Investigations Under 21 CFR part 11—Questions and Answers.'' FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was revised. A summary of changes includes clarifying recommendations for the following: (1) using a risk-based approach for validation of electronic systems used in clinical investigations; (2) preparing for FDA inspections of sponsors and CROs when electronic systems are owned, controlled, or outsourced by the sponsors and CROs for use in clinical investigations; (3) implementing, maintaining, and retaining audit trail information; (4) determining the suitability of information technology (IT) service providers contracted by sponsors or other regulated entities to provide IT services in clinical investigations; and (5) implementing and applying data integrity controls, data security solutions, and electronic source data principles to digital health technology used in clinical investigations. This guidance revises the draft guidance issued in June 2017 and, when finalized, will supersede the guidance for industry entitled ''Computerized Systems Used in Clinical Investigations'' (May 2007).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.'' 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

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 the OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR part 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

## III. Electronic Access

Persons with access to the internet may obtain the draft 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, https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 13, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–05362 Filed 3–15–23; 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; 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 ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act.'' The 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 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.'' The guidance finalizes the draft guidance entitled ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act'' issued on June 4, 2021.

**DATES:** The announcement of the guidance is published in the **Federal Register** on March 16, 2023.

**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–0338 for ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act; 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; or to 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:** 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;* or Diane Maloney, 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 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 the 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 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 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.''

This guidance finalizes the draft guidance entitled ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act'' issued on June 4, 2021 (86 FR 30056). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) clarifying the definition of ''diverted'' by revising the examples clarifying that there are other scenarios besides product dispensed to a patient that could result in diverted product; (2) clarifying FDA's expectations for how trading partners should handle unaccounted for product that is not immediately identified as stolen product; (3) expanding on the definition of ''fraudulent transaction'' to clarify how clerical errors or discrepancies in the product tracing information should be addressed; and (4) clarifying that the definition of ''unfit for distribution'' in this guidance applies only to the verification provisions of the DSCSA and to identifying suspect and illegitimate product. In addition, editorial changes were made to improve clarity.

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 ''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

FDA concludes that this 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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 13, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–05359 Filed 3–15–23; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–0722]**

### Fresenius Kabi USA, LLC, et al.; Withdrawal of Approval of Six Abbreviated New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.