

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]

**BILLING CODE 4160-01-S**

## 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.*

[FR Doc. 2010-10582 Filed 5-4-10; 8:45 am]

**BILLING CODE 4160-01-S**

## 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

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management." The purpose of this meeting is to present the Center for Devices and Radiological Health (CDRH) fiscal year (FY) 2010 priorities. In addition, FDA is interested in engaging in discussions about issues that are of importance to the medical device industry.

**Date and Time:** The public meeting will be held on June 22, 2010, from 9 a.m. to 5 p.m.

**Location:** The public meeting will be held at the Hilton Boston/Woburn, Two Forbes Rd., Woburn, MA 01801. The meeting will not be videotaped or Web cast.

**Contact:** Heather Howell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4320, Silver Spring, MD 20993, 301-796-5718, e-mail:

[heather.howell@fda.hhs.gov](mailto:heather.howell@fda.hhs.gov).

**Registration and Requests for Oral Presentations:** If you wish to attend the public meeting, you must register online at: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm206671.htm>. Provide complete contact information for each attendee, including name, title, company or organization, address, e-mail, and telephone number. Registration requests must be received by 5 p.m. on Wednesday, June 9, 2010.

If you wish to make an oral presentation during any of the sessions at the meeting (see section II of this document), you must indicate this at the time of registration. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan at 301-796-5661 or e-mail: [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) at least 7 days in advance of the meeting.

**Comments:** FDA is holding this public meeting to share information and discuss issues of importance to the medical device industry. CDRH is specifically interested in addressing the following question: What mechanism(s) would you prefer or suggest for FDA to engage with industry? The deadline for responding to this question and for submitting other comments related to this public meeting is Wednesday, June 9, 2010.

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments. Submit written comments 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>. 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.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

CDRH has announced four priority areas of activity for FY 2010, each of which presents significant opportunities to improve CDRH's effectiveness in fulfilling our public health mission. More information, including specific goals and actions associated with each priority, is available under "CDRH Strategic Planning" at <http://www.fda.gov/AboutFDA/CentersOffices/CDRH>.

##### **II. Public Meeting**

The objective of this public meeting is to present CDRH's FY 2010 priorities. In addition, FDA is interested in engaging in discussions about issues that are of importance to the medical device industry. CDRH wishes to obtain feedback/ideas for facilitating two-way communication between CDRH and the medical device industry.

The meeting will open with an introduction of CDRH Senior Staff in attendance. Following introductions, Dr. Jeffrey Shuren, the Director of CDRH, will present the FY 2010 CDRH priorities. Industry representatives and other members of the public will then be given the opportunity to present

comments to CDRH Senior Staff. Attendees from CDRH may respond to questions presented by industry and other members of the public.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at <http://www.regulations.gov>. This information will also be available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

##### **III. Transcripts**

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: April 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-10563 Filed 5-4-10; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2010-N-0002]

#### **Withdrawal of Approval of New Animal Drug Applications; Coumaphos; Novobiocin; Buquinolate and Lincomycin**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of three new animal drug applications (NADAs). In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove portions reflecting approval of the single NADA of the three that is codified.

**DATES:** Withdrawal of approval is effective May 17, 2010.