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This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*.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

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 *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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg. 4th Floor, Silver Spring, MD 20993–0002; or the 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA 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 FD&C Act, as amended by the DSCSA (Pub. L. 113–54). Section 202 of the DSCSA adds section 582(h)(2) to the FD&C Act (21 U.S.C. 360eee–1(h)(2)), which requires FDA to issue guidance to aid certain trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product and terminating notifications. The guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain, and provides recommendations on how trading partners can identify such product and determine whether the product is a suspect product as soon as practicable.

Beginning January 1, 2015, section 582 of the FD&C Act required trading partners, upon determining that a product in their possession or control is illegitimate, to notify: (1) FDA and (2) all immediate trading partners that they have reason to believe may have received the illegitimate product, not later than 24 hours after making the determination. Manufacturers are additionally required under section 582(b)(4)(B)(ii)(II) of the FD&C Act to notify FDA and any immediate trading partners that the manufacturer has reason to believe may possess a product manufactured by (or purported to be manufactured by) the manufacturer, not later than 24 hours after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that a product is illegitimate. Section III.C of this guidance, entitled ''For Manufacturers: High Risk of Illegitimacy Notification'' and highlighted in grey, describes notifications related to products that pose a high risk of illegitimacy, and is marked ''for comment purposes only'' to provide an opportunity for comment before it is finalized. The guidance also addresses how trading partners should notify FDA using Form FDA 3911. In addition, in accordance with section 582(h)(2) of the FD&C Act, the guidance sets forth the process by which trading partners must terminate the notifications using Form FDA 3911, in consultation with FDA, regarding illegitimate product and, for a manufacturer, a product with a high risk of illegitimacy, under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act.

In the **Federal Register** of June 11, 2014 (79 FR 33564), FDA announced the availability of a draft guidance entitled ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' FDA has carefully considered the comments received and made the following changes in response to the comments: Section C, ''For Manufacturers: High Risk of Illegitimacy Notifications,'' on pgs. 8–11 of the guidance, is a new section added in response to comments and questions received. In addition, FDA made minor changes to the Form FDA 3911 and to the instructions for completing the form.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification.'' It does not establish any rights for any person and, with the exception of section IV.B, 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.

## II. Electronic Access

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

## III. 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 0910–0806.

Dated: December 5, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–29588 Filed 12–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Council on Graduate Medical Education

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

**ACTION:** Notice of charter renewal.

**SUMMARY:** HHS is hereby giving notice that the Council on Graduate Medical Education (COGME) has been renewed. The effective date of the renewed charter is September 30, 2016.

**FOR FURTHER INFORMATION CONTACT:** Dr. Kennita Carter, Senior Advisor and Designated Federal Official, Division of Medicine and Dentistry, HRSA, HHS, 15M116, 5600 Fishers Lane, Rockville, MD 20857. Phone: (301) 945–3505; email: *kcarter@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:** COGME is authorized by section 762 (42 U.S.C. 294o) of the Public Health Service Act,