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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0221]

Draft Guidance for Industry and Review Staff on Formal Dispute Resolution: Appeals Above the Division Level; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and review staff entitled "Formal Dispute Resolution: Appeals Above the Division Level." This guidance is intended to provide recommendations for industry on the procedures in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for resolving scientific and procedural disputes that cannot be resolved at the division level. This guidance describes procedures for formally appealing such disputes to the office or center level and providing information to assist FDA officials in resolving the issue(s) presented. This guidance revises the guidance of the same name issued in February 2000.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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301-796-0700; or,

Sheryl Lard-Whiteford,

Center for Biologics Evaluation and Research (HFM-4),

Food and Drug Administration,

1401 Rockville Pike,

Rockville, MD 20852-1448,

301-827-0379.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled "Formal Dispute Resolution: Appeals Above the Division Level." In the course of drug review, CDER and CBER make a wide variety of scientific and procedural decisions that are critical to a sponsor's drug development program. Sometimes, a sponsor may disagree with one of these decisions, and a dispute arises. Because these disputes often involve complex scientific or procedural matters and also may be precedent setting, it is critical that there be procedures in place to encourage open, prompt discussion of such disputes. The procedures and policies described in this guidance are intended to promote rapid resolution of scientific and procedural disputes between sponsors and FDA. This draft guidance is a revision of the guidance of the same name that published in February 2000. The procedures and policies have been updated to reflect the current practices.

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 formal dispute resolution regarding appeals above the division level. 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. The 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 this draft guidance have been approved under OMB control number 0910-0430. This draft guidance is a revision of an earlier version of the guidance. The revised version contains no additional information collections; therefore, it continues to be covered under OMB control number 0910-0430.

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 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: March 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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