4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Complicated Intra-Abdominal Infections: Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Complicated Intra-Abdominal Infections: Developing Drugs for Treatment."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.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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FDA is announcing the availability of a draft guidance for industry entitled "Complicated Intra-Abdominal Infections: Developing Drugs for Treatment." The purpose of this draft guidance is to assist sponsors and investigators in the development of drugs for the treatment of cIAIs.

Intra-abdominal infections are common in clinical practice and comprise a wide variety of clinical presentations and differing sources of infection. The infections can be diffuse across the entire peritoneal cavity or retroperitoneal spaces, or can be localized with one or more

abscesses surrounding diseased or perforated viscera. A wide variety of bacterial pathogens are responsible for cIAIs, including Gram-negative aerobic bacteria, Gram-positive bacteria, and anaerobic bacteria, and there are also mixed infections.

This draft guidance includes recommendations for an efficacy endpoint and a non-inferiority trial design. The efficacy endpoint of clinical success represents the desired outcome of an antibacterial treatment of a cIAI and has been used in previously conducted trials of treatment for cIAI. Clinical success is defined as the complete resolution of the baseline signs and symptoms attributable to cIAI at a fixed time point approximately 28 days following randomization. The draft guidance provides scientific support for a noninferiority margin based on the results of previously conducted clinical trials with various effective antibiotics. The draft guidance also provides a discussion about patients with unmet need who have an infection caused by bacterial pathogens that show resistance to most antibacterial drugs on in vitro susceptibility testing.

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 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 an 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, and the

collections of information referred to in the guidance for clinical trial sponsors "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: September 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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