



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 This guidance finalizes the draft guidance issued on September 20, 2018.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 [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-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:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers." The DSCSA (Title II of Pub. L. 113-54) was signed into law on November 27, 2013. Section 202 of the DSCSA, which added sections 581 and 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee and 360eee-1), set forth new definitions and requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of product through the pharmaceutical distribution supply chain.

A product identifier is defined under section 581(14) of the FD&C Act as a standardized graphic that includes the product's standardized numerical identifier (composed of the National Drug Code and a unique alphanumeric serial number), lot number, and expiration date, in both human- and machine-readable formats. Under sections 582(b)(2)(A) and 582(e)(2) of the FD&C Act, respectively, manufacturers and repackagers are required to "affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce."

In the *Federal Register* of September 20, 2018 (83 FR 47626), FDA announced the availability of the draft guidance of the same title dated September 20, 2018. FDA received several comments on the draft guidance and considered those comments as we finalized the guidance. Among the key substantive changes, we revised the recommendations regarding the expiration date format--specifically, we no longer recommend using a space between the day, month, and year; we now recommend using a hyphen or forward slash between the expiration date elements. In addition, we also modified our statements regarding use of the human-readable

GS1 Global Trade Identification Number to explain the importance of the three segment NDC format for patient safety. We also clarified how to affix or imprint multiple barcodes on the label with sufficient space to avoid confusion in reading or scanning. We made additional, editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 20, 2018.

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 "Product Identifiers Under the Supply Chain Security Act: 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

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 either <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.

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