

computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 023" will be available on the CDRH home page. You may access the CDRH home page at <http://www.fda.gov/cdrh>.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" through the hyperlink at <http://www.fda.gov/cdrh/stdsprog.html>.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at <http://www.fda.gov/cdrh/fedregin.html>.

#### VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 023. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: April 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-10562 Filed 5-4-10; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2009-D-0052]

#### Guidance for Industry on Documenting Statistical Analysis Programs and Data Files; 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

#197 entitled "Documenting Statistical Analysis Programs and Data Files." This guidance is provided to inform study statisticians of recommendations for documenting statistical analyses and data files submitted to the Center for Veterinary Medicine (CVM) for the evaluation of safety and effectiveness in new animal drug applications. These recommendations are intended to encompass the most complex data submissions to CVM, to reduce the number of revisions that may be required for CVM to effectively review statistical analyses and to simplify submission preparation by providing a uniform documentation system.

**DATES:** Submit written or electronic 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.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Anna Nevius, Center for Veterinary Medicine (HFV-163), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8170, [anna.nevius@fda.hhs.gov](mailto:anna.nevius@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of March 16, 2009 (74 FR 11118), FDA published the notice of availability for a draft guidance entitled "Draft Guidance for Industry on Documenting Statistical Analysis Programs and Data Files; Availability" giving interested persons until June 1, 2009, to comment on the draft guidance. FDA received no comments on the draft guidance. Minor editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated April 27, 2009.

##### 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 21 CFR part 514 have been approved under OMB control no. 0910-0032.

#### IV. Comments

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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

#### V. Electronic Access

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

Dated: April 29, 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-N-0224]

#### Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management

**AGENCY:** Food and Drug Administration, HHS