4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Draft Guidance for Industry on Bioequivalence Recommendations for Mesalamine Rectal Suppositories; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Bioequivalence Recommendations for Mesalamine." The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for mesalamine rectal suppositories. The draft guidance is a revised version of a previously issued draft guidance on the same subject.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. 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SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Kris Andre, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of a draft guidance on mesalamine (Draft Mesalamine Rectal Suppository BE Recommendations of 2013).

CANASA (Mesalamine, USP) Rectal Suppositories, new drug application 021252, 500 milligram (mg) and 1,000 mg strengths were approved by FDA in January 2001 and November

2004, respectively. The 500 mg strength is no longer marketed. There are no approved ANDAs for this product.

In May 2007, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for mesalamine rectal suppositories (Draft Mesalamine Rectal Suppository BE Recommendations of May 2007). In that draft guidance, FDA recommended in vivo studies to demonstrate BE of generic mesalamine rectal suppositories: A BE study with clinical endpoints and a fasting BE study with pharmacokinetic endpoints. FDA has reconsidered the recommendations in the Draft Mesalamine Rectal Suppository BE Recommendations of May 2007 and has decided to revise it. In March 2013, FDA withdrew the Draft Mesalamine Rectal Suppository BE Recommendations of May 2007 and posted on its Web site a revised draft guidance for industry, the Draft Mesalamine Rectal Suppository BE Recommendations of 2013. In this revised draft guidance, FDA recommends in vivo and in vitro studies to demonstrate BE of generic mesalamine rectal suppositories: a fasting BE study with pharmacokinetic endpoints and comparative in vitro studies (melting point, differential scanning calorimetry, density, and viscosity). FDA is no longer recommending a BE study with clinical endpoints for demonstration of BE of generic mesalamine rectal suppositories.

In July 2007, Axcan Scandipharm (Axcan), manufacturer of CANASA, submitted a citizen petition requesting that FDA withhold approval of any ANDA application for a generic version of CANASA (mesalamine rectal suppositories) unless certain studies that demonstrated BE were conducted (Docket No. FDA-2007-P-0010, formerly 2007P-0302/CP1). FDA is reviewing the issues raised in the petition and is also reviewing the supplemental information submitted to the docket for this petition. FDA will consider any comments on the Draft

Mesalamine Rectal Suppository BE Recommendations of 2013 before responding to Axcan's citizen petition.

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 the design of BE studies to support ANDAs for mesalamine rectal suppositories. 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. 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: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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