Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443, *Graham.Thompson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The timely review of the safety and efficacy of new drugs and biologics is central to FDA's mission to protect and promote the public health. Since the implementation of PDUFA I in 1993, FDA has used PDUFA resources to improve the timeliness and predictability of new drug review while maintaining FDA's rigorous standards for drug quality, safety and efficacy. With the availability of these additional fee resources, FDA was able to agree to certain review performance goals, including a complete review of NDAs and BLAs and taking regulatory action within specified timeframes. The managed review processes put in place to accomplish this, and the process enhancements including investments in modernized post-market safety and regulatory science over subsequent reauthorizations of PDUFA, have revolutionized the new drug review process, helping to bring critical products to market for patients. The PDUFA program has been reauthorized every 5 years, with the most recent and fifth authorization occurring in 2012. The PDUFA V Performance Goals and Procedures for Fiscal Years 2013 through 2017 can be accessed at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf*.

PDUFA V introduced a new review program for NME NDAs and original BLAs to enhance review transparency and communication between FDA and applicants on these complex applications. FDA committed to engaging an independent contractor to evaluate the Program to understand the Program's effect on the review of these applications. The interim assessment was published March 31, 2015, and can be accessed at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM436448.pdf*. The PDUFA V performance commitments also call for a final assessment of the Program to be published by December 31, 2016, for public comment. The final assessment can be accessed at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm*. A public meeting will be held on March 27, 2017, where the final assessment will be discussed and public stakeholders may present their views on the Program.

II. PDUFA V NME NDA and Original BLA Review Program

FDA's performance goals for review of priority and standard new drug applications, 6 and 10 months respectively, have been in place since the late 1990s. Since that time, additional requirements in the review process and scientific advances in product development have made those goals increasingly challenging to meet, particularly for more complex applications like NME NDAs and original BLAs. FDA further recognizes that increasing communication and transparency between the Agency and applicants during FDA's review has the potential to increase efficiency in the review process.

To promote greater transparency and improve communication between the FDA review team and the applicant, FDA implemented a new review model for NME NDAs and original BLAs in PDUFA V. The Program provides opportunities for increased communication between FDA and applicants, including mid-cycle and late-cycle meetings. To accommodate the increased interaction during regulatory review and to address the need for additional time to review these complex applications, FDA's review clock begins after the 60-day administrative filing review period for applications reviewed under the Program.

The goal of the Program is to improve the efficiency and effectiveness of the first-cycle review process by increasing communications during application review. This will provide sponsors with the opportunity to clarify previous submissions and provide additional data and analyses that are readily available, potentially avoiding the need for an additional review cycle when concerns can be promptly resolved without compromising FDA's standards for approval.

III. Meeting Attendance and Participation

FDA is holding the public meeting on March 27, 2017, from 10 a.m. to 1 p.m. If you wish to attend this public meeting, visit: *https://nmemeeting.eventbrite.com*. Please register by March 20, 2017. If you are unable to attend the public meeting in person, you can register to view a live Webcast of the public meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will not be possible. If you need special accommodations because of a disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the public meeting.

FDA will hold an open public comment period to give the public an opportunity to comment during the public meeting. Registration for open public comment will occur at the registration desk on the day of the public meeting on a first-come, first-served basis.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A link to the transcript will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm501389.htm*.

Dated: December 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29589 Filed 12–8–16; 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; Draft 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 draft guidance for industry entitled ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.'' The draft guidance, when finalized, will 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: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 7, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Food Contact Notifications, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS–275), 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 draft guidance.

FOR FURTHER INFORMATION CONTACT: Kelly Randolph, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1188.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft 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 draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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.

Section 409 of the Federal Food, Drug, and Cosmetic Act (the 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.

Under section 409(h) of the FD&C Act and FDA's implementing regulations, 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 draft 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 draft guidance, infant food is limited to infant formula and/or human milk, and this draft guidance focuses on infants 0–6 months in age. The draft guidance discusses our

recommendations and provides information for: Chemistry recommendations, including migration testing and exposure estimation; *t*oxicology recommendations including exposure-based testing tiers, minimum testing recommendations, and age-dependent cancer risk analysis of carcinogenic constituents; and *a*dministrative recommendations including acknowledgment of an FCN, non-acceptance of an FCN, final letter, inventory of effective FCNs, and premarket notification consultations.

II. Paperwork Reduction Act of 1995

This draft guidance contains proposed 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). ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Federal law at 44 U.S.C. 3506(c)(2)(A) requires Federal Agencies to publish a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice of the proposed collection of information in a future issue of the **Federal Register**.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*. Use the FDA Web sites listed in the previous sentence to find the most current version of the guidance.

Dated: December 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29587 Filed 12–8–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification; 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 guidance for industry entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' The guidance addresses provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). The guidance is intended to aid certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product and specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain. The guidance also describes how trading partners should notify FDA of illegitimate product and sets forth a process for terminating notifications of illegitimate product in consultation with FDA. This guidance also includes a new section, for comment purposes only, that describes when manufacturers should notify FDA of a high risk that a product is illegitimate. Aside from that section, this guidance is a final guidance subsequent to the draft guidance that was issued on June 11, 2014.

DATES: You may submit either electronic or written comments on Agency guidances at any time. However, the portion of this guidance that describes when manufacturers should notify FDA if there is a high risk that a product is illegitimate, is being distributed for comment purposes only. To ensure that the Agency considers your comment on this draft section before it begins work on the final version of this section of the guidance, submit either electronic or written comments on this section by February 7, 2017.

ADDRESSES: You may submit comments 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2014–D–0609 for ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification; 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 Division of Dockets Management 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 Division of Dockets Management. 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