malfunction, or user error may leave the
Improper device design, device
settings include acute care hospitals,
in reports of bloodborne pathogen
more than one person.
be used to obtain blood samples from
that blood lancet devices should never
pathogens. The Agencies recommended
obtain blood from more than one 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
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 dsnicar@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
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
titled “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.


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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


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. Toomer, 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.

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).