DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0589]

Draft Guidance for Industry on Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment." The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP). The science of clinical trial design and our understanding of these diseases have advanced in recent years, and this draft guidance, when finalized, will inform sponsors of the recommendations for clinical development.

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on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 28, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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: 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FDA is announcing the availability of a draft guidance for industry entitled "Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment."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 HABP and VABP. This guidance revises and replaces the draft guidance regarding nosocomial pneumonia published in 1998. The guidance also addresses the clinical development of new drugs to treat drug-resistant bacterial pathogens implicated in HABP/VABP.

The issues in HABP/VABP clinical trials were discussed at a 2009 workshop co-sponsored by FDA and professional societies. The science of clinical trial design and our understanding of these diseases have advanced in recent years, and this draft guidance informs sponsors of the changes in our recommendations. Specifically, the guidance defines a primary efficacy endpoint of all-cause mortality and provides a justification for a noninferiority margin for the design of active-controlled clinical trials that can be used to provide evidence of efficacy for the treatment of HABP/VABP.

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 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 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 0910–0014, the collections of information in 21 CFR part 314 have been approved under 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 0910–0581.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

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: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29799 Filed 11–26–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0590]

Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling." FDA is issuing this guidance with labeling recommendations because of concerns that both healthcare providers and patients may be unaware of the serious adverse health risks associated with using the same blood lancet device for assisted withdrawal of blood from more than one patient, even when the lancet blade is changed for each blood draw. FDA recommends that all blood lancet devices be labeled for use only on a single patient. A statement limiting use to a single patient should also appear on the label attached to the device, if possible. The guidance document is immediately in effect, but it remains subject to comment in