4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1292]

Abbreviated New Drug Application Submissions--Refuse to Receive for Lack of Justification of Impurity Limits; 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 guidance for industry entitled "Abbreviated New Drug Application Submissions--Refuse to Receive for Lack of Justification of Impurity Limits." This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs) and prior approval supplements for which the applicant is seeking approval of a new strength of the drug product. The guidance highlights deficiencies about impurity information that may cause FDA to refuse to receive (RTR) an ANDA.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2014-D-1292 for "Abbreviated New Drug Application Submissions--Refuse to Receive for Lack of Justification of Impurity Limits." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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: 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Abbreviated New Drug Application Submissions--Refuse to Receive for Lack of Justification of Impurity Limits." This guidance is intended to assist applicants preparing to submit to FDA ANDAs and prior approval supplements to ANDAs for which the applicant is seeking approval of a new strength of the drug product. The guidance highlights serious deficiencies in impurity information that may cause FDA to RTR an ANDA. Specifically, these deficiencies include: (1) Failing to provide justification for proposed limits for specified identified impurities in drug substances and drug products that are above qualification thresholds; (2) failing to provide justification for specified unidentified impurities that are above identification thresholds; and (3) proposing limits for unspecified impurities (e.g., any unknown impurity) that are above identification thresholds.

FDA evaluates each submitted ANDA individually to determine whether it is sufficiently complete to permit a substantive review and thus can be received by FDA. The Agency cannot receive an ANDA unless it contains the information required under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) and related regulations (e.g., 21 CFR 314.101(b)(1)). FDA issued the guidance for industry "Abbreviated New Drug Application Submissions--Refuse-to-Receive Standards" to explain in some detail the kind of omissions that can lead to a RTR determination. A draft of this guidance was published on September 17, 2014, with the title "ANDA Submissions--Refuse to Receive for Lack of Proper Justification of Impurity Limits." Upon review of the comments submitted to the draft guidance, FDA removed the word "proper" from the title to emphasize that this guidance does not apply to the technical review of impurity limit justifications submitted in an ANDA.

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 "Abbreviated New Drug Application Submissions--Refuse to Receive for Lack of Justification of Impurity Limits." 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. Electronic Access

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

Dated: August 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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