

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Draft Guidance for Industry on Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment; Availability**AGENCY:**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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment." The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of hospital-acquired bacterial pneumonia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 The science of clinical trial design and our understanding of these diseases have advanced in recent years, and this draft guidance, when finalized, will inform sponsors of the recommendations for clinical development.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on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 28, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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FDA is announcing the availability of a draft guidance for industry entitled "Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment."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

accordance with the Agency's good guidance practices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Shelia Murphey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2510, Silver Spring, MD 20993-0002, 301-796-6302.

SUPPLEMENTARY INFORMATION:

I. Background

On August 26, 2010, the FDA and Centers for Disease Control and Prevention (CDC) issued a joint Initial Communications warning that the use of fingerstick devices (blood lancets) to obtain blood from more than one patient poses a risk of transmitting bloodborne pathogens. The Agencies recommended that blood lancet devices should never be used to obtain blood samples from more than one person.

CDC has noted a progressive increase in reports of bloodborne pathogen transmission (primarily hepatitis B) resulting from the use of a blood lancet in multiple patients in various healthcare provision settings. These settings include acute care hospitals, long term care facilities and assisted living facilities as well as non-residential care settings.

Blood lancet devices may be unsafe when used to draw blood from more than one patient for several reasons. Improper device design, device malfunction, or user error may leave the

blood from one patient on the reusable lancet device base and in a position to contaminate a new lancet blade.

Healthcare users of blood lancets may have difficulty ensuring that all blood contamination has been successfully removed from a reusable lancet base device. The cleaning and disinfection instructions provided with reusable lancet devices may not be adequately validated for efficacy or followed in their entirety. 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.

FDA is making this guidance document immediately available because prior public participation is not appropriate. Due to the urgent public health need to support the joint Initial Communications issued by CDC and FDA concerning the risk of hepatitis transmission caused by the use of blood lancets on more than one patient, FDA believes that current lancet labeling which does not restrict the use of lancets to a single patient must be corrected as quickly as possible. FDA believes that this guidance will provide significant assistance to lancet manufacturers as they work to improve their labeling as recommended.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on blood lancet labeling. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1732 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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 collection of information in this guidance was approved under OMB control number 0910-0485.

V. 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.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0584]

Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Products; 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 "ANDAs: Impurities in Drug Products." This guidance updates recommendations regarding degradation products and updates the draft guidance "ANDAs: Impurities in Drug Products" announced in December 1998 in conformance with the revision of the International Conference on Harmonisation (ICH) guidance for industry "Q3B(R) Impurities in New Drug Products," which was announced in August 2006.

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