4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1181]

Guidance for Industry on Acute Bacterial Skin and Skin Structure 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 guidance for industry entitled "Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the development of new antibacterial drugs to treat acute bacterial skin and skin structure infections (ABSSSI). This guidance finalizes the revised draft guidance of the same name issued on August 27, 2010.

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, 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 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 "Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of ABSSSI.

This guidance describes approaches for entry criteria and trial designs for the evaluation of new drugs for the treatment of ABSSSI. The guidance focuses on the noninferiority trial design and describes an endpoint for which there is a well-defined treatment effect. The guidance also provides the justification for the noninferiority margin. After careful consideration of comments received in response to the draft guidance issued on August 27, 2010, important clarifications about trial populations, designs, and endpoints for ABSSSI were included in this guidance. In addition, this guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of ABSSSI.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), which requires FDA to ". . . review and, as appropriate, revise not fewer than 3 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). This 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: October 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-24787 Filed 10/22/2013 at 8:45 am; Publication Date: 10/23/2013]