

00:00:03:03 - 00:00:20:25

Janesia Robbs:

The FDA hosted an industry webinar on Friday, May 20, that could provide an overview and answer questions on FDA guidance to provide flexibility to manufacturers to increase infant formula supply. During the webinar, we received many questions from attendees that we would like to address at this time.

I'm Janesia Robbs with FDA's Center for Food Safety and Applied Nutrition, Communications and Public Engagement Staff. Here with me today to answer your questions are Dr. Patricia Hansen, deputy director of the CFSAN's Office of Nutrition and Food Labeling, and Mr. John Verbeten, Deputy Director for Operations Enforcement in the Office of Regulatory Affairs.

I will begin with our first question regarding specific types of certificates or certifications. And our first question comes from Ballantine Jager - is a European IFS food certificate fulfilling the cGMP certification requirements. In this case, for example, does certification of cGMP need to be third party audit certificate?

00:01:15:13 - 00:01:43:02

Dr. Patricia Hansen:

The certification regarding cGMPs referred to in our guidance is basically a signed statement or attestation that the manufacturer has established good manufacturing practices, including quality control procedures and in-process controls and testing required by current good manufacturing practice, designed to prevent adulteration of formulas produced at the facility.

If a manufacturer has an IFS food certificate or similar type of document, it will be helpful to provide that as well. In our guidance, we also specify the need to provide a schematic diagram with processing times and temperatures.

Helpful also to identify the control points on the diagram. And importantly, we are asking for a written narrative that includes but is not limited to a summary of the process for creating and processing conditions and critical control points.

If you have an existing hazard analysis and critical control point plan, preventive controls plan or similar plan or other documents that address these issues, then you can provide that. A copy of a recent internal or third-party audit may also be helpful. You do not have to write an entirely new document.

00:02:44:01 - 00:03:02:02

Janesia Robbs:

All right. We have a question from Christine Bradley and it reads, Will FDA plan to conduct an audit of the production facilities before enforcement discretion has been applied if no FDA audit has been conducted?

00:03:04:03 - 00:03:19:10

John Verbeten:

Thank you and good question. At this time, there are no inspections planned. But as these firms are marketing food products in the U.S., they will be subject to inspection and FDA will make those decisions on a case-by-case basis.

00:03:21:04 - 00:03:48:15

Janesia Robbs:

The next question is from Le Guennec Aude. Can we submit organic formula under European organic certification? Because we know that the requirements are different between European organic and U.S. organic regarding milk products.

00:03:48:15 - 00:04:11:14

Dr. Patricia Hansen:

FDA is accepting requests for enforcement discretion involving formulas labeled as organic. I will caution, though, that organic labeling is regulated by USDA and not FDA. And so for particular points regarding compliance may be needed, particularly with respect to organic labeling, manufacturers will need to contact USDA on this issue.

00:04:12:06 - 00:04:40:01

Janesia Robbs:

The next question is from Caroline Suto. Since this concerns dairy products, I assumed that these shipments would have to be accompanied by a veterinary health certificate. Will APHIS import permit be required for infant formula?

00:04:40:01 - 00:04:57:18

John Verbeten:

The quick answer to that is yes. We have been working with the U.S. Department of Agriculture and they have provided us contact points for industry as well as a link to their industry portal, and we can provide that information as part of this webinar.

00:04:58:18 - 00:05:16:05

Janesia Robbs:

We received a question from John Atwater. How can one know what the distribution is down to the retail level if a foreign manufacturer has not distributed product into the US?

00:05:16:26 - 00:05:37:08

Dr. Patricia Hansen:

In our guidance, we requested distribution plans down to the retail level if available. So for manufacturers already distributing products in the U.S. marketplace, we'd expect that such plans would be available. We recognize that for some requesters this will not be possible. We would like to receive from requesters, though, as much information as they have available regarding their distribution plans, including the status of their development.

00:05:39:14 - 00:05:59:11

Janesia Robbs:

Our next question comes from Sarah Powell Price. Will companies approved for formula release be publicly posted?

John Verbeten:

Yes, the agency will post those firms and the products that they're approved for and information on where to find that on fda.gov will be coming later.

00:06:00:13 - 00:06:36:06

Janesia Robbs:

The next question is from Jana Woolford. Who will coordinate distribution if, for example, European exporters do not have access to the market? And similar to that question we received another question from Ralph Pritchard. Is FDA or State Department providing contacts once the FDA has greenlighted the product?

00:06:36:14 - 00:07:05:21

Dr. Patricia Hansen:

Thank you, Janesia. Simply put, the FDA is not coordinating distribution of the formula. Nor are we providing and matching up and making contacts between manufacturers and other aspects of the supply chain they need to engage with in the US.

Janesia Robbs:

And our next question is from Christina Alexander. What is the necessary import permit, and do we still have to apply for it?

00:07:05:21 - 00:07:25:08

John Verbeten:

There is not a specific permit with FDA that is required to import, but as food manufacturing facilities, there is a registration requirement with the FDA and we'll be providing a link where you can go online to FDA.gov and complete your food facility registration for FDA.

00:07:26:03 - 00:07:30:07

Janesia Robbs:

Our next question is from Jeremy. It's been reported that the American government will airfreight via military aircraft formula to the America. Is this true and is it applicable to all products?

00:07:30:07 - 00:08:27:05

Dr. Patricia Hansen:

I think our questioner was referring to Operation Fly Formula. On May 19th, President Biden has launched an effort called Operation Fly Formula, which authorizes the Department of Health and Human Services, which FDA is apart, and the Department of Agriculture to use Department of Defense contractors, commercial aircraft to pick up overseas infant formula so it can get to store shelves more quickly. Only products for the FDA determines meet U.S. health and safety standards and for which we provide a letter of enforcement discretion, under this policy. Only those who are eligible for this program. This is a fast-evolving kind of program and situation, and I can say that we will provide more information on it as it becomes available.

00:08:27:05 - 00:08:59:14

Janesia Robbs:

And then we have a question about metric measures. And are metric measures acceptable on the label? And does the FDA intend to provide consumer resources to help them understand why a product might look different?

Dr. Patricia Hansen:

Good question. Metric measures on the label will be acceptable. FDA does tend to provide consumers with resources to help understand and understand and use the information from where metric units are employed. We'll be posting those and there is a team working on that as I speak. And we're also encouraging our stakeholders, food industry, trade groups, for example, to do similar to help amplify that educational effort for consumers to understand labels where some things they want to.

00:09:28:21 - 00:09:51:09

Janesia Robbs:

Another question, and this one is from Ben Busser. Is a no objection specific to each import, or will that product be allowed from that moment onward forever?

John Verbeten:

Once that no objection is provided, then that will cover all shipments of the product from that particular firm going forward.

00:09:54:28 - 00:10:15:07

Janesia Robbs:

So we received many questions about timeframes for the enforcement discretion, review and process. One question that we received was from Tori Schmitt. What is the FDA specific timeline for the evaluation of new enforcement discretion submissions? But then how many days will submissions be evaluated and notified?

00:10:18:27 - 00:10:42:07

Dr. Patricia Hansen:

That's a great question. I know we received a couple along these lines. FDA is working to review this request for enforcement discretion as quickly as possible. We can't provide a specific timeline for the completion of review requests because it depends in part on the completeness of the requesters application and the substance of the information provided. Another factor is the number of requests in the queue. I can tell you that we have set up a process for initial triage review that is going to assess completeness of the application, completeness that is in terms of the types of information we described, in our enforcement discretion policy guidance.

If there are gaps in the information, we are notifying requesters within days to one week. What happens after that, largely depends on the responsiveness of the requester. We issued our first of enforcement discretion under the enforcement discretion policy guidance on May 24th, just 8 calendar days after publication of the guidance.

So that can give a point of reference that it could be as quickly as that. But again, so much depends on the completeness and the quality of the request and the responsiveness of the requester should we come back with some additional questions or needs for further information.

00:11:43:29 - 00:12:07:18

Janesia Robbs:

One of the most frequently asked questions was, Does the label need to be in English?

00:12:07:18 - 00:12:28:27

Dr. Patricia Hansen:

FDA is prioritizing products that have English language labeling. Or can be quickly relabeled in English.

Janesia Robbs:

We got a question about Operation Formula Fly. We got this question from Gregor Kato from the British Embassy. Could you provide details on the use of Department of Defense air freight to import product and whether that will involve different import procedures?

00:12:28:27 - 00:12:56:19

John Verbeten:

The use of Department of Defense air freight under Operation Formula Fly is being coordinated either through the White House administration or the military directly, and they will have those conversations with the firms involved in the shipment. As far as the import procedures, those will remain the same and entry needs to be filed. The prior notice needs to be filed and we'll handle those shipments as as they arrive in the US.

00:12:59:06 - 00:13:18:24

Janesia Robbs:

We also received several questions regarding timelines of the enforcement discretion period. One question we received was from Lukas Charlie, who is the IMF, an infant formula producer in Germany. Is there any guidance on what the temporary limitation for this regulation will be? Two months? Two years?

00:13:19:06 - 00:13:42:05

Dr. Patricia Hansen:

The enforcement discretion policy by this will expire on November 14, 2022, roughly six months after its issuance. We at FDA are going to continue our efforts in evaluating and monitoring the US infant formula supply and will consider extending that period if needed.

00:13:44:16 - 00:14:03:01

Janesia Robbs:

We received a question from Dandan Chen which reads The application requires the company to disclose inventory available volume. Once approved, does FDA expects the inventory to be fully committed to the US or is it largely driven by the US market demand? And then another question we received related. Once the plant product will be approved by the FDA, will the manufacturer be allocated volumes? Who will be by buying the infant formula, FDA or private sector? And then is there a

target volume that the FDA is looking for to relieve the current formula shortage?

00:14:31:18 - 00:14:54:21

Dr. Patricia Hansen:

That's quite a landscape. Janesia, we're interested in the product volume that the manufacturer would intend to supply to the U.S. market, not overall production volume for distribution globally or in current markets that may not be a market. We're interested in the product volume for the manufacturer would intend to supply to the U.S. market.

We do not at this time have a target volume for this temporary enforcement discretion policy period. We also do not have plans to allocate volume to individual manufacturers. And lastly, as I think I mentioned previously, FDA will not be purchasing infant formula.

00:15:14:27 - 00:15:39:00

Janesia Robbs:

Will FDA be fast tracking customs clearance for formula when they arrive to the USA?

John Verbeten:

Yes, we will. This is a priority obviously for the administration and for the agency and in the import program we will set up our electronic screening systems to help facilitate these shipments as well as providing instructions to our field staff, all with an eye towards moving these products through the system as quickly as possible.

Janesia Robbs:

Will there be a prioritization for consideration of applicants, for example, volume, etc.?

Dr. Patricia Hansen:

FDA is prioritizing its review requests using several factors. A critical factor is the completeness and clarity with which a manufacturer addresses the elements described in the guidance. I mentioned earlier a triage type of thing right up front. Additional factors in our prioritization include the volume available for introduction into commerce and how quickly a manufacturer will be able to make that volume available and distributed. Requestors have potential to fill serious gaps in the supply of certain formulas for example, medical specialty formulas. Those requests will receive special attention.

Janesia Robbs:

And we also received questions related to the November deadline. We received a question from Kay Jensen. If product is important under the enforcement discretion, will it have to be withdrawn by November 14, 2022, or will it be allowed to remain in the market until its expiration?

00:16:59:23 - 00:17:22:20

Dr. Patricia Hansen

Again, good questions. Balance for which enforcement discretion is granted can be introduced into commerce until November the 14th, 2022, but not after that date unless they extend the expiration of our

guidance. We do not intend to direct manufacturers to withdraw products that are already in commerce on that date.

00:17:22:20 - 00:17:44:14

Janesia Robbs:

We received a question from Leslie Hoagland, and it reads, from a retailer perspective, if there is a vendor outside of the U.S. shipping to multiple U.S. retailers, do all retailers need to collect the same information to be able to import after FDA approval?

00:17:46:02 - 00:18:02:04

John Verbeten:

So the first the first part here is that the enforcement discretion is being applied to the manufacture of the products and the specific products that they provided information to FDA for. The retailers or importers here in the United States the import process will require, you know, the identification of who the manufacturers, who the shipper is, who that importer is, and then where the product is going, who the consignee is. So in that respect, all of the information, regardless of who the importer is, the same pieces of information need to be provided.

00:18:26:00 - 00:18:49:05

Janesia Robbs:

Another question about the November 14, 2022 deadline, and it comes from Elisa Baker Johnson. Will extension beyond November 14th be decided on a case-by-case basis?

00:18:49:07 - 00:19:09:22

Dr. Patricia Hansen:

In a word, no. If FDA decides on an extension beyond on November the 14 is necessary, we will announce the extension publicly and we will apply to all stakeholders.

Janesia Robbs:

Will a the manufacturer lose their place in the document review order if they should be requested to provide additional information to FDA.

00:19:10:07 - 00:19:35:20

Dr. Patricia Hansen:

Generally speaking, no. We are doing some overall prioritization which will guide the review to overall.

Janesia Robbs:

And we received the question from Ash Barty, will manufacturers be allowed to provide additional information once they have submitted their request for enforcement discretion?

Dr. Patricia Hansen:

Yes, but I mentioned earlier the questions arise during the review of a manufacturer's request. FDA may ask for additional information. Once we receive it, we will continue our review. If manufacturers have noticed a gap, they themselves notice a gap in what they've submitted, they can supplement their request.

00:19:55:00 - 00:20:13:26

Janesia Robbs:

This question is from Michael Dikes. Will state approval be required to import infant formula?

John Verbeten:

The United States Federal Government has jurisdiction over the importation of products into the US, so no. State approval is not required for import into the US. And our next question comes from Bob Waltrip.

00:20:14:13 - 00:20:35:20

Janesia Robbs:

And our next question comes from B. Waltrip. If enforcement discretion is granted for our product, what is the status of our product longer term?

00:20:36:16 - 00:21:00:21

Dr. Patricia Hansen:

Receiving a letter of enforcement discretion for your product will allow you to introduce it into commerce up to and including November 14, 2022. It will not provide long term or indefinite access to the U.S. market. If your product currently meets the definition of a new infant formula, that's the legal definition of the new infant formula, after the enforcement discretion period is over, you will need to meet all statutory choice requirements that apply to infant formulas, in order to have long term access to the U.S. marketplace. So. That means even though your product may have been commerce in the U.S. for several months and hasn't changed its legal status, this is an infant formula. And I would like to take a moment here to touch briefly on this one, although fully exploring it could take a full webinar itself.

What is the new infant formula? Under our federal food, drug and cosmetic act, a new infant formula includes an infant formula manufactured by a person that has not previously manufactured infant formula. That's within the context of the marketed manufacturing market for the US market. So if you are a manufacturer who has not been in the US marketplace previously, you introducing a formula. That formula is an infant formula. And a new infant formula also includes an infant formula manufactured by a person which has previously manufactured infant formula and in which there is a major change in process and or formulation from any kind or any previous formulation. And some examples of major changes in manufacturing plants and production lines, employment of significant new technologies, fundamental change in the packaging use, additions of a new macro nutrient, and the new protein fat or carbohydrate source or substantial change in the amount of those macro nutrients. And lastly, addition of new ingredients. That list is not all inclusive, but it is meant to give you a sense of what can legally make you a new infant formula.

00:23:06:17 - 00:23:27:10

Janesia Robbs:

And the next question is related from Dr. I C Taylor. Could you please also provide a link to the mentioned FDA bacteriological analytical manual of the test methods that you prefer?



Dr. Patricia Hansen:

We will add links to our resources, of course.

00:23:27:10 - 00:23:41:17

Janesia Robbs:

We have a question from Andre Santos. Would the sale of infant formula from a certain country be allowed to sell to individuals from that country? In the United States, for example, a Vietnamese market. A Brazilian market. A Mexican market or a Chinese market?

00:23:43:16 - 00:24:02:26

John Verbeten:

The enforcement discretion being provided by the agency is specific to particular manufacturers and is not broad based in the way that the question implies.

00:24:03:04 - 00:24:24:13

Janesia Robbs:

We received many questions on the pathway or a process for long term entry into the U.S market with questions about registrations and notifications, regular requirements, etc., Pat can you talk a little bit about this.

00:24:25:06 - 00:24:46:00

Dr. Patricia Hansen:

And so I'm happy to give a little bit more, Janesia. But as I said, to cover this adequately really would take an entire webinar in itself. But for now, I will just refer people to our website and I'll note we'll be adding a couple of resources to the links provided in our earlier webinar. And I'll refer you also to the regulations and Title 21 of the Code of Federal Regulations, primarily part 106, with some additional detail on topics such as nutrient specification and labeling in part 107. And we'll be providing links to a couple of the most critical resources that are up so that folks get fully acquainted with the regulatory requirements for introducing a new infant formula to the marketplace.

00:25:11:24 - 00:25:38:29

Janesia Robbs:

And our next question is on micro testing and this come from D. Chen. Do the Cronobacter and Salmonella testing samples numbers have to be the exact number stated by FDA.

00:25:39:00 - 00:25:58:15

Dr. Patricia Hansen:

Regarding the microbiological testing, you can provide results using different sampling numbers to start your enforcement discussion requests. But ultimately, FDA will need the results using the recommended minimum sampling numbers to fully evaluate the request and grant enforcement discretion. If you do not have results using those recommended minimum sampling numbers, you should indicate a date by which you expect to be able to confirm.

00:25:58:15 - 00:26:29:20

Janesia Robbs:

All right. So we have another question from Ben Busser. Given the shortages, why are U.S. Customs still actively increasingly blocking deliveries of online purchases of infant formulas from abroad?

00:26:30:00 - 00:26:53:23

John Verbeten:

That's a good question. And, you know, while we are taking this enforcement discretion approach and creating a pathway for, you know, foreign suppliers to market their products in the U.S., we are also going to continue with our consumer protection mission and continuing to stop products that are either subject to an import alert. And we're also going to stop shipments of products that are not authorized either under the enforcement discretion or historically, because we cannot allow the distribution of these products until there has been the appropriate review by the agency.

00:26:53:23 - 00:27:20:22

Janesia Robbs:

All right. So moving on to, we received a few questions on testing and test methods. Here's an example of one common question that we got in this category, and it was from Jay Atwater. What if test methods were not the AOAC international specified test method?

00:27:22:14 - 00:27:40:12

Dr. Patricia Hansen:

In this case, the test methods used should be specified and a copy of the method provided they're providing some flexibility around test methods, but we do need to know specifically what method was used to obtain the results and if it is not a compendium method, a copy of the method is critical.

00:27:40:17 - 00:28:01:09

Janesia Robbs:

And then we also received a number of questions about nutrient testing, for example, from Audd, for the summary of nutrient test results are results from only one batch requested or average of the results related to more than one batch related. We received another question from Nan, can the testing results be from a different batch other than the batch for importing?

00:28:25:19 - 00:28:46:03

Dr. Patricia Hansen:

What we are looking for and what we outlined in the guidance, is the most recent batch or lot produced at each applicable facility and for each formula. We want a summary of the test results conducted with the final product stage of the level of each nutrient required by our regulations, 21 CFR 107.100. For nutrients that are not required by our regulations, an example would be DHA. For example, many infant formulas contain that complained that. The nutrients added by the infant formula manufacturer, we would like a summary of the test results for that nutrient presented in units for 100 kilograms.

00:29:10:25 - 00:29:33:29

Janesia Robbs:

All right. So to conclude today's additional question and answer session, we like to thank you and again, if you have any questions, please see our Food Information Center. And that link is on the slide, as well as the link to send the information described in the guidance to the email box listed on the side, bullet number two. And then if you have any general questions about the guidance or need more information about the guidance, see the first link in the bullet. And with that, we will say goodbye. And thank you again for tuning in. And more information will be shared as it is presented to us. Thank you.