4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0589]

Draft Guidance for Industry on Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment." The purpose of this guidance is to assist sponsors in all phases of development of antiretroviral drugs for the treatment of HIV. This draft guidance revises the guidance for industry entitled "Antiretroviral Drugs Using Plasma HIV RNA Measurements--Clinical Considerations for Accelerated and Traditional Approval" issued in October 2002.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6370, Silver Spring, MD 20993-0002, 301-796-1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment." This guidance revises the guidance for industry entitled "Antiretroviral Drugs Using Plasma HIV-RNA Measurements--Clinical Considerations for Accelerated and Traditional Approval" issued in October 2002. Significant changes from the 2002 version include: (1) More details on nonclinical development of antiretroviral drugs; (2) a greater emphasis on recommended trial designs for HIV-1 infected heavily treatment-experienced patients (those with multiple-drug, resistant virus and few remaining therapeutic options); (3) use of a primary endpoint evaluating early virologic changes for studies in heavily treatment-experienced patients; and (4) use of the traditional approval pathway for initial approval of all antiretrovirals with primary analysis time points dependent on the indication sought instead of an accelerated approval pathway followed by traditional approval. Longer term trials may be appropriate for patients who are treatment-

naïve or have limited prior experience, whereas shorter term trials may be appropriate for patients with limited treatment options.

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 developing antiretroviral drugs for the treatment of HIV-1 infection. 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 guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget 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 0910-0014, the collections of information in 21 CFR part 314 have been approved under 0910-0001, and the collections of information referred to in the guidance for industry entitled "Establishment and Operation of Clinical Trial Data Monitoring Committees" have been approved under 0910-0581.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. 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: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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