guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: May 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09529 Filed 5–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1814]

Preparation of Food Contact Notifications for Food Contact Substances in Contact With Infant Formula and/or Human Milk; 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 final guidance for industry entitled ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.'' This guidance is intended to provide industry with our current thinking on how to prepare a food contact notification (FCN) submission for our review and evaluation of the safety of food contact substances (FCSs) used in contact with infant formula and/or human milk.

DATES: The announcement of the guidance is published in the **Federal Register** on May 9, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2016–D–1814 for ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.'' 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.

- 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 its 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.gpo.gov/fdsys/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.

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 Division of Food Contact Notifications/Office of Food Additive Safety, 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: Vanee Komolprasert, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1217.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.'' We are issuing 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 alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

Section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) establishes an FCN process as the primary method by which we regulate food additives that are FCSs. As defined in section 409(h)(6) of the FD&C Act, the term ''food contact substance'' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

Pursuant to section 409(h) of the FD&C Act and FDA's implementing regulations [1], FCN submissions must contain a comprehensive discussion of the basis for the manufacturer's or supplier's determination that the use of the FCS that is the subject of the notification is safe. This guidance contains recommendations regarding how the scientific information in FCNs for infant food use should demonstrate that the FCS is safe for the specific intended use in contact with infant food. For purposes of the guidance, infant food is limited to infant formula and/or human milk, and this guidance focuses on infants 0–6 months in age. The guidance discusses our recommendations and provides information for: A. *Chemistry Recommendations,* including Migration Testing and Exposure Estimation; B. *Toxicology Recommendations* including Exposure Based Testing Tiers, Minimum Testing Recommendations, and Age Dependent Cancer Risk Analysis of Carcinogenic Constituents; and C. *Administrative Recommendations* including Acknowledgment of an FCN, Non-acceptance of an FCN, Final Letter, Inventory of Effective FCNs, and Premarket Notification Consultations (PNCs).

In the **Federal Register** of December 9, 2016 (81 FR 89110), we announced a draft guidance for industry and gave interested parties an opportunity to submit comments by February 7, 2017, for us to consider before beginning work on the final version of the guidance. We received a few comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include modifying the Exposure Based Testing Tiers 2 and 3 to be consistent with FDA's ''Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations. Specifically, the upper bound of Tier 2 now includes an exposure equal to or less than 2.5 micrograms per kilogram of body weight per day (µg/kg bw/day) and lower bound of Tier 3 is now greater than 2.5 µg/kg bw/day. The guidance announced in this notice finalizes the draft guidance dated December 2016.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0495.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *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.

Dated: May 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09530 Filed 5–8–19; 8:45 am]

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[1] 21 CFR 170.101(a) (*https://www.ecfr.gov/cgi-bin/text-idx?SID=56face021b3741c1fba7e997df53d3de&mc=true&node=pt21.3.170&rgn=div5#se21.3.170_1101*).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4693]

Postapproval Pregnancy Safety Studies; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Postapproval Pregnancy Safety Studies.'' When finalized, the purpose of this guidance will be to provide sponsors and investigators with recommendations on how to design investigations to assess the outcomes of pregnancies in women exposed to drugs and biological products regulated by FDA (*i.e.,* pregnancy safety studies). This draft guidance, when finalized, will represent the current thinking of FDA on postapproval pregnancy safety studies. This draft guidance is intended to help industry develop more comprehensive and scientifically sound studies to assess the safety of drug and biological products during pregnancy in the postmarketing setting. The previous guidance for industry entitled ''Establishing Pregnancy Exposure Registries,'' issued on August 23, 2002, has been withdrawn.

DATES: Submit either electronic or written comments on the draft guidance by July 8, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any 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'').