

observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In June 2013, the ICH Steering Committee agreed that a draft guidance entitled “Elemental Impurities” should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q3D Expert Working Group.

The draft guidance provides guidance on control of elemental impurities and expectations for test requirements for regulatory filings.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on this topic.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. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: October 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–24786 Filed 10–22–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1181]

Guidance for Industry on Acute Bacterial Skin and Skin Structure Infections: 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 guidance for industry entitled “Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the development of new antibacterial drugs to treat acute bacterial skin and skin structure infections (ABSSSI). This guidance finalizes the revised draft guidance of the same name issued on August 27, 2010.

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 “Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of ABSSSI.

This guidance describes approaches for entry criteria and trial designs for the evaluation of new drugs for the treatment of ABSSSI. The guidance focuses on the noninferiority trial design and describes an endpoint for which there is a well-defined treatment effect. The guidance also provides the justification for the noninferiority margin. After careful consideration of comments received in response to the draft guidance issued on August 27, 2010, important clarifications about trial populations, designs, and endpoints for ABSSSI were included in this guidance. In addition, this guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of ABSSSI.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to “. . . review and, as appropriate, revise not fewer than 3 guidance documents per year . . . for the conduct of clinical trials with respect to antibacterial and antifungal drugs”

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents 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 (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and

will be posted to the docket at <http://www.regulations.gov>.

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: October 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-24787 Filed 10-22-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0241]

Guidance for Industry on Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine; 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 #188 entitled “Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine.” The purpose of this guidance is to assist sponsors or non-applicants with filling out Form FDA 1932, “Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report,” in both paper and electronic format, as required by FDA regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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:

Margarita Brown, Center for Veterinary Medicine (HFV-241), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9048. margarita.brown@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 25, 2010 (75 FR 29352), FDA published the notice of availability for a draft guidance #188 entitled “Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine,” giving interested persons until August 9, 2010, to comment on the draft guidance. FDA made changes to the draft document in response to these comments, to clarify the information that we expect to receive, to reflect ongoing International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) activities in which FDA is participating, and to provide direction for voluntary use of CVM internal terms for medication errors. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated May 24, 2010.

II. Significance of Guidance

This level 1 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 the 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.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)) have been approved under 0910-0645.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: October 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0343]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 14 on Bacterial Endotoxins Test General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 14: Bacterial Endotoxins Test General Chapter.” The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Bacterial Endotoxins Test General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding