

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0395]

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Certifier J. Hawkins

Draft Guidance for Industry on Acute Bacterial Sinusitis: Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Acute Bacterial Sinusitis: Developing Drugs for Treatment." The purpose of this guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drug products for the treatment of acute bacterial sinusitis (ABS). The agency's thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of our current thinking in this area. In addition, it will fulfill a statutory requirement to publish such a guidance enacted in the Food and Drug Administration Amendments Act of 2007 (FDAAA).

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD

20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Steve Gitterman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6134, Silver Spring, MD 20993-0002, 301-796-1600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Acute Bacterial Sinusitis: Developing Drugs for Treatment." The purpose of this guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drug products for the treatment of ABS. This guidance revises the draft guidance regarding ABS published in 1998. Section 911 of the FDAAA (Public Law 110-85) adds section 511 to the Federal Food, Drug, and Cosmetic Act that directs the Secretary for Health and Human Services to "issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis." This guidance will fulfill this statutory requirement.

The design of clinical trials for ABS was the subject of an Anti-Infective Drug Products Advisory Committee meeting on October 28, 2003. In addition, other advisory committee meetings have focused on the development of

specific drug products for this indication. As a result of these public discussions, as well as review of pending applications at FDA, the agency's thinking in this area has evolved in recent years, and this guidance informs sponsors of the changes in our recommendations. Specifically, this guidance recommends that ABS clinical trials be designed as superiority rather than noninferiority trials, and discusses some possible study designs that might be employed in an ABS trial designed to show superiority. This guidance also recommends that microbiological information be obtained in at least one of the controlled studies. This guidance discusses patient-reported outcome instruments for assessing clinical response, and the use of time to resolution as a possible approach to assessing the primary endpoint. As required by FDAAA, this guidance also addresses the use of animal models and surrogate markers in the development of drugs for the treatment of ABS.

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 drugs for the treatment of acute bacterial sinusitis. 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.

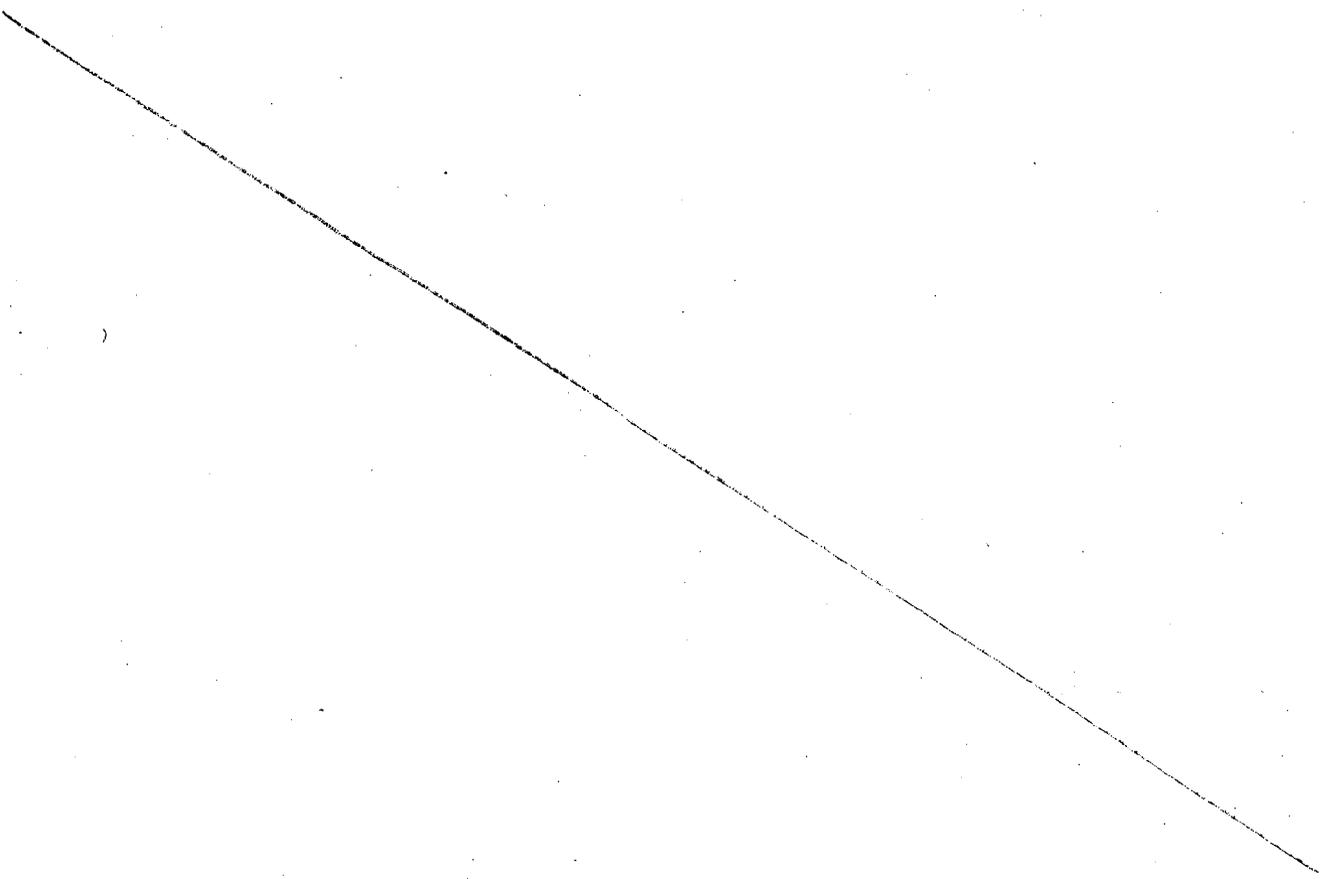
II. The Paperwork Reduction Act of 1995

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 part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have

been approved under OMB control number 0910-0001; and the collections of information referred to in the guidance entitled "Establishment and Operation of Clinical Trial Data Monitoring Committees" have been approved under OMB control number 0910-0581.

III. Comments

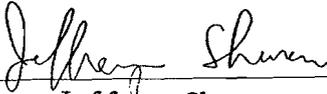
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.



IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: OCT 24 2007
October 24, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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