**Sent:** Tuesday, March 01, 2022 5:33 AM  
**To:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>  
**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** RE: (b)(4)  
**Importance:** High

**EXTERNAL EMAIL:** Only click links or open attachments if you recognize the sender and know the content is safe. Hi Debbie,  
I heard back from the labeling team and their response was that FDA does not provide for the use of a (b)(4) in place of any mandatory label information on the product for any food products.

Please let me know if this fully answers your question or if there is any other way that I can be helpful.

Sincerely,

Andrea

*Andrea Lotze M.D.*

*Medical Director, Infant Formula and Medical Foods Staff  
Center for Food Safety and Applied Nutrition  
FDA*

---

**From:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>  
**Sent:** Monday, February 28, 2022 4:29 PM  
**To:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] RE: (b)(4)

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Thank you Andrea.

Debbie

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**Debra K Rooney PhD**  
Associate Director  
Regulatory Affairs  
Pediatrics US

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3300 Stelzer Road  
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**From:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Sent:** Monday, February 28, 2022 4:26 PM

**To:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>

**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [REDACTED]<sup>(b)(4)</sup>

**Importance:** High

**EXTERNAL EMAIL:** Only click links or open attachments if you recognize the sender and know the content is safe. Hi Debbie,  
I have reached

out to the labeling team and hope to get back to you shortly.

Sincerely,

Andrea

*Andrea Lotze M.D.*

*Medical Director, Infant Formula and Medical Foods Staff*

*Center for Food Safety and Applied Nutrition*

*FDA*

**From:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>

**Sent:** Monday, February 28, 2022 3:56 PM

**To:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** [EXTERNAL] RE: [REDACTED]<sup>(b)(4)</sup>

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Hi Andrea. Thank you for getting this back to me so quickly.

I do have another question for the labeling group. The [REDACTED]<sup>(b)(4)</sup> would be printed directly on the can so both the mandatory and voluntary information (the same information that is on the back of the current paper label) would be readily available at the point of purchase (or distribution in the case of WIC) by using a [REDACTED]<sup>(b)(4)</sup>. Can the labeling group provide a scenario where the mandatory information would not be readily available at point of purchase by using a [REDACTED]<sup>(b)(4)</sup>? It's not clear when this would occur.

I apologize for asking for a bit more clarity.

Sincerely,

Debbie



**Debra K Rooney PhD**  
Associate Director  
Regulatory Affairs  
Pediatrics US

Abbott Nutrition  
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3300 Stelzer Road  
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[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)

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**From:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Sent:** Monday, February 28, 2022 2:42 PM

**To:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>

**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** RE: [REDACTED]

**EXTERNAL EMAIL:** Only click links or open attachments if you recognize the sender and know the content is safe. Hi Debbie,  
Thank you so

much for reaching out about this. The feedback from our labeling group is as follows:

Title 21 CFR 101.15(c)(2) indicates that if the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language. We have allowed infant formulas to provide the foreign language on the back of a peel back label; however, we would object to the use of a [REDACTED] to contain the foreign language information since the mandatory label information would not be readily available to the consumer at time of purchase.

I hope that this is helpful, or at the very least answers the question.

Take care,

Andrea

*Andrea Lotze M.D.*

*Medical Director, Infant Formula and Medical Foods Staff*

*Center for Food Safety and Applied Nutrition*

*FDA*

---

**From:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>

**Sent:** Monday, February 28, 2022 12:01 PM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Subject:** [EXTERNAL] [REDACTED]

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Hi Andrea and Carrie. As you know, we are increasing our [REDACTED]

[REDACTED]. One of the options we are considering is filling the current can for [REDACTED]

The current [REDACTED]

[REDACTED]. I have never been asked that question and  
have not seen it addressed in the regulations so I'm looking for some guidance on this as soon as possible.  
Thanks in advance.

Debbie



**Debra K Rooney Phd**

Associate Director  
Regulatory Affairs  
Pediatrics US

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[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)

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**From:** [Callen,Cheryl,US-Arlington](#)  
**To:** [Lotze, Andrea](#)  
**Cc:** [Oh,Michelle,US-Bridgewater](#); [Assar, Carrie](#)  
**Subject:** [EXTERNAL] RE: [b](4) Notification Questions  
**Date:** Tuesday, March 29, 2022 4:14:00 PM  
**Attachments:** [image001.png](#)

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Thanks Andrea!

**From:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>  
**Sent:** Tuesday, March 29, 2022 3:53 PM  
**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** RE: [b](4) Notification Questions  
**Importance:** High

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Hi Cheryl,  
Thank you so much for reaching out about this. We are working internally on being able to provide a response as soon as possible and hope to provide an update by the end of the week.  
Sincerely,  
Andrea

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Sent:** Tuesday, March 29, 2022 12:22 PM  
**To:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>  
**Subject:** RE: [EXTERNAL] RE: [b](4) Notification Questions

**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 Andrea and Carrie,  
Last week we submitted a Before First Processing notification [b](4) submitted 3/23 for use of an [b](4) [b](4) infant formula. We also submitted a Major Notification [b](4) submitted 3/24 for use of an [b](4) from [b](4) [b](4) infant formula. [b](4)

[b](4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

I know this

is very compressed timing for review of a major notification but we would appreciate your consideration of this issue when reviewing submissions.

We are happy to answer any questions or provide more information.

Regards,

Cheryl

---

**From:** Callen,Cheryl,US-Arlington

**Sent:** Tuesday, March 29, 2022 8:50 AM

**To:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [b] Notification Questions

Thanks Andrea – will send the information later this morning.

Regards,

Cheryl

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**From:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Sent:** Tuesday, March 29, 2022 8:49 AM

**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [b] Notification Questions

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---

Hi Cheryl,

I would greatly appreciate it if you could email us the information for now, then I can loop in our upper management and schedule a phone call as needed.

Thank you so much.

Andrea

---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Sent:** Tuesday, March 29, 2022 8:20 AM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: [b] Notification Questions

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Hi Carrie,

I have an update on our supply situation. Would you prefer to discuss or would you like me to email

the information?

Regards,

Cheryl

---

**From:** Callen,Cheryl,US-Arlington

**Sent:** Wednesday, March 23, 2022 12:47 PM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: (b)(4) Notification Questions

Thanks Carrie –

---

**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Sent:** Wednesday, March 23, 2022 12:43 PM

**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: (b)(4) Notification Questions

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---

Thank you, Cheryl. We discussed this inquiry about an hour ago and your decision below aligns with our conclusion.

Best,

Carrie

---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Sent:** Wednesday, March 23, 2022 12:20 PM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: (b)(4) Notification Questions

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Hi Carrie,

We talked this over in the Nestle team and decided to (b)(4)

We

will keep you updated if our supply situation changes.

Let us know if there are any questions.

Regards,

Cheryl

---

**From:** Callen,Cheryl,US-Arlington

**Sent:** Wednesday, March 23, 2022 10:04 AM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: (b)(4) Notification Questions

Hi Carrie—

Thanks – we understand. I think we will go ahead and submit for the use of [b] (4). This will allow more time to consider the [b] (4).

Regards,

Cheryl

---

**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Sent:** Wednesday, March 23, 2022 10:02 AM

**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: [b] (4) Notification Questions

This message is from an EXTERNAL SENDER. BE CAUTIOUS, particularly with links and attachments.

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Hi Cheryl,

I had actually planned on reaching out to you this afternoon about this. We have no objections to submission of a [b] (4) for the use of [b] (4) as an [b] (4) for [b] (4) because this [b] (4) have already been notified to FDA. However, we need more time to internally discuss the [b] (4) [b] (4).

Best,

Carrie

**Carrie Assar, PharmD, MS**

*Team Leader*

*Infant Formula and Medical Foods Staff*

Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)



---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Sent:** Wednesday, March 23, 2022 9:55 AM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** [EXTERNAL] RE: [b] (4) Notification Questions

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Hi Carrie,

I wanted to check in with you about our approach described below? We are preparing to submit this week.

Thanks

Cheryl

---

**From:** Callen,Cheryl,US-Arlington

**Sent:** Friday, March 18, 2022 3:50 PM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh, Michelle, US-Bridgewater

<[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** [REDACTED] (b) (4) Notification Questions

Hi Carrie,

In light of the increased demand for [REDACTED] (b) (4) powder infant formula, our current [REDACTED] (b) (4) supplier, [REDACTED] (b) (4). The use of [REDACTED] (b) (4)

Below we are providing our rationale and intended approach and would greatly appreciate your feedback.

(b) (4)

(b) (4)

Thanks for your consideration and we look forward to your questions and feedback.

Regards,

Cheryl and Michelle

**From:** Marcy Sussman  
**To:** Lotze, Andrea  
**Cc:** Assar, Carrie; Brian Shira  
**Subject:** [EXTERNAL] RE [b](4) Manufacturing Orders  
**Date:** Friday, May 13, 2022 9:39:24 AM

**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 Andrea,

I'm following up on this email to see if you've had an opportunity to review. Wanted to get a sense of when we may hear something back about enforcement discretion.

Thank you,

Marcy

---

**From:** Marcy Sussman

**Sent:** Tuesday, May 3, 2022 12:07 PM

**To:** Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>

**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Brian Shira <Brian.Shira@perrigo.com>

**Subject:** [b](4) Manufacturing Orders

Dear Andrea,

At one of our previous calls with the Agency, we discussed providing you with information related to [b](4) manufacturing orders (MOs) of infant formula

[b](4)

Below is a table which shows the values. [b](4)

[b](4)

In light of the current situation regarding supply of infant formula, we are requesting a [b](4)

[b](4). There is a total of approximately [b](4). All other testing meets specifications. Please let us know as soon as possible whether we can move ahead with this formula.

Best regards,

Marcy

**Marcy Sussman**, RAC | Director, Nutritional Regulatory Affairs

Perrigo Company plc | Nutritionals

Cell: (b)(6)

[marcy.sussman@perrigo.com](mailto:marcy.sussman@perrigo.com)

[www.perrigo.com](http://www.perrigo.com)

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**From:** [Mackey, Amy](#)  
**To:** [Lotze, Andrea](#)  
**Cc:** [Assar, Carrie](#); [Rostorfer, Jena L](#)  
**Subject:** [EXTERNAL] (b)(4)  
**Date:** Thursday, April 14, 2022 8:29:53 PM  
**Attachments:** [image001.jpg](#)  
[\(2022.03.02\) Postmarketing Safety Report for \(b\)\(4\)](#) [pdf](#)

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Dear Andrea and Carrie—

You may recall that as a condition of our (b)(4), we provide post-market safety reports to (b)(4). (b)(4) has requested that we similarly send the latest report to FDA. The attached document reviews (b)(4).

Please let me know if you have any questions.

Kind regards-- Amy



**Amy Mackey, PhD**  
Director  
Regulatory Affairs

Abbott Nutrition  
3300 Stelzer Road  
Department 104070, RP3-2  
Columbus OH 43219

O: +1 614-624-4492  
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M: (b)(6)  
[amy.mackey@abbott.com](mailto:amy.mackey@abbott.com)

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**From:** [Mischler, Tricia](#)  
**To:** [Kulas, Megan](#)  
**Subject:** [EXTERNAL] Thank You...  
**Date:** Friday, March 11, 2022 9:19:01 AM  
**Attachments:** [image002.png](#)  
[image476448.png](#)  
[image744490.png](#)  
[image167982.png](#)  
[image452845.png](#)  
[image716993.png](#)

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Hi, Megan. I just wanted to say a big THANK YOU for sending the final letter on <sup>(b)(4)</sup> this morning.

I know you probably had a lot on your plate this week with attending a conference, and I sincerely appreciate the priority you gave to getting the letter to us sooner than expected.

Have a great weekend!



**Tricia Mischler, MSPH**  
Regulatory Affairs, Nutrition



phone 812 449 7955  
email [tricia.mischler@rb.com](mailto:tricia.mischler@rb.com)  
**Mead Johnson Nutrition**  
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February 3, 2022

**Andrea Lotze, M.D.**  
Medical Director  
Infant Formula and Medical Foods Staff  
Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition

Dear Dr. Lotze,

As a follow-up to your letter dated 1/28/2022, reference to [REDACTED]<sup>(b)(4)</sup> use for the medical condition [REDACTED]<sup>(b)(4)</sup> has been [REDACTED]<sup>(b)(4)</sup> from the [REDACTED]<sup>(b)(4)</sup> websites.

Should we determine a need for expanding the product indications for [REDACTED]<sup>(b)(4)</sup> in the future, we will provide the rationale via an exempt infant formula submission as indicated in your letter. Please feel free to contact me if you have additional questions or concerns.

Sincerely,

*Cristie Harry*

**Cristie Harry, RD**  
Associate Director, US Regulatory Science



May 3, 2022

**Andrea Lotze, M.D.**  
Medical Director  
Infant Formula and Medical Foods Staff  
Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition

Dear Dr. Lotze,

In response to your letter dated 4/19/2022, footnotes associating [b] have been [b] from [b] and [b]. Third party websites are also being reviewed for similar references. While digital changes have been made quickly, we do have non-digital pieces that need to be updated which will require more time; therefore, we are requesting an additional 6 months of enforcement discretion to enable us to make these necessary changes. As we discussed earlier today, the use of the [b]

As mentioned in a previous communication, should we determine a need for expanding the product indications for [b] in the future, we will provide the rationale via an exempt infant formula submission as indicated. Please feel free to contact me if you have additional questions or concerns.

Best regards,

*Cristie Harry*

**Cristie Harry, RD**  
Associate Director, US Regulatory Science

**From:** [Assar, Carrie](#)  
**To:** [Kavanaugh, Claudine](#); [Hansen, Patricia A](#)  
**Cc:** [Lotze, Andrea](#)  
**Subject:** FW: [EXTERNAL] (b) (4) Infant Formula Site  
**Date:** Monday, March 28, 2022 2:04:00 PM  
**Attachments:** [image001.png](#)  
[image003.png](#)

---

For discussion Tuesday afternoon...

---

**From:** DEL TORO Miguel <[miguel.deltoro@nutricia.com](mailto:miguel.deltoro@nutricia.com)>  
**Sent:** Monday, March 28, 2022 2:01 PM  
**To:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** [EXTERNAL] (b) (4) Infant Formula Site

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FOIA EXEMPT TREATMENT REQUESTED  
CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION

Hi both – Happy Spring!

(b) (4)



Many thanks for any information you can share. I can also be available for a call tomorrow noon-2 Eastern or Wednesday 11-2.

Sincerely,  
Miguel

**Miguel DEL TORO**  
**Associate General Counsel, Regulatory**  
Danone North America | Nutricia North America  
77 Upper Rock Circle, Ste. 303, Rockville, MD 20854  
T: (301) 518 3857  
[miguel.deltoro@nutricia.com](mailto:miguel.deltoro@nutricia.com)  
Pronouns: He, Him, His

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**From:** [Robert Baldo, Gillian L](#)  
**To:** [Harry, Cristie](#)  
**Cc:** [Welenc-Masters, Alice](#); [Assar, Carrie](#)  
**Subject:** RE: [EXTERNAL] Final Letter Comment Follow-up  
**Date:** Thursday, March 3, 2022 5:25:00 PM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)  
[image004.png](#)  
[image005.png](#)  
[image006.png](#)  
[image007.png](#)

---

Dear Cristie:

Thank you for reaching out. We appreciate the opportunity to respond to any questions regarding our comments.

We will review your question and respond with a message to submission reference number <sup>(b) (4)</sup> .

Sincerely,

Gillian

---

**From:** Harry, Cristie <Cristie.Harry@rb.com>  
**Sent:** Thursday, March 03, 2022 4:21 PM  
**To:** Robert Baldo, Gillian L <Gillian.RobertBaldo@fda.hhs.gov>  
**Cc:** Welenc-Masters, Alice <Alice.Welenc-Masters@rb.com>  
**Subject:** [EXTERNAL] Final Letter Comment Follow-up

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Gillian,

I am writing as a follow-up to label comments on <sup>(b) (4)</sup> surrounding the listing of our partial hydrolysate ingredient. I have included the final letter comment below for your reference:

(b) (4)  
[REDACTED]  
(b) (4)  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

Based on the regulation and guidance for labeling hydrolyzed protein from more than one source, it appears that the word "and" is acceptable to connect these two ingredients since <sup>(b) (4)</sup>. Please see the excerpts from the regulation and the guidance on hydrolyzed blends.

**EDITORIAL NOTE ON PART 102**

**Editorial Note:** Nomenclature changes to part 102 appear at 81 FR 49895, July 29, 2016.

**§ 102.22 Protein hydrolysates.**

The common or usual name of a protein hydrolysate shall be specific to the ingredient and shall include the identity of the food source from which the protein was derived.

- (a) "Hydrolyzed wheat gluten," "hydrolyzed soy protein," and "autolyzed yeast extract" are examples of acceptable names. "Hydrolyzed casein" is also an example of an acceptable name, whereas "hydrolyzed milk protein" is not an acceptable name for this ingredient because it is not specific to the ingredient (hydrolysates can be prepared from other milk proteins). The names "hydrolyzed vegetable protein" and "hydrolyzed protein" are not acceptable because they do not identify the food source of the protein.

- (b) [Reserved]

[58 FR 2876, Jan. 6, 1993]

**FDA guidance on protein hydrolysates blends:**

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide>

CFR 169

**17. How do you declare protein hydrolysates that are made of blends of proteins?**

**Answer:** For proteins that are blended prior to being hydrolyzed an appropriate name for the hydrolyzed protein product must be sufficiently descriptive of the protein product and must include all of the various proteins that were used to make the hydrolyzed protein. For example a hydrolyzed protein made from a blend of corn and soy protein would be "hydrolyzed corn and soy protein." However, if the proteins are hydrolyzed prior to blending, then the common or usual name must be specific to each individual hydrolyzed protein (e.g., "hydrolyzed corn protein" and "hydrolyzed soy protein"), and the ingredients must be declared in their order of predominance. In addition, any other ingredients that are blended with the hydrolyzed protein products must also be declared by their common or usual names in the ingredient statement in order of predominance. 21 CFR 101.22(h)(7)

(b) (4)



After reviewing the regulation and food labeling guide, it seems that our listing meets the intent of the regulation including declared allergens. We would appreciate any additional guidance or suggestions from the labeling group if there remains a concern about this listing; otherwise, for now, we plan to continue using this listing as is.

Best regards,  
Cristie



in

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**From:** Harry, Cristie  
**To:** Robert Baldo, Gillian L  
**Subject:** RE: [EXTERNAL] Checking in  
**Date:** Wednesday, March 30, 2022 7:44:19 AM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)  
[image004.png](#)  
[image005.png](#)

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Thanks, Gillian, for your quick response. This will certainly be a help for our <sup>(b)(4)</sup> needs. Hope you are doing well!

---

**From:** Robert Baldo, Gillian L <Gillian.RobertBaldo@fda.hhs.gov>  
**Sent:** Tuesday, March 29, 2022 3:21 PM  
**To:** Harry, Cristie <Cristie.Harry@rb.com>  
**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] Checking in

Dear Cristie:

At this time, we have no further questions for <sup>(b)(4)</sup> regarding the <sup>(b)(4)</sup> used in the production of <sup>(b)(4)</sup>.

Please contact the individual CSOs, referencing submission numbers, if you have any questions about the review of any submissions concerning <sup>(b)(4)</sup> changes.

Thank you.

Sincerely,  
Gillian

**Gillian Robert-Baldo, M.S., Ph.D.**

CONSUMER SAFETY OFFICER

*United States Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutrition and Food Labeling  
Infant Formula and Medical Foods Staff*

Email [Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)  
phone 240-402-1460

---

**From:** Harry, Cristie <[Cristie.Harry@rb.com](mailto:Cristie.Harry@rb.com)>  
**Sent:** Monday, March 28, 2022 4:46 PM

**To:** Robert Baldo, Gillian L <[Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)>  
**Subject:** [EXTERNAL] Checking in

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Gillian,

We received a call from our supply chain folks asking for (b)(4)

[REDACTED] With so many packaging material shortages, we are doing what we can to address supplier material availability to help maintain our stock of (b)(4) formula packaging. We would appreciate any updates on the materials involved in these (b)(4) notifications, even if there are additional sections of the submission that are still under review. Thanks in advance for your guidance--Cristie



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**From:** Harry, Cristie  
**To:** Assar, Carrie  
**Subject:** RE: [EXTERNAL] <sup>(b)(4)</sup> of 2"-FL  
**Date:** Tuesday, March 15, 2022 1:14:15 PM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)  
[image004.png](#)  
[image005.png](#)  
[image006.png](#)

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So sorry to have bothered you as I found them in there after all—think I might need new glasses!

**From:** Harry, Cristie  
**Sent:** Tuesday, March 15, 2022 7:41 AM  
**To:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] <sup>(b)(4)</sup> of 2'-FL  
Thanks, Carrie, for your response. I just realized that our <sup>(b)(4)</sup> names are not in the drop-down listing. Shall I add them or will this be a problem for this <sup>(b)(4)</sup> submission? Thanks for your help—Cristie

**From:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Sent:** Monday, March 14, 2022 7:54 AM  
**To:** Harry, Cristie <Cristie.Harry@rb.com>  
**Subject:** RE: [EXTERNAL] <sup>(b)(4)</sup> of 2'-FL

Hi Cristie,  
Thank you for reaching out with this inquiry. The <sup>(b)(4)</sup> for 2'-FL can be provided as one submission for all the impacted products. Please include the ingredient specification sheet as well as the GRN for the <sup>(b)(4)</sup> 2'-FL ingredient in the submission.

Best,  
Carrie

**Carrie Assar, PharmD, MS**

*Team Leader  
Infant Formula and Medical Foods Staff*

Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)

**From:** Harry, Cristie <Cristie.Harry@rb.com>  
**Sent:** Monday, March 14, 2022 8:28 AM  
**To:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** [EXTERNAL] <sup>(b)(4)</sup> of 2'-FL

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Good morning! I wanted to get your advice on how best to handle submitting a <sup>(b)(4)</sup> for our 2'-FL ingredient for our products—<sup>(b)(4)</sup>

(b) (4)

(b) (4)

Other ideas for ease

of review would be welcome, too. Thanks in advance for your guidance--Cristie



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**From:** [Walsh, Jenn](#)  
**To:** [Kulas, Megan](#)  
**Subject:** RE: [EXTERNAL] Agency Questions for IFNs<sup>(b)(4)</sup>  
**Date:** Thursday, February 24, 2022 10:13:21 AM

---

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Hi Megan,  
I communicated to our supplier that they need to submit a FMF.<sup>(b)(4)</sup>  
<sup>(b)(4)</sup>, so please disregard if you receive. I will let you know when they plan to submit the FMF. Thank you for your help.  
Jenn

*(she, her, hers)*

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**Jenn Walsh, MS, RD**

Manager  
Regulatory Affairs

Abbott Nutrition  
3300 Stelzer Rd  
Dept 104070, Bldg. RP3-2  
Columbus, OH 43219

O: 614-624-6338  
M: (b)(6)  
[jennifer.walsh6@abbott.com](mailto:jennifer.walsh6@abbott.com)

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**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>

**Sent:** Thursday, February 24, 2022 8:50 AM

**To:** Walsh, Jenn <[jennifer.walsh6@abbott.com](mailto:jennifer.walsh6@abbott.com)>

**Subject:** RE: [EXTERNAL] Agency Questions for IFNs<sup>(b)(4)</sup>

**EXTERNAL EMAIL:** Only click links or open attachments if you recognize the sender and know the content is safe.

Hi Jenn,

Thank you for your email. The supplier will need a FMF.

Please send the information to Jessica Urbelis at [Jessica.Urbelis@fda.hhs.gov](mailto:Jessica.Urbelis@fda.hhs.gov)

Please let me know if you have any questions.

Best,  
Megan

---

**From:** Walsh, Jenn <[jennifer.walsh6@abbott.com](mailto:jennifer.walsh6@abbott.com)>

**Sent:** Tuesday, February 22, 2022 12:16 PM

**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>

**Subject:** [EXTERNAL] Agency Questions for IFNs<sup>(b)(4)</sup>

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Hi Megan,

We are working with our suppliers to answer the outstanding questions for [REDACTED] (b)(4), specifically regarding the [REDACTED] (b)(4). The supplier has noted this [REDACTED] (b)(4) was filed in a Drug Master File (DMF) [REDACTED] (b)(4) which discloses the confidential information comparable to filing a Food Master File or 3480 form. Does [REDACTED] (b)(4) need to submit a FMF if the material information was already submitted as part of a DMF?

Thank you,

Jenn

(she, her, hers)

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**Abbott**

**Jenn Walsh, MS, RD**

Manager  
Regulatory Affairs

Abbott Nutrition  
3300 Stelzer Rd  
Dept 104070, Bldg. RP3-2  
Columbus, OH 43219

O: 614-624-6338  
M(b)(6)  
[jennifer.walsh6@abbott.com](mailto:jennifer.walsh6@abbott.com)

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**From:** Harry, Cristie  
**To:** Lotze, Andrea  
**Cc:** Assar, Carrie  
**Subject:** RE: [EXTERNAL] Claims for [§ 87(4)]  
**Date:** Tuesday, May 3, 2022 3:54:24 PM  
**Attachments:** image404444.png  
image786254.png  
image221423.png  
image486745.png  
image099370.png  
FDA response for [§ 87(4)] references in labeling 03MAY22.pdf

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Andrea and Carrie,

Please see the attached response to your letter regarding [§ 87(4)] claims.

Thank you for your time this morning to discuss this in more detail.

Best regards,

Cristie



[§ 87(4)]

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**From:** Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>

**Sent:** Tuesday, April 19, 2022 2:03 PM

**To:** Harry, Cristie <Cristie.Harry@rb.com>

**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>

**Subject:** [EXTERNAL] Claims for [§ 87(4)]

Attached is correspondence regarding claims associated with [§ 87(4)]

Sincerely,  
Andrea  
*Andrea Lotze M.D.*  
*Medical Director, Infant Formula and Medical Foods Staff*  
*Center for Food Safety and Applied Nutrition*  
*FDA*

**From:** [Assar, Carrie](#)  
**To:** [Corey Bosselman](#)  
**Subject:** RE: [EXTERNAL] Conversion from <sup>(b)(4)</sup> (Confirmation of notification type)  
**Date:** Tuesday, February 15, 2022 6:45:00 PM  
**Attachments:** [image002.png](#)

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Hi Corey,  
Thank you for reaching out with this question. PBM/Perrigo may submit the change in <sup>(b)(4)</sup> as a Before First Processing Submission under 21 CFR 106.140.

Please let me know if you have any other questions.

Sincerely,

Carrie

**Carrie Assar, PharmD, MS**

*Team Leader  
Infant Formula and Medical Foods Staff*

Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)



---

**From:** Corey Bosselman <Corey.Bosselman@perrigo.com>  
**Sent:** Tuesday, February 15, 2022 2:10 PM  
**To:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** [EXTERNAL] Conversion from <sup>(b)(4)</sup> (Confirmation of notification type)

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Dear Dr. Assar,

The supplier of PBM's <sup>(b)(4)</sup> has notified us that they will no longer manufacture <sup>(b)(4)</sup>  
<sup>(b)(4)</sup> beginning January 01, 2023. We intend to submit a notification to the agency for 3 previously-cleared infant formulas, where the only notified change will be to the source of the <sup>(b)(4)</sup>  
<sup>(b)(4)</sup>

We wanted to check with the agency prior to submitting this as a Before First Processing notification, to ensure that it is the appropriate classification of the change. Would you please confirm if this can be submitted as a "BFP", or if it needs to be submitted as a "90-day notification"?

Thank you for your assistance and hope you are well!

Sincerely,

Corey

**Corey Bosselman, MS** | Regulatory Affairs Project Manager

**Perrigo Nutritionals** | Regulatory Affairs, Nutrition

652 Peter Jefferson Parkway, Suite 300, Charlottesville, VA 22911

Office: (434) 297-1082 | Cell: <sup>(b)(6)</sup>

[Corey.Bosselman@perrigo.com](mailto:Corey.Bosselman@perrigo.com)

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**From:** [Callen,Cheryl,US-Arlington](#)  
**To:** [Robert Baldo, Gillian L](#)  
**Cc:** [Assar, Carrie](#)  
**Subject:** RE: [EXTERNAL] FW: Final Letter - Before First Processing (BFP) Submission: Non-Exempt Infant Formula - Submission Ref #: <sup>(b)(4)</sup> [REDACTED]  
**Date:** Friday, March 11, 2022 10:22:03 AM  
**Attachments:** [image001.png](#)

---

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Hi Gillian,  
Thanks for clarifying. To confirm, we are not using or planning to use the material with <sup>(b)(4)</sup> [REDACTED]. If this changes, we will follow the guidance provided below and in the final letter for <sup>(b)</sup> [REDACTED]

Have a great weekend!

Regards,  
Cheryl

---

**From:** Robert Baldo, Gillian L <Gillian.RobertBaldo@fda.hhs.gov>  
**Sent:** Friday, March 11, 2022 10:09 AM  
**To:** Callen,Cheryl,US-Arlington <Cheryl.Callen@us.nestle.com>  
**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] FW: Final Letter - Before First Processing (BFP) Submission: Non-Exempt Infant Formula - Submission Ref #: <sup>(b)(4)</sup> [REDACTED]

This message is from an EXTERNAL SENDER. BE CAUTIOUS, particularly with links and attachments.

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Good Morning Cheryl:

Thank you for reaching out.

We are referring to <sup>(b)(4)</sup> [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED], and an infant formula submission would be necessary.

I hope this is helpful. Please contact me with any further questions.

Sincerely,  
Gillian

**Gillian Robert-Baldo, M.S., Ph.D.**

CONSUMER SAFETY OFFICER

*United States Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutrition and Food Labeling  
Infant Formula and Medical Foods Staff*

Email [Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)

phone 240-402-1460

---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Sent:** Thursday, March 10, 2022 6:21 PM

**To:** Robert Baldo, Gillian L <[Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)>

**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** [EXTERNAL] FW: Final Letter - Before First Processing (BFP) Submission: Non-Exempt Infant Formula - Submission Ref # (b)(4)

**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 Gillian,

Thanks for your response to our notification. We do have a question regarding the statement about the use of (b)(4)

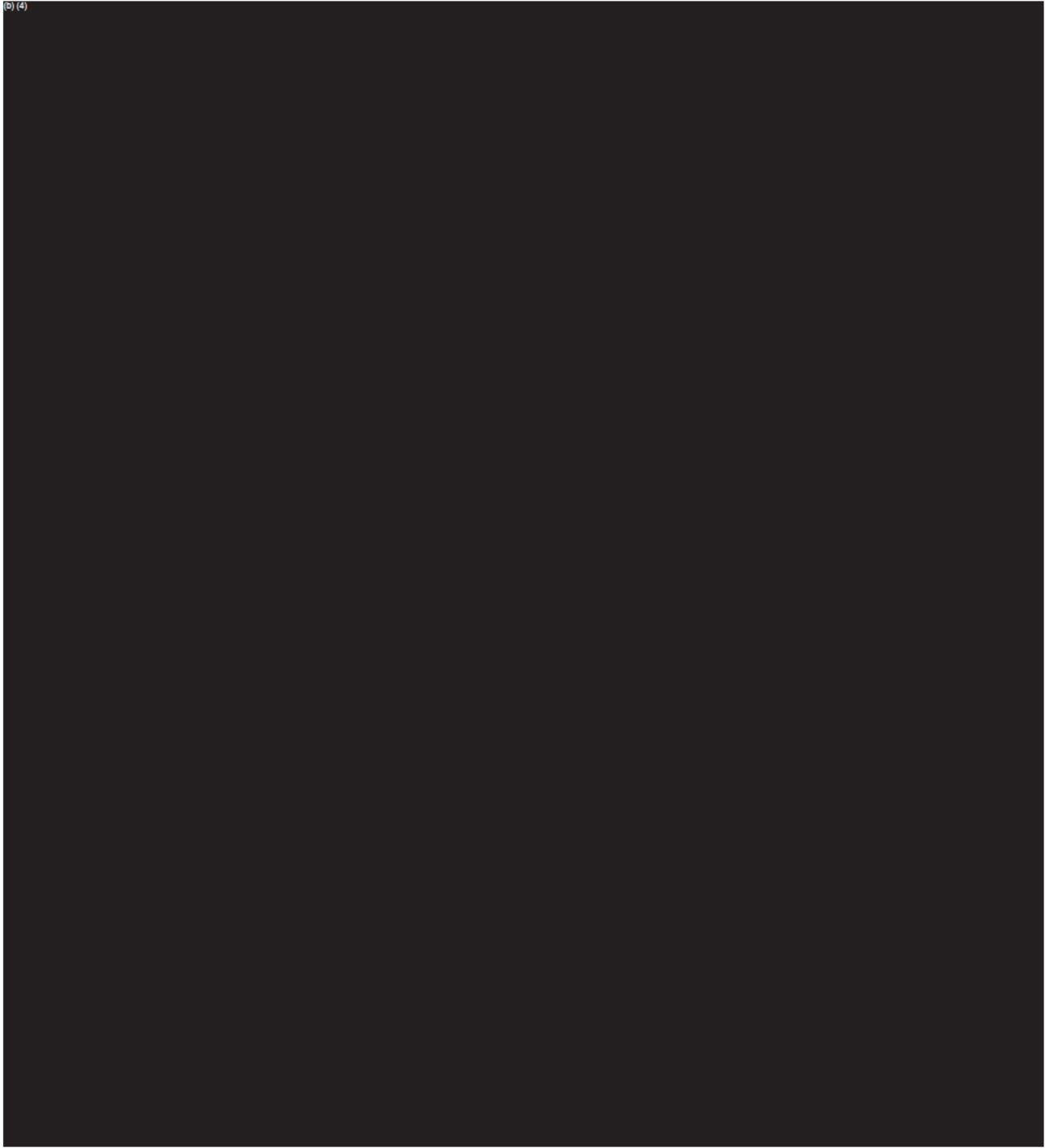
(b)(4)  
(b)(4)  
(b)(4)  
(b)(4)

We appreciate the clarification.

Regards,

Cheryl

(b) (4)



---

**From:** [cfsan-admin@cfsan.fda.gov](mailto:cfsan-admin@cfsan.fda.gov) <[cfsan-admin@cfsan.fda.gov](mailto:cfsan-admin@cfsan.fda.gov)>  
**Sent:** Wednesday, March 9, 2022 3:04 PM  
**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Cc:** [Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov); [Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov); [mitchell.maison@fda.hhs.gov](mailto:mitchell.maison@fda.hhs.gov)  
**Subject:** Final Letter - Before First Processing (BFP) Submission: Non-Exempt Infant Formula -  
Submission Ref #: (b) (4)

This message is from an EXTERNAL SENDER. BE CAUTIOUS, particularly with links and

attachments.

**Submission Reference:** [REDACTED]

(b) (4)

Dear Ms. Callen,

Attached is the response for submission [REDACTED] regarding the following product(s):

(b) (4)

Sincerely yours,

Gillian Robert Baldo Ph.D.  
Consumer Safety Officer  
Infant Formula and Medical Foods Staff, HFS-850  
Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition

**From:** [Beker, Leila \\*](#)  
**To:** [Cindy Barber](#)  
**Cc:** [Assar, Carrie](#)  
**Subject:** RE: [EXTERNAL] help  
**Date:** Wednesday, May 25, 2022 4:40:00 PM

---

Hi Cindy,

Thanks for asking, I'm doing well and helping the team as a contractor, part-time.

I needed to check with Carrie regarding your request to review the outline for the [b](4) [b](4) since I cannot act as your consultant. If you send it in to Carrie with a cc to me, I can provide some considerations in a pre-submission courtesy review and help identify "red flags". Please be sure that the comments and issues that have been provided previously are addressed in the outline to ensure that previous issues are resolved.

All the best,

Leila

---

**From:** Cindy Barber <[Cynthia.Barber@perrigo.com](mailto:Cynthia.Barber@perrigo.com)>  
**Sent:** Tuesday, May 24, 2022 1:47 PM  
**To:** Beker, Leila \* <[Leila.Beker@fda.hhs.gov](mailto:Leila.Beker@fda.hhs.gov)>  
**Subject:** [EXTERNAL] help

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Hi Leila,

I hope you are doing well and hopefully enjoying yourself some in these turbulent times.

As you may know our [b](4) with [b](4) As they regroup for another try, I was wondering if you could review our outline for re-submittal to see if you think it would be sufficient?

Thank you!!

Cindy

**Cynthia M. Barber, M.Sc. Ph.D.** | Sr Director Sci Affairs  
Perrigo Company | Self-Care  
Office: +1 434 297 1131 | Cell: [b](6)

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**From:** Tonucci, Linda H  
**To:** "Rooney, Debra K"  
**Subject:** RE: [EXTERNAL] IFN number for an export product  
**Date:** Thursday, February 17, 2022 12:55:00 PM  
**Attachments:** [image002.png](#)

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You too! Take care!

**From:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>  
**Sent:** Thursday, February 17, 2022 12:49 PM  
**To:** Tonucci, Linda H <[Linda.Tonucci@fda.hhs.gov](mailto:Linda.Tonucci@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] IFN number for an export product

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LOL! No worries. <sup>(b)(4)</sup> and we are just making sure our records are in fine fettle.

Appreciate you taking the time to look knowing how busy you are.

Take care!

Debbie



**Debra K Rooney Phd**  
Associate Director  
Regulatory Affairs  
Pediatrics US

Abbott Nutrition  
Dept 104070, RP3-2  
3300 Stelzer Road  
Columbus, OH 43219-3034

O: +1 614-624-3884  
F: +1 614-727-3884  
[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)

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**From:** Tonucci, Linda H <[Linda.Tonucci@fda.hhs.gov](mailto:Linda.Tonucci@fda.hhs.gov)>  
**Sent:** Thursday, February 17, 2022 12:34 PM  
**To:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>  
**Subject:** RE: [EXTERNAL] IFN number for an export product

**EXTERNAL EMAIL:** Only click links or open attachments if you recognize the sender and know the content is safe. Hi Debbie,  
I found it! So

sorry – you are correct – looks like our final letter was sent as an email to Julianne Burkholder on 9/21/16 (see attached screenshot) and I did not include the IFN.

The IFN is <sup>(b)(4)</sup>

I hope this helps! Sorry for the delay (5 1/2 years) in getting this to you!

Linda

**Linda H. Tonucci, Ph.D.**

*Consumer Safety Officer*

*Infant Formula and Medical Foods Staff*

**Center for Food Safety and Applied Nutrition**

**Office of Nutrition and Food Labeling**

**U.S. Food and Drug Administration**

Tel: 240-402-1785

[linda.tonucci@fda.hhs.gov](mailto:linda.tonucci@fda.hhs.gov)



---

**From:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>

**Sent:** Thursday, February 17, 2022 10:05 AM

**To:** Tonucci, Linda H <[Linda.Tonucci@fda.hhs.gov](mailto:Linda.Tonucci@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] IFN number for an export product

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Thanks so much, Linda. Let me know if you need any other identifying information.

Debbie



**Abbott**

**Debra K Rooney Phd**  
Associate Director  
Regulatory Affairs  
Pediatrics US

Abbott Nutrition  
Dept 104070, RP3-2  
3300 Stelzer Road  
Columbus, OH 43219-3034

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F: +1 614-727-3884  
[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)

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**From:** Tonucci, Linda H <[Linda.Tonucci@fda.hhs.gov](mailto:Linda.Tonucci@fda.hhs.gov)>

**Sent:** Thursday, February 17, 2022 10:03 AM

**To:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>

**Subject:** RE: [EXTERNAL] IFN number for an export product

**EXTERNAL EMAIL:** Only click links or open attachments if you recognize the sender and know the content is safe. Hi Debbie,  
Yes – I still

review the exports. I will see what I can find, and I'll get back to you!

Linda

**From:** Rooney, Debra K <[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)>

**Sent:** Thursday, February 17, 2022 9:57 AM

**To:** Tonucci, Linda H <[Linda.Tonucci@fda.hhs.gov](mailto:Linda.Tonucci@fda.hhs.gov)>

**Subject:** [EXTERNAL] IFN number for an export product

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Good morning Linda. I know you used to review exports so I'm hoping you can help here. We have an export submission dated 9/15/16 for [b](4) in the [b](4) that doesn't have an IFN number in the final letter. Was a number assigned and can you provide the number for our records? Thanks so much!

Debbie



**Abbott**

**Debra K Rooney Phd**  
Associate Director  
Regulatory Affairs  
Pediatrics US

Abbott Nutrition  
Dept 104070, RP3-2  
3300 Stelzer Road  
Columbus, OH 43219-3034

O: +1 614-624-3884  
F: +1 614-727-3884  
[debra.rooney@abbott.com](mailto:debra.rooney@abbott.com)

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**From:** Harry, Cristie  
**To:** Lotze, Andrea  
**Cc:** Assar, Carrie  
**Subject:** RE: [EXTERNAL] <sup>(b)(4)</sup> Labeling  
**Date:** Thursday, February 3, 2022 1:24:37 PM  
**Attachments:** [image858219.png](#)  
[image479057.png](#)  
[image511318.png](#)  
[image118175.png](#)  
[image546148.png](#)  
03FEB22 FDA-Lotze <sup>(b)(4)</sup>.pdf

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Andrea,

Attached is a response to your letter from last Friday; please don't hesitate to contact me if you have questions.

Best regards,

Cristie



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**From:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Sent:** Friday, January 28, 2022 11:20 AM

**To:** Harry, Cristie <[Cristie.Harry@rb.com](mailto:Cristie.Harry@rb.com)>

**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** [EXTERNAL] <sup>(b)(4)</sup> Labeling

Dear Ms. Harry,

Attached is a letter regarding labeling for <sup>(b)(4)</sup> Infant Formula that has not been notified to FDA, inclusive of claims associated with the medical condition <sup>(b)(4)</sup>, an

apparent new medical indication and intended use for [REDACTED]<sup>(b)(4)</sup>. We would greatly appreciate a prompt response.

Sincerely,

Andrea Lotze

*Andrea Lotze M.D.*

*Medical Director, Infant Formula and Medical Foods Staff*

*Center for Food Safety and Applied Nutrition*

*FDA*

**From:** [Stowers, Emily](#)  
**To:** [Robert Baldo, Gillian L](#)  
**Subject:** RE: [EXTERNAL] NRC Requirements Re: [b] (4)  
**Date:** Friday, March 4, 2022 2:50:24 PM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)  
[image004.png](#)  
[image005.png](#)

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Hi Gillian,

Thank you for looking into this for us. I greatly appreciate your quick response. Have a nice weekend.

Kind regards,  
Emily

---

**From:** Robert Baldo, Gillian L <Gillian.RobertBaldo@fda.hhs.gov>  
**Sent:** Friday, March 4, 2022 1:46 PM  
**To:** Stowers, Emily <Emily.Stowers@rb.com>  
**Subject:** RE: [EXTERNAL] NRC Requirements Re: [b] (4)

Dear Emily:

Again, thank you for reaching out. We always appreciate the opportunity to respond to any questions or concerns.

After reconsidering the information provided, we do not have any questions about the levels of

[b] (4)

(b) (4)

We apologize for our error, which resulted from consulting an incorrect table, and for any inconvenience that resulted for you. Please disregard this question for both submissions, reference [b] (4).

Please feel free to contact me with any further questions.

Sincerely,  
Gillian

**Gillian Robert-Baldo, M.S., Ph.D.**  
CONSUMER SAFETY OFFICER

*United States Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutrition and Food Labeling*

*Infant Formula and Medical Foods Staff*

Email [Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)  
phone 240-402-1460

---

**From:** Stowers, Emily <[Emily.Stowers@rb.com](mailto:Emily.Stowers@rb.com)>  
**Sent:** Thursday, March 03, 2022 3:08 PM  
**To:** Robert Baldo, Gillian L <[Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] NRC Requirements Re: [REDACTED]

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Hi Gillian,

Thank you very much for the update and for your help on this.

Sincerely,  
Emily

---

**From:** Robert Baldo, Gillian L <[Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)>  
**Sent:** Thursday, March 3, 2022 1:40 PM  
**To:** Stowers, Emily <[Emily.Stowers@rb.com](mailto:Emily.Stowers@rb.com)>  
**Subject:** RE: [EXTERNAL] NRC Requirements Re: [REDACTED]

Dear Emily:

Thank you for reaching out. We are looking into your question and will respond as soon as possible.

Sincerely,  
Gillian

---

**From:** Stowers, Emily <[Emily.Stowers@rb.com](mailto:Emily.Stowers@rb.com)>  
**Sent:** Thursday, March 03, 2022 1:36 PM  
**To:** Robert Baldo, Gillian L <[Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)>  
**Subject:** [EXTERNAL] NRC Requirements Re: [REDACTED]

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Hi Gillian,

I've reviewed the questions you sent yesterday on [REDACTED]. I'm concerned about the questions related to [REDACTED]  
[REDACTED] Our team started with the published NRC requirements

and converted them to units per 100 g rat diet (attached). Are we using an incorrect reference?

Kind regards,  
Emily

**Emily Stowers, MA, RD, LD**  
**Regulatory Associate Manager, Innovation & Operations**  
Nutrition

M: 812.459.3514  
[Reckitt.com](http://Reckitt.com)

2400 W. Lloyd Expressway  
Evansville, IN 47721



in

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**From:** [Jeanne Hoskin](#)  
**To:** [Assar, Carrie](#)  
**Cc:** [Lotze, Andrea](#); [Gyan Rai](#)  
**Subject:** Re: [EXTERNAL] Question  
**Date:** Monday, March 28, 2022 9:26:06 AM  
**Attachments:** [image001.png](#)

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Good morning, Carrie, and thank you for the clarification - understood on all points. If ByHeart goes forward with this or alternate plan, we will reach out again and answer your questions before any submission is made.  
Appreciate and have a good day -  
Jeanne

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**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Sent:** Saturday, March 26, 2022 11:28 AM  
**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>  
**Subject:** RE: [EXTERNAL] Question

Dear Jeanne,  
A verification submission is provided to FDA after the completion of a new infant formula submission under 21 CFR 106.120 and after the first production and before the introduction of that new infant formula into interstate commerce. This type of submission is not used to notify changes to FDA, and thus a verification submission is not appropriate for the packaging change you describe below.  
We consider a change in packaging that is a food contact substance to be a major change, and it appears that is the case for the change you describe below. The infant formula powder would come into contact with the <sup>(b) (4)</sup> after the seal is removed by the parent/caregiver. A BFP submission cannot be used for a major change.

We have a few questions related to the packaging change in your email. <sup>(b) (4)</sup>

Additionally, you state <sup>(b) (4)</sup>

" (b) (4)  
... "

Regards,

Carrie

**Carrie Assar, PharmD, MS**

*Team Leader*

*Infant Formula and Medical Foods Staff*

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

[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)



---

**From:** Jeanne Hoskin <jeanne@byheart.com>  
**Sent:** Wednesday, March 23, 2022 5:09 PM  
**To:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Cc:** Lotze, Andrea <Andrea.Lotze@fda.hhs.gov>; Gyan Rai <Gyan@byheart.com>  
**Subject:** [EXTERNAL] Question

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CONFIDENTIAL

Dear Carrie,

How are you? Thank you again for reviewing our submission, we appreciate you and the team's assistance throughout the process!

ByHeart has partnered with [REDACTED]

[REDACTED], to donate infant formula to parents in need. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

We are requesting your assistance in guiding us how best to submit this information. We note an option is available under the verification submission, informing of a new packaging configuration if it was not included in the original submission. We can upload this information for the [REDACTED] and provide the food contact information via FMF. Or is this a "Before First Processing" submission where the same information would be made available? We expect either option to have no wait time to implementation.

We look forward to your advisement on this.

Thank you and sincerely,

Jeanne

**Jeanne Hoskin, PhD | ByHeart**

VP of Regulatory

C: ((b)(6))

131 Varick Street, 11th Floor, New York, NY 10013

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**From:** [Jeanne Hoskin](#)  
**To:** [Assar, Carrie](#)  
**Subject:** Re: [EXTERNAL] Re: ByHeart Infant Formula Manufacturing Facilities  
**Date:** Wednesday, March 9, 2022 12:43:48 PM  
**Attachments:** [image001.png](#)

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Ok thank you Carrie, again sorry for any confusion. I noted the same thing on Google maps. If you need anything else, please let me know.

Jeanne

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**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Sent:** Wednesday, March 9, 2022 11:44 AM  
**To:** Jeanne Hoskin  
**Subject:** RE: [EXTERNAL] Re: ByHeart Infant Formula Manufacturing Facilities  
Hi Jeanne,  
The compliance officer indicated that there is no firm associated with [REDACTED] (b)(4), the updated number you provided in your email below for [REDACTED] (b)(4). She notes that the original FEI [REDACTED] (b)(4) is correct for [REDACTED] (b)(4) except the address is different. The address in the FDA system is [REDACTED] (b)(4). However, when I entered that address into Google Maps, the results noted that it is the same location as [REDACTED] (b)(4). So the slightly different addresses do not appear to be an issue.

Sincerely,

Carrie

---

**From:** Assar, Carrie  
**Sent:** Tuesday, March 8, 2022 2:15 PM  
**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Subject:** RE: [EXTERNAL] Re: ByHeart Infant Formula Manufacturing Facilities  
Thank you, Jeanne, for this very helpful information. I will pass it along to the compliance officer.

Best,

Carrie

**Carrie Assar, PharmD, MS**

*Team Leader*

*Infant Formula and Medical Foods Staff*

Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)



---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Sent:** Tuesday, March 8, 2022 11:10 AM  
**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** [EXTERNAL] Re: ByHeart Infant Formula Manufacturing Facilities

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Hi Carrie,

The [REDACTED]<sup>(b)(4)</sup> [REDACTED]. The number in the submission was associated with  
<sup>(b)(4)</sup> [REDACTED]

I apologize for any confusion.

Jeanne

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---

**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Sent:** Monday, March 7, 2022 5:55:20 PM

**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>

**Subject:** ByHeart Infant Formula Manufacturing Facilities

Dear Jeanne,

We are in the process of adding the [REDACTED]<sup>(b)(4)</sup> notified in submission [REDACTED]<sup>(b)(4)</sup> listed below to the annual infant formula inspection schedule, and a few questions arose from our compliance officer who manages the list. We are hoping that you can help with answers to her questions.

<sup>(b)(4)</sup>

- [REDACTED]
- [REDACTED]
- [REDACTED]

Questions:

<sup>(b)(4)</sup>

Any information you can provide would be greatly appreciated.

Thank you,

Carrie

**Carrie Assar, PharmD, MS**

*Team Leader*

*Infant Formula and Medical Foods Staff*

Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)



**From:** [Callen,Cheryl,US-Arlington](#)  
**To:** [Assar, Carrie](#)  
**Cc:** [Oh,Michelle,US-Bridgewater](#); [Lotze, Andrea](#)  
**Subject:** RE: [EXTERNAL] RE: [§ 104] Notification Questions  
**Date:** Tuesday, April 19, 2022 9:20:50 AM  
**Attachments:** [image001.png](#)

---

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Hi Carrie and Andrea,

Thank you for the quick review. Please let Gillian know we very much appreciate it!

Regards,

Cheryl

---

**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Sent:** Tuesday, April 19, 2022 9:16 AM  
**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] RE: [§ 104] Notification Questions

This message is from an EXTERNAL SENDER. BE CAUTIOUS, particularly with links and attachments.

---

Hi Cheryl,

I'm writing to let you know that Dr. Robert-Baldo just submitted the final letter for submission [§ 104] for the [§ 104]. An email notification with the final letter was sent from IFTRACK to Ms. Oh, and I also attached here for your reference.

Best,

Carrie

[Carrie Assar, PharmD, MS](#)

*Team Leader*

*Infant Formula and Medical Foods Staff*

Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)



---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Sent:** Monday, April 4, 2022 10:36 AM

**To:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** [EXTERNAL] RE: [§ 104] Notification Questions

**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 Andrea and Carrie. We really appreciate it and will respond as quickly as possible in the event there are questions during the review process.

Regards,  
Cheryl

---

**From:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>  
**Sent:** Monday, April 4, 2022 9:53 AM  
**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** RE: [REDACTED] Questions

This message is from an EXTERNAL SENDER. BE CAUTIOUS, particularly with links and attachments.

---

Hi Cheryl,  
We will do our best to proceed with an expedited review. Because there are sometimes questions that come up during the course of a review that only become evident as our reviewers look at the submission in depth, we cannot absolutely guarantee completion by the end of the week of April 17. However, we fully understand the need for an expedited process and will do our best to get this done within that timeframe.

Sincerely,  
Andrea

---

**From:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>  
**Sent:** Tuesday, March 29, 2022 3:53 PM  
**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** RE: [REDACTED] Notification Questions  
**Importance:** High

Hi Cheryl,  
Thank you so much for reaching out about this. We are working internally on being able to provide a response as soon as possible and hope to provide an update by the end of the week.

Sincerely,  
Andrea

---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Sent:** Tuesday, March 29, 2022 12:22 PM  
**To:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>  
**Subject:** RE: [EXTERNAL] RE: [REDACTED] Notification Questions

**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 Andrea and Carrie,  
Last week we submitted a Before First Processing notification [REDACTED] submitted 3/23) for use of an [REDACTED] (b) (4). We also submitted a Major [REDACTED] Notification [REDACTED] (b) (4) submitted 3/24) for use of an [REDACTED] (b) (4) [REDACTED] - (b) (4) [REDACTED]  
[REDACTED] (b) (4) [REDACTED] (b) (4) [REDACTED]

(b) (4)



I know this

is very compressed timing for review of a major notification but we would appreciate your consideration of this issue when reviewing submissions.

We are happy to answer any questions or provide more information.

Regards,  
Cheryl

---

**From:** Callen,Cheryl,US-Arlington

**Sent:** Tuesday, March 29, 2022 8:50 AM

**To:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [b] Notification Questions

Thanks Andrea – will send the information later this morning.

Regards,  
Cheryl

---

**From:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>

**Sent:** Tuesday, March 29, 2022 8:49 AM

**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Cc:** Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] RE: [b] Notification Questions

This message is from an EXTERNAL SENDER. BE CAUTIOUS, particularly with links and attachments.

---

Hi Cheryl,

I would greatly appreciate it if you could email us the information for now, then I can loop in our upper management and schedule a phone call as needed.

Thank you so much.

Andrea

---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Sent:** Tuesday, March 29, 2022 8:20 AM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: <sup>(b)(4)</sup> Notification Questions

**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 Carrie,

I have an update on our supply situation. Would you prefer to discuss or would you like me to email the information?

Regards,

Cheryl

---

**From:** Callen,Cheryl,US-Arlington

**Sent:** Wednesday, March 23, 2022 12:47 PM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: <sup>(b)(4)</sup> Notification Questions

Thanks Carrie –

---

**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Sent:** Wednesday, March 23, 2022 12:43 PM

**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: <sup>(b)(4)</sup> Notification Questions

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---

Thank you, Cheryl. We discussed this inquiry about an hour ago and your decision below aligns with our conclusion.

Best,

Carrie

---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Sent:** Wednesday, March 23, 2022 12:20 PM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: <sup>(b)(4)</sup> Notification Questions

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Hi Carrie,

We talked this over in the Nestle team and decided to <sup>(b)(4)</sup>

We will keep you updated if our supply situation changes.

Let us know if there are any questions.

Regards,

Cheryl

---

**From:** Callen,Cheryl,US-Arlington

**Sent:** Wednesday, March 23, 2022 10:04 AM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: [REDACTED] Notification Questions

Hi Carrie—

Thanks – we understand. I think we will go ahead and submit for the use of [REDACTED]<sup>(b)(4)</sup> This will allow more time to consider the [REDACTED]<sup>(b)(4)</sup>.

Regards,

Cheryl

---

**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Sent:** Wednesday, March 23, 2022 10:02 AM

**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** RE: [EXTERNAL] RE: [REDACTED] Notification Questions

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Hi Cheryl,

I had actually planned on reaching out to you this afternoon about this. We have no objections to submission of a [REDACTED]<sup>(b)(4)</sup> for the use of [REDACTED]<sup>(b)(4)</sup>

[REDACTED]<sup>(b)(4)</sup> because this [REDACTED]<sup>(b)(4)</sup> have already been notified to FDA. However, we need more time to internally discuss the [REDACTED]<sup>(b)(4)</sup>

[REDACTED]  
Best,

Carrie

**Carrie Assar, PharmD, MS**

*Team Leader*

*Infant Formula and Medical Foods Staff*

Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)



---

**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>

**Sent:** Wednesday, March 23, 2022 9:55 AM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>

**Subject:** [EXTERNAL] RE: [REDACTED] Notification Questions

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Hi Carrie,

I wanted to check in with you about our approach described below? We are preparing to submit this week.

Thanks  
Cheryl

**From:** Callen,Cheryl,US-Arlington

**Sent:** Friday, March 18, 2022 3:50 PM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Oh, Michelle, US-Bridgewater

<Michelle.Oh@US.nestle.com>

**Subject:** Notification Questions

Hi Carrie,

In light of the increased demand for [§7(4)] powder infant formula, our current [§7(4)] supplier,

Below we are providing our rationale and intended approach and would greatly appreciate your feedback.

(D) (4)

(D) (4)

Thanks for your consideration and we look forward to your questions and feedback.

Regards,

## Cheryl and Michelle

**From:** [Mischler, Tricia](#)  
**To:** [Robert Baldo, Gillian L](#)  
**Subject:** RE: [EXTERNAL] RE: Potential delay in the review of certain submissions  
**Date:** Friday, March 11, 2022 11:36:52 AM  
**Attachments:** [image154046.png](#)  
[image854061.png](#)  
[image366875.png](#)  
[image680424.png](#)  
[image619778.png](#)

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Well received and noted, with thanks.



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---

**From:** Robert Baldo, Gillian L <Gillian.RobertBaldo@fda.hhs.gov>  
**Sent:** Friday, March 11, 2022 9:31 AM  
**To:** Mischler, Tricia <Tricia.Mischler@reckitt.com>; Harry, Cristie <Cristie.Harry@rb.com>; Stowers, Emily <Emily.Stowers@rb.com>; Waddington, Sidney <Sidney.Waddington@rb.com>  
**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>; Kulas, Megan <Megan.Kulas@fda.hhs.gov>; Suggs-Anderson, Shawne <Shawne.Suggs-Anderson@fda.hhs.gov>  
**Subject:** [EXTERNAL] RE: Potential delay in the review of certain submissions

Good Morning:

I am adding another submission to this list, <sup>(b)(4)</sup> [REDACTED]  
Please alert us to any other submissions that include a packaging amendment or packaging with a <sup>(b)(4)</sup> [REDACTED] that is produced using this <sup>(b)(4)</sup> [REDACTED] that is under review.

Thank you.

Sincerely,  
Gillian

**Gillian Robert-Baldo, M.S., Ph.D.**

CONSUMER SAFETY OFFICER

*United States Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutrition and Food Labeling  
Infant Formula and Medical Foods Staff*

Email [Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)  
phone 240-402-1460

---

**From:** Robert Baldo, Gillian L  
**Sent:** Friday, February 25, 2022 5:55 PM  
**To:** Mischler, Tricia <[Tricia.Mischler@reckitt.com](mailto:Tricia.Mischler@reckitt.com)>; Harry, Cristie <[Cristie.Harry@rb.com](mailto:Cristie.Harry@rb.com)>; Stowers, Emily <[Emily.Stowers@rb.com](mailto:Emily.Stowers@rb.com)>; Waddington, Sidney <[Sidney.Waddington@rb.com](mailto:Sidney.Waddington@rb.com)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Suggs-Angerson, Shawne <[Shawne.Suggs-Angerson@fda.hhs.gov](mailto:Shawne.Suggs-Angerson@fda.hhs.gov)>  
**Subject:** Potential delay in the review of certain submissions

Good Evening:

(b) (4) has supplied us with the chemical name and CAS number of the substance that MJN has indicated is used as a (b) (4) for the (b) (4) in (b) (4) (b) (4). We have asked for further information, which we will be reviewing. This email is to alert you to a potential delay in our review of the following submission reference numbers: (b) (4) (b) (4) and any other submission that includes a packaging amendment or packaging with (b) (4). In addition, we are asking MJN to alert us to any submissions that include a packaging amendment or packaging with a (b) (4) (b) (4) that is produced using the same (b) (4). Please contact us with any questions.

Sincerely,

**Gillian Robert-Baldo, M.S., Ph.D.**

CONSUMER SAFETY OFFICER

*United States Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutrition and Food Labeling  
Infant Formula and Medical Foods Staff*

Email [Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)

phone 240-402-1460

**From:** [Walsh, Jenn](#)  
**To:** [Assar, Carrie](#)  
**Subject:** RE: [EXTERNAL] RE: Submission Rejection - Exempt Infant Formula Submission - Submission Ref #: (b)(4)  
**Date:** Thursday, April 28, 2022 2:08:55 PM  
**Attachments:** [image001.jpg](#)  
  [image002.png](#)

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**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 Carrie,

Thank you the explanation. Apologies for missing this, I will resubmit with the (b)(4)

Thank you,

Jenn

(she, her, hers)

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---

	<b>Jenn Walsh, MS, RD</b> Manager Regulatory Affairs	Abbott Nutrition 3300 Stelzer Rd Dept 104070, Bldg. RP3-2 Columbus, OH 43219	O: 614-624-6338 M: (b)(6) <a href="mailto:jennifer.walsh6@abbott.com">jennifer.walsh6@abbott.com</a>
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**From:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Sent:** Thursday, April 28, 2022 7:48 AM

**To:** Walsh, Jenn <[jennifer.walsh6@abbott.com](mailto:jennifer.walsh6@abbott.com)>

**Subject:** RE: [EXTERNAL] RE: Submission Rejection - Exempt Infant Formula Submission - Submission Ref #: (b)(4)

**EXTERNAL EMAIL:** Only click links or open attachments if you recognize the sender and know the content is safe. Hi Jenn,  
For submission (b)(4), the notified product is an exempt infant formula. The exempt infant formula submission regulation in 21 CFR 107.50(b)(4) requires "a complete quantitative formulation for the infant formula" be included in the submission. (b)(4)

Regards,

Carrie

**Carrie Assar, PharmD, MS**

*Team Leader*

*Infant Formula and Medical Foods Staff*

Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
[carrie.assar@fda.hhs.gov](mailto:carrie.assar@fda.hhs.gov)

---

**From:** Walsh, Jenn <[jennifer.walsh6@abbott.com](mailto:jennifer.walsh6@abbott.com)>

**Sent:** Wednesday, April 27, 2022 1:54 PM

**To:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** [EXTERNAL] RE: Submission Rejection - Exempt Infant Formula Submission - Submission Ref #: (b)(4)

**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 Carrie,

I apologize, (b)(4)

(b) (4)

Thank you for the clarification.

Sincerely,

Jenn

(she, her, hers)

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**Jenn Walsh, MS, RD**  
Manager  
Regulatory Affairs

Abbott Nutrition  
3300 Stelzer Rd  
Dept 104070, Bldg. RP3-2  
Columbus, OH 43219

O: 614-621-6338  
M: (b)(6)  
[jennifer.walsh6@abbott.com](mailto:jennifer.walsh6@abbott.com)

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**From:** [cfsan-admin@cfsan.fda.gov](mailto:cfsan-admin@cfsan.fda.gov) <[cfsan-admin@cfsan.fda.gov](mailto:cfsan-admin@cfsan.fda.gov)>

**Sent:** Friday, April 22, 2022 1:03 PM

**To:** Walsh, Jenn <[jennifer.walsh6@abbott.com](mailto:jennifer.walsh6@abbott.com)>

**Cc:** [Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)

**Subject:** Submission Rejection - Exempt Infant Formula Submission - Submission Ref #: (b)(4)

**EXTERNAL EMAIL:** Only click links or open attachments if you recognize the sender and know the content is safe.

**Submission Rejection - Exempt Infant Formula Submission - Submission Ref #:**

(b)(4)

Good Afternoon,

This is a notification that Submission (b)(4) has been rejected for the reason(s) listed below:

(b)(4)

**From:** [Gyan Rai](#)  
**To:** [Kulas, Megan](#)  
**Cc:** [Assar, Carrie](#)  
**Subject:** RE: [EXTERNAL] Request for Call  
**Date:** Friday, March 4, 2022 11:05:39 AM

---

**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 Megan,  
I was just typing you a separate email when yours came through!!

Thank you again- and both of you- for all the support and feedback you have provided over the period of this submission. We have officially passed the baton to our commercial team.

I am sure we will get in touch with you soon regarding other product innovations in our pipeline- but sincere gratitude towards the entire helpful staff for helping us achieve this milestone as a new infant formula company.

Have a wonderful weekend.

Best regards,  
Gyan

[Gyan Rai, PhD | ByHeart](#)  
Senior Director, Regulatory  
C: (b)(6)  
131 Varick Street, 11th Floor, New York, NY 10013

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**From:** Kulas, Megan <Megan.Kulas@fda.hhs.gov>  
**Sent:** Friday, March 4, 2022 10:59 AM  
**To:** Gyan Rai <Gyan@byheart.com>  
**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] Request for Call

Hi Gyan,

The final letter was sent through IFTRACK this morning.

Have a great weekend,  
Megan

---

**From:** Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>  
**Sent:** Wednesday, March 2, 2022 9:24 AM  
**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Request for Call

**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 Megan,  
Good morning.

I have a procedural question- given your note below that all questions on (b)(4) are adequately resolved, I tried to get into the system to attach the verification letter. However, it opened up a dialog box that the 'submission is till under review'. We were wondering when can we expect the final approval so that I can submit the verification in the system?

Appreciate your help with this.

Thanks,  
Gyan

[Gyan Rai, PhD | ByHeart](#)  
Senior Director, Regulatory  
C: (b)(6)  
131 Varick Street, 11th Floor, New York, NY 10013

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---

**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Sent:** Friday, February 25, 2022 11:46 AM  
**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Ron Belldegrun <[ron@byheart.com](mailto:ron@byheart.com)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>; Koh-Fallet, Sharon <[Sharon.Koh-Fallet@fda.hhs.gov](mailto:Sharon.Koh-Fallet@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Request for Call

Hi Jeanne,

Thank you for the follow-up email. Sharon reviewed the provided information and found it adequate. We are finalizing the submission to send the final letter.

Best,  
Megan

---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Sent:** Friday, February 25, 2022 9:51 AM  
**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Koh-Fallet, Sharon <[Sharon.Koh-Fallet@fda.hhs.gov](mailto:Sharon.Koh-Fallet@fda.hhs.gov)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Ron Belldegrun <[ron@byheart.com](mailto:ron@byheart.com)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>  
**Subject:** RE: [EXTERNAL] Request for Call

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CONFIDENTIAL

Dear Megan

We anxiously await your response verifying the compliance of [D(4)] under 21CFR 175.300. Per our discussion on 18 Feb 2022, we are expecting to hear from you by the end of today.

I also wanted to inform you that Gyan and I have searched for and found publications for the use of [D(4)] as a [D(4)]; however, we did not find any concerns regarding the suitability or safety of this substance for this application.

Thank you and sincerely,  
Jeanne

**Jeanne Hoskin, PhD | ByHeart**  
VP of Regulatory  
C: (b)(6)  
131 Varick Street, 11th Floor, New York, NY 10013  
[www.byheart.com](http://www.byheart.com)

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therefrom is disclaimed. If you received this in error, please contact the sender and delete the material from any computer

---

**From:** Jeanne Hoskin  
**Sent:** Friday, February 18, 2022 6:59 PM  
**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Koh-Fallet, Sharon <[sharon.koh-fallet@fda.hhs.gov](mailto:sharon.koh-fallet@fda.hhs.gov)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Ron Belldegrun <[ron@byheart.com](mailto:ron@byheart.com)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>  
**Subject:** FW: [EXTERNAL] Request for Call

Dear Megan and Sharon,

Thank you for your time today. On the call you indicated (b)(4)



We heard from you on the call that if the component has prior sanction, then a food contact authorization is not needed. We also understand that you plan to (b)(4)



We will add the 1978 FDA letter to the (b)(4) submission, and also the attached letter from (b)(4)



Thank you again for your help and support in moving this across the finish line. We are eagerly awaiting a response and expect you will answer next week by email as you stated on the call or set up a call if needed. Please let us if we can help in any way.

Thank you and sincerely,

Jeanne

---

**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Sent:** Wednesday, February 16, 2022 3:06 PM  
**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] Request for Call

Hi Jeanne,

Here is the call in information:

## Join Zoom Meeting

us: (b)(6)

[https://fda.zoomgov.com/i/\(b\)\(6\) ?pwd=Ryt0bVNxRW9FSmdlNDJZNmE5Z1Nidz09](https://fda.zoomgov.com/i/(b)(6) ?pwd=Ryt0bVNxRW9FSmdlNDJZNmE5Z1Nidz09)

(b)(6)

## **Join by Telephone**

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

US: (b)(6)

(Toll

Free)

(b)(6)

[International numbers](#)

## **Join from an H.323/SIP room system**

(b)(6) (US West)  
(US East)

(b)(6) [@sip.zoomgov.com](mailto:@sip.zoomgov.com)

Talk to you Friday,

Megan

---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>

**Sent:** Wednesday, February 16, 2022 11:48 AM

**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Subject:** RE: [EXTERNAL] Request for Call

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recognize the sender and know the content is safe.

Thank you, Megan, we'll take Option 1 - Friday, February 18, 2022, 1-1:30pm.  
Appreciate. We'll wait for your invite.  
Jeanne

---

**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Sent:** Wednesday, February 16, 2022 10:28 AM  
**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Request for Call

Good Morning Jeanne,

Thank you for your response yesterday.

Please see the options below that are available for a phone call with Dr. Andrea Lotze, Dr. Carrie Assar, Dr. Koh-Fallet, and myself:

Option 1: Friday, February 18, 2022 1-1:30pm  
Option 2: Tuesday, February 22, 2022 2-2:30pm

Please indicate which option works for you and I will send you the call in information.

Best,  
Megan

---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Sent:** Tuesday, February 15, 2022 6:50 PM  
**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>  
**Subject:** RE: [EXTERNAL] Request for Call

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Dear Megan  
Thank you for the update of 14 Feb 2022. We want to make sure we are doing everything possible to help FDA complete a timely review. Could you please provide a general description and scope of the remaining questions and the information you still need from our suppliers? This morning we contacted our suppliers who submitted their food master files on Jan 7, 2022, and they are receiving questions from the agency only now. We want to

understand the nature of the outstanding questions and if there is any assistance we can provide in moving towards completion.

To that end we are requesting a call with you and whoever else might be appropriate, including Dr. Koh-Fallet, to better understand the status of our submission and any outstanding questions. We really appreciate your ongoing diligence on our submission.

Thank you and I hope to hear from you shortly.

Jeanne

**Jeanne Hoskin, PhD | ByHeart**

VP of Regulatory

C: (b)(6)

131 Varick Street, 11th Floor, New York, NY 10013

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---

**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>

**Sent:** Monday, February 14, 2022 2:42 PM

**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>

**Subject:** RE: [EXTERNAL] Request for Call

Dear Jeanne,

Your submission, (b)(4), remains under review. FDA is in communication with your packaging suppliers (b)(4). For example, Dr. Sharon Koh-Fallet is in communications with (b)(4) clarifying some questions from FDA.

We appreciate your patience as we continue our review of this submission beyond the extension date.

Best,  
Megan

---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Sent:** Friday, February 11, 2022 11:33 AM  
**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>  
**Subject:** [EXTERNAL] Request for Call

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Dear Megan and Carrie

I hope all is well. We are now <sup>(b) (4)</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

It would be helpful to understand where we stand on the review and if you need anything else from ByHeart to help accelerate the timeline. We request a call next week at your earliest convenience, thank you.

I look forward to hearing from you. Happy Weekend.

Sincerely,  
Jeanne

**Jeanne Hoskin, PhD | ByHeart**

VP of Regulatory

C: (b)(6)

131 Varick Street, 11th Floor, New York, NY 10013

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**From:** [Jeanne Hoskin](#)  
**To:** [Kulas, Megan](#)  
**Cc:** [Assar, Carrie](#); [Lotze, Andrea](#); [Ron Belldegrun](#); [Gyan Rai](#); [Koh-Fallet, Sharon](#)  
**Subject:** RE: [EXTERNAL] Request for Call  
**Date:** Friday, February 25, 2022 11:58:47 AM

---

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THANK YOU ALL!!! We greatly appreciate your final response and all your help and guidance over the years!! Looking forward to receiving the final letter.

Sincerely,  
Jeanne and Gyan

---

**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Sent:** Friday, February 25, 2022 11:46 AM  
**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Ron Belldegrun <[ron@byheart.com](mailto:ron@byheart.com)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>; Koh-Fallet, Sharon <[Sharon.Koh-Fallet@fda.hhs.gov](mailto:Sharon.Koh-Fallet@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Request for Call

Hi Jeanne,

Thank you for the follow-up email. Sharon reviewed the provided information and found it adequate. We are finalizing the submission to send the final letter.

Best,  
Megan

---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Sent:** Friday, February 25, 2022 9:51 AM  
**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Koh-Fallet, Sharon <[Sharon.Koh-Fallet@fda.hhs.gov](mailto:Sharon.Koh-Fallet@fda.hhs.gov)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Ron Belldegrun <[ron@byheart.com](mailto:ron@byheart.com)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>  
**Subject:** RE: [EXTERNAL] Request for Call

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CONFIDENTIAL

Dear Megan

We anxiously await your response verifying the compliance of [§ 175.300] under 21CFR 175.300. Per our discussion on 18 Feb 2022, we are expecting to hear from you by the end of today.

I also wanted to inform you that Gyan and I have searched for and found publications for the use of [§ 175.300] as a [§ 175.300]; however, we did not find any concerns regarding the suitability or safety of this substance for this application.

Thank you and sincerely,  
Jeanne

**Jeanne Hoskin, PhD | ByHeart**  
VP of Regulatory  
C: (b)(6)  
131 Varick Street, 11th Floor, New York, NY 10013  
[www.byheart.com](http://www.byheart.com)

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**From:** Jeanne Hoskin  
**Sent:** Friday, February 18, 2022 6:59 PM  
**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Koh-Fallet, Sharon <[sharon.koh-fallet@fda.hhs.gov](mailto:sharon.koh-fallet@fda.hhs.gov)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Ron Belldegrun <[ron@byheart.com](mailto:ron@byheart.com)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>  
**Subject:** FW: [EXTERNAL] Request for Call

Dear Megan and Sharon,

Thank you for your time today. On the call you indicated (b)(4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

We heard from you on the call that if the component has prior sanction, then a food contact authorization is not needed. We also understand that you plan to (b)(4)

[REDACTED]

[REDACTED]

[REDACTED]

We will add the 1978 FDA letter to the (b)(4) submission, and also the attached letter from (b)(4)

[REDACTED]

Thank you again for your help and support in moving this across the finish line. We are eagerly awaiting a response and expect you will answer next week by email as you stated on the call or set up a call if needed. Please let us if we can help in any way.

Thank you and sincerely,

Jeanne

---

**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
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**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Request for Call

Hi Jeanne,

Here is the call in information:

[Join Zoom Meeting](#)

US: (b)(6)

[https://fda.zoomgov.com/j/ \(b\)\(6\) pwd=Ryt0bVNxRW9FSmdlNDJZNmE5Z1Nidz09](https://fda.zoomgov.com/j/ (b)(6) pwd=Ryt0bVNxRW9FSmdlNDJZNmE5Z1Nidz09)

(b)(6)

## Join by Telephone

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

US: (b)(6) (Toll Free)

(b)(6)

[International numbers](#)

## Join from an H.323/SIP room system

(b)(6) (US West)  
(b)(6) (US East)

(b)(6) [@sip.zoomgov.com](mailto:@sip.zoomgov.com)

(b)(6)

Talk to you Friday,

Megan

---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Sent:** Wednesday, February 16, 2022 11:48 AM  
**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Request for Call

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Thank you, Megan, we'll take Option 1 - Friday, February 18, 2022, 1-1:30pm.

Appreciate. We'll wait for your invite.

Jeanne

---

**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Sent:** Wednesday, February 16, 2022 10:28 AM  
**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>  
**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Request for Call

Good Morning Jeanne,

Thank you for your response yesterday.

Please see the options below that are available for a phone call with Dr. Andrea Lotze, Dr. Carrie Assar, Dr. Koh-Fallet, and myself:

Option 1: Friday, February 18, 2022 1-1:30pm

Option 2: Tuesday, February 22, 2022 2-2:30pm

Please indicate which option works for you and I will send you the call in information.

Best,

Megan

---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>

**Sent:** Tuesday, February 15, 2022 6:50 PM

**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>

**Subject:** RE: [EXTERNAL] Request for Call

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Dear Megan

Thank you for the update of 14 Feb 2022. We want to make sure we are doing everything possible to help FDA complete a timely review. Could you please provide a general description and scope of the remaining questions and the information you still need from our suppliers? This morning we contacted our suppliers who submitted their food master files on Jan 7, 2022, and they are receiving questions from the agency only now. We want to understand the nature of the outstanding questions and if there is any assistance we can provide in moving towards completion.

To that end we are requesting a call with you and whoever else might be appropriate, including Dr. Koh-Fallet, to better understand the status of our submission and any outstanding questions. We really appreciate your ongoing diligence on our submission.

Thank you and I hope to hear from you shortly.

Jeanne

**Jeanne Hoskin, PhD** | ByHeart

VP of Regulatory

C: (b)(6)

131 Varick Street, 11th Floor, New York, NY 10013

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---

**From:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>

**Sent:** Monday, February 14, 2022 2:42 PM

**To:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>

**Subject:** RE: [EXTERNAL] Request for Call

Dear Jeanne,

Your submission<sup>(b)(4)</sup>, remains under review. FDA is in communication with your packaging suppliers  
(b)(4). For example, Dr. Sharon Koh-Fallet is in communications with<sup>(b)(4)</sup>  
clarifying some questions from FDA.

We appreciate your patience as we continue our review of this submission beyond the extension date.

Best,

Megan

---

**From:** Jeanne Hoskin <[jeanne@byheart.com](mailto:jeanne@byheart.com)>

**Sent:** Friday, February 11, 2022 11:33 AM

**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>

**Cc:** Lotze, Andrea <[Andrea.Lotze@fda.hhs.gov](mailto:Andrea.Lotze@fda.hhs.gov)>; Gyan Rai <[Gyan@byheart.com](mailto:Gyan@byheart.com)>

**Subject:** [EXTERNAL] Request for Call

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you

[redacted] recognize the sender and know the content is safe.

Dear Megan and Carrie

I hope all is well. We are now [redacted]  
[redacted]  
[redacted]  
[redacted]

It would be helpful to understand where we stand on the review and if you need anything else from ByHeart to help accelerate the timeline. We request a call next week at your earliest convenience, thank you.

I look forward to hearing from you. Happy Weekend.

Sincerely,  
Jeanne

**Jeanne Hoskin, PhD | ByHeart**

VP of Regulatory

C: (b)(6)

131 Varick Street, 11th Floor, New York, NY 10013

[www.byheart.com](http://www.byheart.com)

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**From:** [Robert Baldo, Gillian L](#)  
**To:** [Corey Bosselman](#)  
**Cc:** [Marcy Sussman](#); [Assar, Carrie](#)  
**Subject:** RE: [EXTERNAL] Status update on [REDACTED]  
**Date:** Tuesday, March 22, 2022 1:26:00 PM

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Dear Corey:

Thank you for reaching out. Our workload continues to increase and we apologize for our part in the delay of this submission.

We are aware of the current infant formula shortages. Therefore, I will advise you that we are preparing our response to your submission at this time. I do not anticipate any further reviewer questions; however, our response has to be reviewed. I am hopeful that it will be ready to send by the end of this week or early next week.

Please let me know if you have any further questions.

Sincerely,  
Gillian

**Gillian Robert-Baldo, M.S., Ph.D.**

CONSUMER SAFETY OFFICER

*United States Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutrition and Food Labeling  
Infant Formula and Medical Foods Staff*

Email [Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)  
phone 240-402-1460

---

**From:** Corey Bosselman <Corey.Bosselman@perrigo.com>  
**Sent:** Monday, March 21, 2022 2:18 PM  
**To:** Robert Baldo, Gillian L <Gillian.RobertBaldo@fda.hhs.gov>  
**Cc:** Marcy Sussman <Marcy.Sussman@perrigo.com>; Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] Status update on [REDACTED]

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Robert-Baldo,

I am just following up on the response below from 03/01/22. Are you able to provide any further updates on the timing of the response letter for [REDACTED]?

Thank you again!

Sincerely,  
Corey

**Corey Bosselman, MS** | Regulatory Affairs Project Manager  
**Perrigo Nutritionals** | Regulatory Affairs, Nutrition  
455 Second Street, S.E., Suite 100, Charlottesville, VA 22902  
Office: (434) 297-1082 | Cell: (b)(6)  
[Corey.Bosselman@perrigo.com](mailto:Corey.Bosselman@perrigo.com)

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**From:** Robert Baldo, Gillian L <[Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)>  
**Sent:** Tuesday, March 1, 2022 5:53 PM  
**To:** Corey Bosselman <[Corey.Bosselman@perrigo.com](mailto:Corey.Bosselman@perrigo.com)>  
**Cc:** Marcy Sussman <[Marcy.Sussman@perrigo.com](mailto:Marcy.Sussman@perrigo.com)>; Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Status update on [b](4)

Dear Corey:

We are currently completing our review of this submission. I am hopeful that we will be able to send the response letter to you within the next two weeks.

Sincerely,  
Gillian

**Gillian Robert-Baldo, M.S., Ph.D.**  
CONSUMER SAFETY OFFICER  
*United States Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutrition and Food Labeling  
Infant Formula and Medical Foods Staff*

Email [Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)  
phone 240-402-1460

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**From:** Corey Bosselman <[Corey.Bosselman@perrigo.com](mailto:Corey.Bosselman@perrigo.com)>  
**Sent:** Monday, February 28, 2022 11:03 AM  
**To:** Robert Baldo, Gillian L <[Gillian.RobertBaldo@fda.hhs.gov](mailto:Gillian.RobertBaldo@fda.hhs.gov)>  
**Cc:** Marcy Sussman <[Marcy.Sussman@perrigo.com](mailto:Marcy.Sussman@perrigo.com)>  
**Subject:** [EXTERNAL] Status update on [b](4)

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Dear Dr. Robert-Baldo,

We are reaching out to see if you are able to provide any update on the status of notification [REDACTED] (b) (4). Due to the recent infant formula recall Perrigo has been asked by the agency to increase manufacture of infant formulas similar to those involved in the recall. Our production team is currently evaluating our upcoming manufacturing schedule, and any update on possible timing for [REDACTED] (b) (4) would greatly assist us in creating an accurate timeline for production.

Thank you for your assistance!

Sincerely,  
Corey Bosselman

**Corey Bosselman, MS** | Regulatory Affairs Project Manager  
**Perrigo Nutritionals** | Regulatory Affairs, Nutrition  
455 Second Street, S.E., Suite 100, Charlottesville, VA 22902  
Office: (434) 297-1082 | Cell: (b)(6)  
[Corey.Bosselman@perrigo.com](mailto:Corey.Bosselman@perrigo.com)

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**From:** [Callen,Cheryl,US-Arlington](#)  
**To:** [Suggs-Anderson, Shawne](#)  
**Cc:** [Assar, Carrie](#); [Kulas, Megan](#)  
**Subject:** RE: [EXTERNAL] Submission Message Update (b)(4) packaging)  
**Date:** Tuesday, April 12, 2022 12:31:17 PM

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Thanks Shawne – we will take care of this

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**From:** Suggs-Anderson, Shawne <[Shawne.Suggs-Anderson@fda.hhs.gov](mailto:Shawne.Suggs-Anderson@fda.hhs.gov)>  
**Sent:** Tuesday, April 12, 2022 12:25 PM  
**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Submission Message Update (b)(4) packaging)

This message is from an EXTERNAL SENDER. BE CAUTIOUS, particularly with links and attachments.

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Hi Cheryl,  
You need to respond, as you did in a message, to the pending questions dated 2/25/22 so that it can be removed as a pending question in (b)(4)

Regards,  
Shawne

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**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Sent:** Monday, April 11, 2022 8:44 AM  
**To:** Suggs-Anderson, Shawne <[Shawne.Suggs-Anderson@fda.hhs.gov](mailto:Shawne.Suggs-Anderson@fda.hhs.gov)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Submission Message Update (b)(4) packaging)

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Hi Shawne and Megan,  
I responded via message to FDA. Let me know if you would like me to respond in another place in IFTRACK.

Regards,  
Cheryl

---

**From:** Suggs-Anderson, Shawne <[Shawne.Suggs-Anderson@fda.hhs.gov](mailto:Shawne.Suggs-Anderson@fda.hhs.gov)>  
**Sent:** Friday, April 8, 2022 2:53 PM  
**To:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Subject:** RE: [EXTERNAL] Submission Message Update [b](4) packaging)

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Hi Cheryl,

Please respond to the current pending questions in IFTRACK for [b](4) follows:  
[b](4) contacted FDA directly.

In addition, I wanted to let you know that our packaging reviewer intends to inform [b](4) that an [b](4) .

Regards,  
Shawne

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**From:** Callen,Cheryl,US-Arlington <[Cheryl.Callen@us.nestle.com](mailto:Cheryl.Callen@us.nestle.com)>  
**Sent:** Wednesday, April 06, 2022 4:49 PM  
**To:** Suggs-Anderson, Shawne <[Shawne.Suggs-Anderson@fda.hhs.gov](mailto:Shawne.Suggs-Anderson@fda.hhs.gov)>; Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Cc:** Assar, Carrie <[Carrie.Assar@fda.hhs.gov](mailto:Carrie.Assar@fda.hhs.gov)>; Oh,Michelle,US-Bridgewater <[Michelle.Oh@US.nestle.com](mailto:Michelle.Oh@US.nestle.com)>; Green,Sara,US-Arlington <[Sara.Green@US.nestle.com](mailto:Sara.Green@US.nestle.com)>  
**Subject:** [EXTERNAL] Submission Message Update [b](4) packaging)

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Hi Shawne and Megan,  
Thank you for your messages related to the open questions regarding the change in the [b](4) used for some of our packaging. We have been discussing with [b](4) and they have been working with their suppliers to resolve the matter.  
I expect [b](4) will be in touch with the FDA packaging contact within the next few days.

Thank you for your patience!

Regards,  
Cheryl

**From:** Mischler\_Tricia  
**To:** Kulas\_Megan  
**Cc:** Assar\_Carrie  
**Subject:** RE: [EXTERNAL] [REDACTED] Submission Status Update  
**Date:** Wednesday, March 9, 2022 4:00:00 PM  
**Attachments:** image01.png  
image03.png  
image04.png  
image05.png  
image06.png  
image07.png  
image08.png

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Perfect! Thank you so much for letting me know. Hope your conference is going good and apologies for interrupting your time away with questions.

Cheers,  
Tricia

---

**From:** Kulas, Megan <Megan.Kulas@fda.hhs.gov>  
**Sent:** Wednesday, March 9, 2022 3:57 PM  
**To:** Mischler, Tricia <Tricia.Mischler@reckitt.com>  
**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] [REDACTED] Submission Status Update

Hi Tricia,  
We are in the final stages of the submission and are working to get it finalized as soon as possible. We hope to have it completed by early next week.  
Best,  
Megan

---

**From:** Mischler, Tricia <Tricia.Mischler@reckitt.com>  
**Sent:** Tuesday, March 8, 2022 7:14 PM  
**To:** Kulas, Megan <Megan.Kulas@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] [REDACTED] - Submission Status Update

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Megan, thank you for letting me know. I have searched high and low this afternoon and never received an email that you posted a message – ughhh! Since that [REDACTED] was so minor and it's been almost a month since we sent that in, do you have any timetable that I could share with our business partners? As you can imagine, this will come as quite a surprise and I'd like to give them an estimate, if at all possible.

Thanks so much for your help!  
Tricia

---

**From:** Kulas, Megan <Megan.Kulas@fda.hhs.gov>  
**Sent:** Tuesday, March 8, 2022 3:14 PM  
**To:** Mischler, Tricia <Tricia.Mischler@reckitt.com>  
**Cc:** Assar, Carrie <Carrie.Assar@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] [REDACTED] Submission Status Update

Hi Tricia,

I sent a submission message through IFTRACK where I indicated that we will not have our review completed by the review extension date because MJN sent in an amendment with [REDACTED] on 02/16/2022. Please let me know if you did not receive the below message:

Submission	From	Message	Sent Date
[REDACTED]	Megan.Kulas@fda.hhs.gov	<p>Hi Tricia,</p> <p>Thank you for your amendment dated 02/16/2022. Since there was a change to [REDACTED] FDA will need additional time to review this change. Thus, will not have our review complete by the review extension date.</p> <p>Thank you, Megan</p>	2/17/2022 12:38 PM EST

Best,  
Megan

---

**From:** Mischler, Tricia <Tricia.Mischler@reckitt.com>  
**Sent:** Tuesday, March 8, 2022 7:53 AM

**To:** Kulas, Megan <[Megan.Kulas@fda.hhs.gov](mailto:Megan.Kulas@fda.hhs.gov)>  
**Subject:** [EXTERNAL] (b) (4) - Submission Status Update  
**Importance:** High

**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.

Good morning, Megan. Our business is anxious to finalize the (b) (4) given the market conditions, and we noticed the 180 day review period expired last week.

Could you please provide an update at your earliest convenience?



**Tricia Mischler, MSPH**  
Regulatory Affairs, Nutrition



phone 812 449 7955  
email [tricia.mischler@rb.com](mailto:tricia.mischler@rb.com)  
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