4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-0065]

Competitive Generic Therapies; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Competitive Generic Therapies." On August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), was signed into law. Under FDARA, a section was added to the FD&C Act that established a new process to designate, and expedite the development and review of, certain drugs intended for submission or submitted in an abbreviated new drug application (ANDA) and for which there is "inadequate generic competition." This draft guidance provides a description of the process that applicants should follow to request designation of a drug as a competitive generic therapy (CGT) and the criteria for designating a drug as a CGT. This draft guidance also includes information on the actions FDA may take to expedite the development and review of an ANDA for a drug designated as a CGT. This draft guidance also provides information on how FDA implements the statutory provisions providing for a 180-day exclusivity period for certain first approved applicants that submit ANDAs for drugs designated as CGTs.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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-2019-D-0065 for "Competitive Generic Therapies." 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 the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993-0002, 240-402-7936.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Competitive Generic Therapies." On August 18, 2017, FDARA (Pub. L. 115-52) was signed into law. As part of FDARA, the Generic Drug User Fee Amendments were reauthorized (Title III) to continue timely access to high-quality affordable generic medicines. FDARA also created other enhancements associated with generic drugs. Specifically, section 803 of FDARA amended the FD&C Act to add section 506H (21 U.S.C. 356h), which established a new process to designate, and expedite the development and review of, certain drugs intended for submission or submitted in an ANDA and for which there is "inadequate generic competition."

FDA recognizes that various factors may influence a generic drug applicant's decision to develop a certain drug. For instance, some drugs may not attract a high level of interest from generic drug applicants if there is a limited market for the products and/or if the products are more difficult to develop. Nevertheless, these drugs can play an important role in diagnosing, treating, and preventing various types of diseases or conditions, and incentivizing generic competition for these products can help ensure patients have access to the medicines they need. The provisions associated with CGTs are intended to incentivize effective development, efficient review, and timely market entry for drugs for which there is inadequate generic competition.

This guidance provides a description of the process that applicants should follow to request designation of a drug as a CGT and the criteria for designating a drug as a CGT. This guidance also includes information on the actions FDA may take to expedite the development and review of ANDAs for drugs designated as CGT. These actions may help to clarify the regulatory expectations for a particular drug, assist applicants in developing a more complete submission, and ultimately promote a more efficient and effective ANDA review process and help reduce the number of review cycles necessary to obtain ANDA approval.

This guidance also provides information on how FDA implements the statutory provisions providing for a 180-day exclusivity period for certain first approved applicants that submit ANDAs for CGTs. FDARA created a new type of 180-day exclusivity, different from 180-day patent challenge exclusivity, for the first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book at the time of original submission of the ANDA. This new 180-exclusivity under FDARA ("CGT exclusivity") is intended to incentivize competition for drugs that are not protected by patent or exclusivity and for which there is inadequate generic competition.

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 "Competitive Generic Therapies." 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 314.94, including the submission of ANDAs and designations such as CGT product development, have been approved under OMB control number 0910-0001 (including 0910-0338 for Form FDA 356h). The collections of information associated with product development meetings, presubmission meetings, and mid-review cycle meetings between applicants and FDA have been approved under OMB control number 0910-0797.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: February 12, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-02598 Filed: 2/15/2019 8:45 am; Publication Date: 2/19/2019]