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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Formal Dispute Resolution: Appeals Above the Division Level; Revised Draft Guidance for Industry and Review Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry and review staff entitled "Formal Dispute Resolution: Appeals Above the Division Level."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 and review staff on the procedures in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) for resolving scientific and/or medical 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 This draft guidance revises the draft guidance of the same name issued March 13, 2013.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the

draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the revised draft guidance to http://www.regulations.gov.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: Khushboo Sharma, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6468, Silver Spring, MD 20993-0002, 301-796-0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry and review staff entitled "Formal Dispute Resolution: Appeals Above the Division Level." In the course of the review of applications for user fee products, a wide variety of scientific and/or medical issues

are discussed that are critical to a sponsor's drug product development program. Sometimes, a sponsor may disagree with the Agency on a matter, and a dispute arises. Because these disputes often involve complex scientific and/or medical matters, it is critical that there be procedures in place to help ensure open, prompt discussion of such disputes. The procedures and policies described in this guidance are intended to promote rapid resolution of scientific and/or medical disputes between sponsors and CDER or CBER.

This draft guidance revises the draft guidance of the same name issued March 13, 2013 (78 FR 15955). Based on the docket comments for the draft guidance as well as on its own initiative, FDA made the following changes. The scope of the guidance was expanded to include formal dispute resolution requests for human drug applications covered under the Biosimilar User Fee Act of 2012. Additionally, certain areas were revised to provide more clarity, such as when a matter is and is not appropriate for a formal dispute resolution request, and information to include in the supporting background information. Also, this guidance clarifies that CDER and CBER intend to manage formal requests for appeals of scientific and/or medical disputes related to an application for a user fee product under any of the available regulatory mechanisms (i.e., 21 CFR 10.75, 312.48(c), 314.103(c)), through the formal dispute resolution process.

This revised 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 formal dispute resolution requests for appeals above the division level. 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. The Paperwork Reduction Act of 1995

This revised 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 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: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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