4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-D-0282] (formerly 2005D-0183)

Draft Guidance for Industry on Attachment to Guidance on Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting Hepatitis C Virus Resistance Data; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Attachment to Guidance on Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HCV Resistance Data." The purpose of this attachment is to assist sponsors in submitting hepatitis C virus (HCV) clinical virology data, which are important for supporting clinical trials of products in development for the treatment of HCV. HCV resistance data submitted in appropriately formatted datasets is a critical component in the review of investigational antiviral products for the treatment of HCV. The information in this attachment will facilitate the development and regulatory review of anti-HCV products.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Attachment to Guidance on Antiviral Product Development--Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HCV Resistance Data." The purpose of this attachment is

to assist sponsors in submitting HCV clinical virology data, which are important for supporting clinical trials of products in development for the treatment of HCV. This attachment revises and replaces the attachment on submitting HCV resistance data published in June 2006 and represents FDA's current thinking regarding how sponsors should submit HCV resistance data. The revised attachment provides the format, recommended definitions, standardization of column headings and variables, and recommended data for submission of HCV resistance datasets.

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 submitting HCV clinical virology data. 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 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 21 CFR part 312 have been approved under OMB control number 0910-0014.

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: February 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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