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.

[FR Doc. 2010–29795 Filed 11–26–10; 8:45 am]

BILLING CODE 4160–01–P

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

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: Devinder Gill, Center for Drug Evaluation and Research (HFD–630), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8483.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "ANDAs: Impurities in Drug Products." In December 1998, FDA issued the draft guidance "ANDAs: Impurities in Drug Products," and in August 2005, FDA revised it in conformance with the "Q3B(R) Impurities in New Drug Products" guidance for industry that was announced in August 2006.

We are issuing the final guidance to: (1) Update information on listing of degradation products, setting acceptance criteria, and qualifying degradation products (thresholds and procedures) in abbreviated new drug applications (ANDAs) in conformance with the revision of the guidance for industry on Q3B(R) and (2) remove those sections of the 1998 draft guidance containing recommendations that are no longer needed because they are addressed in the more recent Q3B(R). The Q3B(R) was developed by the ICH to provide guidance on impurities in drug products for new drug applications (NDAs). However, the Agency believes that many of the recommendations provided on impurities in NDAs also apply to ANDAs.

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 impurities in drug products submitted as ANDAs. 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. 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.

III. 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. 2010–29896 Filed 11–26–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0150; Formerly Docket No. 2007D–0367]

Guidance for Industry on Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval; 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 "Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval." The purpose of this guidance is to provide information on FDA's current thinking regarding appropriate use of noninferiority (NI) clinical trial designs to evaluate antibacterial drug products. The Agency's thinking in this area has evolved in recent years in response to a number of public discussions on the use of active-controlled trials designed to show NI as the basis for approval of antibacterial drug products. This guidance finalizes the draft guidance published in the **Federal Register** of October 15, 2007.

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 "Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval." The purpose of this guidance is to inform industry, sponsors, applicants, researchers, and the public on the appropriate uses of NI clinical trial designs to evaluate antibacterial drug products and to amend ongoing or completed trials accordingly. In the **Federal Register** of October 15, 2007 (72 FR 58312), FDA announced a notice of availability of the draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval" in response to numerous public discussions that focused primarily on the following indications: Acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and acute bacterial otitis media. Since FDA issued the draft guidance, there have been public discussions on consistent and reliable estimates of the efficacy of active treatment to placebo for other infectious disease indications for the NI trial design. The public comments received on the draft guidance have been considered and the guidance has been revised as appropriate. The guidance emphasizes that adequate scientific evidence should be provided to support the proposed NI margin for any indication being studied in any proposed, ongoing, or completed active-controlled trial designed to show NI.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).