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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. FDA-2008-D-0419]

Draft Guidance for Industry on Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.” The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of acute bacterial exacerbations of chronic bronchitis in patients with chronic obstructive pulmonary disease (ABECB-COPD). The agency’s thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of the changes in our recommendations. In addition, it will fulfill a statutory requirement enacted in the Food and Drug Administration Amendments Act of 2007 (FDAAA) to publish such a guidance.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit

written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Steven 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 Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.” The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of ABECB–COPD. This guidance revises the draft guidance regarding ABECB published in 1998. Section 911 of FDAAA (Public Law 110–85) adds section 511 to the Federal Food, Drug, and Cosmetic Act that directs the

Secretary of Health and Human Services to “issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat * * * acute bacterial exacerbation of chronic bronchitis.”

The design of ABECB clinical trials was discussed at a meeting of the Anti-Infective Drugs Advisory Committee on February 19, 2002, and an IDSA/PhRMA/FDA workshop on November 19 and 20, 2002. In addition, other advisory committee meetings have focused on the development of specific drugs for this indication. As a result of these public discussions, as well as review of applications at FDA, the agency’s thinking in this area has evolved in recent years, and this draft guidance informs sponsors of the changes in our recommendations. Specifically, this draft guidance recommends that ABECB–COPD clinical trials be designed as superiority rather than noninferiority trials, and discusses some possible study designs that might be employed in an ABECB–COPD trial designed to show superiority. This draft guidance discusses patient-reported outcome instruments for assessing clinical response, and the use of time to resolution of symptoms as a possible approach to assessing the primary endpoint in clinical studies.

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 ABECB–COPD. 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 draft 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 “Establishment and Operation of Clinical Trial Data Monitoring Committees” have been approved under OMB control number 0910–0581.

III. Comments

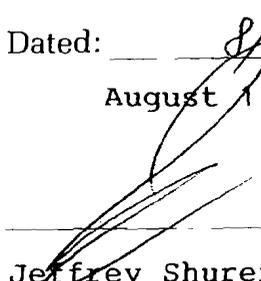
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

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.regulations.gov>.

Dated: 8/13/08
August 13, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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