



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-4615]

Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format; 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 "Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format." This guidance is intended to assist holders of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) with their submission of required marketing status notifications. This guidance finalizes the draft guidance of the same title issued on January 31, 2019.

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-4615 for "Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format." 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.

- 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.gpo.gov/fdsys/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.

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 multi-center guidances, add appropriate addresses. No more than four addresses in this section per 1998 Document Drafting Handbook.]

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930, elizabeth.giaquinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled " Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format." This guidance is intended to assist holders of NDAs and ANDAs approved under the FD&C Act with their submission of required marketing status notifications. The FDA Reauthorization Act of 2017 (Pub. L. 115-52) (FDARA) added section 506I to the FD&C Act (21 U.S.C. 356i), which imposes additional reporting requirements on NDA and ANDA holders regarding the marketing status of approved drug products. This guidance identifies the required content for these marketing status notifications and the format by which these notifications should be submitted to the Agency.

This guidance finalizes the draft guidance entitled Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format issued on January 31, 2019 (84 FR 749). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance were made to address requests for clarity in complying with the reporting requirements of section 506I of the FD&C Act.

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 "Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format." 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 regulations require NDA and ANDA holders to notify the Agency of the marketing status of drug products approved under NDAs and ANDAs. FDARA added section 506I to the FD&C Act, which imposes marketing status reporting requirements for notification of withdrawal from sale; notification of drugs not available for sale, and reports on marketing status. This guidance contains no collection 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. However, this guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information have been approved under OMB control numbers 0910-0001 and 0910-0759.

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> or

<https://www.regulations.gov>.

Dated: August 4, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-17463 Filed: 8/10/2020 8:45 am; Publication Date: 8/11/2020]