DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1120]

Guidance for Industry on Abbreviated New Drug Application Submissions—Refuse-to-Receive Standards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''ANDA Submissions—Refuse-to-Receive Standards.'' It finalizes the draft guidance with the same name that published on October 1, 2013. This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs) and related submissions (i.e., prior approval supplements for new strengths). The guidance represents the FDA's current thinking regarding the types of serious deficiencies that may cause FDA to refuse-to-receive the submission.

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

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benjamin Chacko, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1673, Silver Spring, MD 20993–0002, 240–402–7924.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''ANDA Submissions—Refuse-to-Receive Standards.'' 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 deficiencies that may cause FDA to refuse-to-receive an ANDA. A refuse-to-receive decision indicates that FDA determined that an ANDA is not sufficiently complete to permit a substantive review.

Under the provisions of the Generic Drug User Fee Amendments of 2012, the Office of Generic Drugs (OGD) is tasked with a number of activities, including the development of ''enhanced refusal to receive standards for ANDAs and other related submissions by the end of year 1 of the program. . . .'' Recent data underscore the need for improvement in the quality of original ANDA submissions. Between 2009 and 2012, OGD refused to receive 497 ANDAs, primarily because the submissions contained serious deficiencies. FDA evaluates each incoming ANDA individually to determine whether its format and content meet threshold standards 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)). This guidance explains in some detail the kind of omissions that can lead to a refuse-to-receive determination. The guidance is intended to assist applicants preparing ANDAs and related submissions to help improve the quality of those submissions and ensure that their format and content are sufficiently complete to permit a substantive review.

This guidance finalizes the draft guidance published in the **Federal Register** on October 1, 2013 (78 FR 60292). Comments on the draft guidance were considered while finalizing this guidance. Specifically, certain changes from the draft guidance include clarifying the definitions of ''major'' and ''minor'' deficiencies, clarifying the remedy process and period for minor deficiencies, and providing a non-exhaustive list of minor deficiencies. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''ANDA Submissions—Refuse-to-Receive Standards.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This 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 collection of information in 21 CFR part 314 for ANDA and related submissions has been approved under OMB control number 0910–0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

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

Dated: September 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22068 Filed 9–16–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1292]

Draft Guidance for Industry on Abbreviated New Drug Application Submissions—Refuse To Receive for Lack of Proper Justification of Impurity Limits; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDA Submissions—Refuse to Receive for Lack of Proper Justification of Impurity Limits.'' This draft guidance is intended to assist applicants preparing to submit

to FDA abbreviated new drug applications (ANDAs) and related submissions (i.e., prior approval supplements) for which the applicant is seeking approval of a new strength of the drug product. The draft guidance highlights deficiencies about impurity information that may cause FDA to refuse to receive an ANDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 17, 2014.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, 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 draft guidance for industry entitled ''ANDA Submissions—Refuse to Receive Lack of Proper Justification of Impurity Limits.'' This draft 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 draft guidance highlights serious deficiencies in impurity information that may cause FDA to refuse to receive an ANDA. Specifically, these deficiencies include: (1) Failing to justify proposed limits for specified identified impurities in drug substances and drug products that are above qualification thresholds; (2) failing to justify proposed limits for specified unidentified impurities that are above identification thresholds; and (3) proposing limits for unspecified impurities (e.g., any unknown impurity) above identification thresholds.

Under the provisions of the Generic Drug User Fee Amendments of 2012, the Office of Generic Drugs (OGD) is tasked with a number of activities, including the development of ''enhanced refusal to receive standards for ANDAs and other related submissions by the end of year 1 of the program. . . .'' Recent data underscore the need for improvement in the quality of original ANDA submissions. Between 2009 and 2012, OGD refused to receive 497 ANDAs, primarily because the submissions contained serious deficiencies. FDA evaluates each incoming ANDA individually to determine whether its format and content meet threshold criteria 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 draft guidance for industry ''ANDA Submissions—Refuse-to-Receive Standards'' to explain in some detail the kind of omissions that can lead to a refuse-to-receive determination. This guidance is being issued concurrently with the final version of the guidance for industry, ''ANDA Submissions—Refuse to Receive Standards.'' FDA intends to develop additional guidance documents further clarifying the enhanced refusal to receive standards.

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 Agency's current thinking on ''ANDA Submissions—Refuse to Receive for Lack of Proper Justification for Impurity Limits.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 have been approved under 0910–0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

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

Dated: September 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 30, 2014, from 8 a.m. to 5:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White