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 final 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 (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. In addition, this guidance describes when manufacturers should notify FDA of a high risk that a product is illegitimate. This guidance responds to comments from stakeholders in order to clarify certain points and finalizes the remaining draft portion of the final guidance for industry entitled "Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification," issued in December 2016.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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-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 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 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.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 this 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. 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: Sarah Venti, 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. 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.

This guidance finalizes the remaining draft portion of the guidance for industry entitled "Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification," issued in December 2016. In particular, this guidance finalizes section III.C, which was issued for comment purposes in the December 2016 guidance. This guidance will now be final in its entirety and replaces the December 2016 guidance.

In *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." In response to comments received on that guidance, in the Federal Register of December 9, 2016 (81 FR 89112) FDA announced the availability of a guidance of the same title. This guidance was published as a final guidance for industry with the exception of Section C entitled "For Manufacturers: High Risk of Illegitimacy Notifications". This new section was published as a draft guidance for industry and was added in response to comments and questions received about the 2014 guidance. In addition, based on comments on the 2014 guidance, Form FDA 3911, and the instructions for completing the form, were slightly revised.

FDA received comments on the 2016 guidance from various stakeholders (e.g., pharmacy groups, wholesale distributor trade groups). In response to these comments, FDA has made some changes for clarity to the December 2016 version of the guidance. The changes include: clarifying what FDA believes an "immediate trading partner" to be; replacing "suspicious" with "questionable" throughout the document; deleting the reference to "pedigree" in section III.A.1; clarifying that trading partners should consider whether product has been subject to a public alert or announcement of drug quality when considering scenarios that could increase the chances that a suspect product could enter the supply chain; in section III.B, clarifying that FDA's recommendations apply only "as applicable" to the individual trading partners; clarifying that trading partners only work with *authorized* trading partners in section III.B; and stating that trading partners should consult with manufacturers when conducting an investigation of suspect product.

In response to stakeholder comments, FDA has also made some changes to the newly final section, III.C. These include: clarifying that while manufacturers need not notify FDA of suspect product, they must do so if the circumstances surrounding the suspect product include at least one of three types of high risk factors; clarifying that manufacturers can learn of product with a high risk of illegitimacy either through their own investigation of suspect product, or through information they receive from a variety of other sources, including from within their own company, from their trading partners, from the FDA, or from other domestic and/or foreign regulatory authorities; clarifying that a manufacturer must make a notification to FDA where it is investigating the validity of the claim that a product has been stolen or diverted, and the manufacturer has reason to believe that an immediate trading partner has the potentially stolen or diverted product in its possession; and clarifying that while not a requirement, FDA does suggest that manufacturers inform trading partners of "specific high risk[s]".

Finally, while FDA received a few comments on section IV of this guidance, which addresses notifications for illegitimate products and products with a high risk of illegitimacy,

along with termination of those notifications, FDA did not incorporate the feedback from comments on response times because we feel that a 10-day response time is a reasonable amount of time for the Agency to review and evaluate such requests for the termination of notification of illegitimate product. Similarly, FDA did not add language on disclosure because the information submitted to FDA using Form FDA 3911 is treated like all other records obtained by FDA in regard to disclosure. FDA did make some revisions for clarity however, which include adding a brief discussion and footnote to FDA's guidance document *Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act*. In addition, editorial changes were made throughout the entire guidance for clarity and references to section III.C being published for comment purposes only were removed.

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.

As noted, section IV.B of this guidance, which sets forth the process by which trading partners must terminate notifications of illegitimate product and products with a high risk of illegitimacy in consultation with FDA, has binding effect, where indicated by the use of the words *must*, *shall*, or *required*. Such binding effect is authorized by section 582(h)(2)(A) of the FD&C Act, wherein Congress granted authorization to FDA to implement the process for terminating notifications of illegitimate product in consultation with FDA through guidance.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is

not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collection of information in this guidance has been approved under OMB control number 0910-0806.

III. Electronic Access

Persons with access to the internet may obtain the 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 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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