Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–708–1707, email: *CRDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application 216401, for omecamtiv mecarbil tablets, submitted by Cytokinetics, Inc. The proposed indication is to reduce the risk of cardiovascular death and heart failure events in patients with symptomatic chronic heart failure with reduced ejection fraction. The committee will discuss whether the phase 3 trial (GALACTIC–HF) establishes substantial evidence of effectiveness of omecamtiv mecarbil and whether the benefits of omecamtiv mecarbil outweigh the risks when used according to the applicant's proposed dosing regimen.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before November 29, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 18, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 21, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Rhea Bhatt (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21769 Filed 10–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0814]

Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry.'' We are issuing this guidance document to protect public health by helping to stabilize the supply of infant formula in the United States and to maintain a consistent supply of a variety of infant formula products. Under the guidance, we intend to exercise enforcement discretion until January 6, 2023, for infant formula products that are listed in letters of enforcement discretion that FDA has issued or will issue to specific manufacturers, in response to information provided under our May 2022 ''Infant Formula Enforcement Discretion Policy: Guidance for Industry,'' which remains in effect until November 14, 2022. For those manufacturers that wish to continue to market specific products in the United States under enforcement discretion after January 6, 2023, the guidance further details additional steps that manufacturers can take toward lawful marketing of such products—and the timeline under which such steps should be taken—for FDA to consider the continued exercise of enforcement discretion. This guidance document will help infant formula manufacturers meet applicable regulatory requirements while ensuring that consumers have continued access to formulas that are currently fulfilling the needs of infants consuming such products. We are also announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA). The proposed collection pertains to the submission of information necessary to facilitate FDA's exercise of enforcement discretion, as discussed in the guidance document.

DATES: Fax written comments on the collection of information by November 7, 2022. FDA is requesting immediate OMB approval of this emergency processing. The announcement of the guidance is published in the **Federal Register** on October 6, 2022.

ADDRESSES: You may submit either electronic or written comments on any Agency guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically,

including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0814 for ''Infant Formula Enforcement Discretion Policy: Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Claudine Kavanaugh, Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling (HFS–830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2373; or Philip L. Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry.'' We issued the guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines infant formula as a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk (section 201(z) of the FD&C Act (21 U.S.C. 321(z)). Our regulations define infants as persons not more than 12 months old (21 CFR 105.3(e)). Among other requirements, section 412(c)(1)(B) of the FD&C Act (21 U.S.C. 350a(c)(1)(B)) and FDA regulations (21 CFR 106.120) require an infant formula manufacturer to submit notice (*i.e.,* a new infant formula submission) to FDA at least 90 days before a new infant formula is introduced or delivered for introduction into interstate commerce.

Infant formula is often used as the sole source of nutrition by a vulnerable population during a critical period of growth and development. In general, the laws and regulations that apply to food also apply to infant formula, but additional requirements that are specific to infant formula appear in section 412 of the FD&C Act and in our regulations at 21 CFR parts 106 and 107.

The voluntary recall and facility shutdown conducted by Abbott Nutrition in 2022 created a supply disruption with respect to certain types of infant formula, which has been exacerbated by the overall strains on supply chains during the COVID–19 pandemic. As part of the Federal Government's response to the infant formula shortage, on May 16, 2022, FDA issued the ''Infant Formula Enforcement Discretion Policy: Guidance for Industry'' (May 2022 Enforcement Discretion Guidance; available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-enforcement-discretion-policy*) discussing our intent to consider, on a case-by-case basis, the temporary exercise of enforcement discretion for the introduction into interstate commerce of infant formula that may not meet certain statutory and regulatory requirements; the guidance remains in effect until November 14, 2022. The May 2022 Enforcement Discretion Guidance describes the information that an infant formula manufacturer should provide to FDA if the manufacturer wishes to have FDA consider the exercise of enforcement discretion relating to the introduction

into interstate commerce (including importation) of infant formula that is safe and nutritionally adequate but that may not comply with all FDA statutory and regulatory requirements. Consistent with the policies described in the May 2022 Enforcement Discretion Guidance, certain manufacturers have submitted information to FDA to substantiate the safety and nutritional adequacy of specific infant formula products and, following FDA's thorough review of the information provided, are marketing such products under FDA's exercise of enforcement discretion.

This guidance sets forth our current thinking on circumstances under which we intend to exercise temporary enforcement discretion for certain infant formula products beyond November 14, 2022, and to advise infant formula manufacturers marketing products in accordance with letters of enforcement discretion issued under the May 2022 Enforcement Discretion Guidance about: (1) the type of information to provide to FDA; and (2) our timing expectations related to such information, if they would like us to consider the continued exercise of enforcement discretion with respect to their products. This guidance document will remain in effect until October 18, 2025, and FDA expects that all infant formula products will comply with applicable U.S. requirements by the end of the enforcement discretion period.

We issued this guidance without prior public comment under section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2) because we determined that prior public participation is not feasible or appropriate, as this guidance provides time-sensitive clarifications regarding FDA's intent to exercise enforcement discretion with respect to specific formula products that are currently fulfilling the needs of infants in the United States.

As with all FDA guidance documents, the public may comment on the guidance at any time.

II. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

III. Paperwork Reduction Act of 1995

FDA requested, and OMB has approved, emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). Immediate implementation of the information collection is critical to providing predictability, stability, and continuity in the infant formula market, specifically with respect to those products currently available to infants in the Unites States under FDA's exercise of enforcement discretion. Because we believe that routine procedures, which allow for a 60-day comment period, would prevent our ability to immediately implement the information collection, we requested a waiver from the requirement to publish a 60-day notice for the information collection (see 5 CFR 1320.13(a)(2)(iii)).

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ONE-TIME ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submit information in accordance with timing and content schedule discussed in guidance document for both exempt and non-exempt infant formulas	115	1	115	24	2,760
Letter of Intent	15	1	15	5	75
Plan to Meet Applicable Infant Formula Requirements	15	1	15	90	1,350
Total					4,185

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate is based on submissions received in response to the May 2022 Enforcement Discretion Guidance, for which we account for 115 respondents, each of whom submitted one request. We assume it requires an average of 24 hours to prepare each submission, and therefore calculate a total of 2,760 burden hours (115 requests × 24 hours). Of those 115 respondents, we have currently issued 12 letters of enforcement discretion but may issue additional letters through November 14, 2022. We therefore assume that a total of 15 respondents will initiate requesting enforcement discretion and final a letter of intent. We assume this requires an average of 5 hours to prepare, for a total of 75 burden hours (15 letters × 5 hours). We estimate these same 15 respondents will then submit a compliance plan and assume each plan will require an average of 90 hours to prepare, for a total of 1,350 burden hours (15 plans × 90 hours).

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21794 Filed 10–5–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0589]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.