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In the **Federal Register** of December 9, 2016 (81 FR 89110), we announced a draft guidance for industry and gave interested parties an opportunity to submit comments by February 7, 2017, for us to consider before beginning work on the final version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]

BILLING CODE 4164–01–P

[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'').

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–2018–D–4693 for ''Postapproval Pregnancy Safety Studies; Draft Guidance for Industry; Availability.'' 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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6469, Silver Spring, MD 20993, 301–796–6169; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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. Currently, collection of safety data in drugs and biological products used during pregnancy usually occurs after approval. Pregnancy registries have been used to collect these data. However, in the years since FDA first issued guidance on this topic, scientific methodologies for assessing safety in pregnancy in the postmarketing setting have evolved.

FDA held a 2-day public meeting in 2014 during which stakeholders, including birth defect experts from academia, industry, professional organizations, and patient groups, discussed the use of pregnancy registries and other epidemiologic studies to collect postmarketing safety data on the use of drug and biological products during pregnancy. In addition, FDA conducted reviews of pregnancy registries, including assessment of pregnancy registry methods and enrollment.

This draft guidance, when finalized, will represent the current thinking of FDA on postapproval pregnancy safety studies. Based on FDA reviews and the 2014 public meeting, the revisions in this draft guidance reflect the most up-to-date recommendations for protocol specifications and scientific standards for pregnancy safety studies and include a broader scope of methods for collection of safety information for drug and biological products used during pregnancy, including pharmacovigilance activities and other postapproval safety studies. The previous guidance for industry entitled ''Establishing Pregnancy Exposure Registries,'' issued on August 23, 2002, has been withdrawn.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on postapproval pregnancy safety studies. 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.

II. The Paperwork Reduction Act of 1995

This 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 have been approved under OMB control number 0910–0001 as follows: (1) 21 CFR 314.50(d) for submitting technical sections of the content and format of a new drug application for pregnancy registry design considerations; (2) 21 CFR 314.80(c)(2)(iii) for submitting postmarketing safety reports; and (3) 21 CFR 314.81(b)(2)(vii) for submitting postmarketing study updates in annual reports. The collections of information in 21 CFR 312.23(a)(6) for submitting pregnancy registry design considerations in a protocol for investigational new drug applications have been approved under OMB control number 0910–0014. The collections of

information in 21 CFR 310.305(c) and 21 CFR 314.80(c)(2)(iii) and (e) for submitting postmarketing safety reports have been approved under OMB control number 0910–0230. The collections of information for submitting postmarketing safety reports under MedWatch have been approved under OMB control number 0910–0291. The collections of information in 21 CFR 201.56 and 201.57, including 21 CFR 201.57(c)(9)(i)(A) for preparing human prescription drug labeling to include pregnancy registries and relevant contact information under the subheading Pregnancy Exposure Registry have been approved under OMB control number 0910–0572. The collections of information contained in the guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' (available at *https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127073.pdf*) have been approved under OMB control number 0910–0581. The collections of information in the ''Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling'' final rule have been approved under OMB control number 0910–0624. The collections of information in 21 CFR 50.25 for the elements of informed consent have been approved under OMB control number 0910–0755.

III. Electronic Access

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

Dated: May 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09527 Filed 5–8–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB Number 0915–0327—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Before submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 8, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title, below, for reference.

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision.

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service (PHS) Act, which instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS (the Secretary) that comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program), and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that choose to participate in the 340B Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) of the PHS Act prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity.

Need and Proposed Use of the Information: To ensure its ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency, and integrity, HRSA developed a process of registration for covered entities to address specific statutory mandates. Specifically, section 340B(a)(9) of the PHS Act requires HRSA to notify manufacturers of the identities of covered entities and of their status pertaining to certification and annual recertification in the 340B Program pursuant to section 340B(a)(7) and the establishment of a mechanism to prevent duplicate discounts as outlined at section 340B(a)(5)(A)(ii) of the PHS Act.

Also, section 340B(a)(1) of the PHS Act requires each participating manufacturer to enter into an agreement with the Secretary to offer covered outpatient drugs to 340B covered entities.

Finally, section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities.

HRSA is requesting approval for existing information collections. HRSA notes that the previously approved collections are mostly unchanged, except that HRSA has transitioned completely to online versus hardcopy forms. In doing so, some of the forms have been revised to increase program efficiency and integrity. Below are descriptions of each of the forms and any resulting revisions in both the registration and pricing component of