4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0973]

Complicated Intra-Abdominal Infections: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Complicated Intra-Abdominal Infections: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of complicated intra-abdominal infections (cIAIs). Specifically, this guidance addresses FDA's current thinking regarding the overall drug development program for the treatment of cIAIs, including clinical trial designs to support approval of drugs. This guidance finalizes the draft guidance of the same name issued October 1, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the 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: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Complicated Intra-Abdominal Infections: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of cIAIs.

Intra-abdominal infections including cIAIs are common in clinical practice and comprise a wide variety of clinical presentations and differing sources of infection. Different bacterial pathogens are responsible for cIAI, including Gram-negative aerobic bacteria, Gram-positive bacteria, and anaerobic bacteria, including mixed infections. This guidance describes the efficacy endpoint of clinical success as resolution of the baseline signs and symptoms attributable to cIAI. The guidance provides a scientific justification for a noninferiority margin.

This guidance finalizes the draft guidance of the same name issued October 1, 2012. After consideration of comments received in response to the draft guidance, FDA updated the guidance to include clarifications about the primary efficacy endpoint and the use of prior nontrial antibacterial drugs. In addition, issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804 of the Food and Drug Safety and Innovation Act of 2012

(Public Law 112-144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. 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 (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

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 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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