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 This new section was published as a draft guidance for industry and was added in response to comments and questions received about the 2014 guidance.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.

[FR Doc. 2021–11732 Filed 6–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0338]

Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act; 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 revised draft guidance for industry entitled ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act.'' The draft guidance is intended to help industry better understand the definitions of ''suspect'' and ''illegitimate'' product as defined in the Drug Supply Chain Security Act (DSCSA). The draft guidance lays out FDA's current understanding of the following key terms used to define ''suspect'' and ''illegitimate'' product: ''Counterfeit,'' ''diverted,'' ''stolen,'' ''fraudulent transaction,'' and ''unfit for distribution.'' This revised draft guidance clarifies certain points of the draft guidance for industry ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act'' issued in March 2018 (March 2018

draft guidance), including FDA's current understanding of the term ''stolen.''

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 3, 2021.

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–0338 for ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act; 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, 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 revised draft guidance for industry entitled ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act.'' This guidance interprets the terms used in the definition of ''suspect product'' set forth in section 581(21) of Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee(21)), and the definition of ''illegitimate product'' set forth in section 581(8) of the FD&C Act to assist trading partners in meeting verification obligations (including notification) under section 582(b)(4), (c)(4), (d)(4), and (e)(4) (21 U.S.C. 360eee–1 (b)(4), (c)(4), (d)(4), and (e)(4)), respectively.

This draft guidance is intended to help industry better understand the definitions of ''suspect'' and ''illegitimate'' product as defined in section 581 of the FD&C Act. The draft guidance lays out FDA's current understanding of the following key terms used to define ''suspect'' and ''illegitimate'' product in section 581 of FD&C Act: ''Counterfeit,'' ''diverted,'' ''stolen,'' ''fraudulent transaction,'' and ''unfit for distribution.'' In response to comments received from stakeholders, this draft guidance revises the March 2018 draft guidance. Most significantly, this revised draft guidance: (1) Provides for FDA's current understanding of the term ''stolen''; (2) identifies certain scenarios that are unlikely to result in diverted product; (3) revises the definition of ''unfit for distribution'' by tying it more closely to the language in the DSCSA and referencing ''serious adverse health consequences or death to humans''; and (4) revises the definition of ''fraudulent transaction'' to apply to situations where information has been ''knowingly'' falsified.

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 ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act.'' 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.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: May 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11735 Filed 6–3–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3175]

Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers; 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 entitled ''Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers.'' The guidance is intended to address questions regarding product identifiers that, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Drug Supply Chain Security Act (DSCSA), are required to be affixed to, or imprinted on, packages and homogenous cases of certain drug products intended to be introduced in a transaction into commerce. This guidance is intended to clarify FDA's interpretation of these requirements, including as they relate to the linear barcode requirements under the Code of Federal Regulations. This guidance finalizes the draft guidance issued on September 20, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on June 4, 2021.

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–2018–D–3175 for ''Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers.'' 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 the 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 the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tia Harper-Velazquez, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4262, Silver Spring, MD 20993–0002, 301–796–3130.

SUPPLEMENTARY INFORMATION: