

Dated: November 17, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-30146 Filed 11-22-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0784]

#### Draft Guidance for Industry on Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry #217 entitled "Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals."

The draft guidance, when finalized, is intended to provide guidance to industry for designing and conducting clinical effectiveness studies, and describes criteria that the Center for Veterinary Medicine (CVM) thinks are the most appropriate for the evaluation of the effectiveness of anticoccidial drugs intended for use in poultry and other food-producing animals. The draft guidance also suggests times during the evaluation of effectiveness when sponsors may wish to consult with CVM.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 23, 2012.

**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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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:

Emily R. Smith, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276-8344, [emily.smith2@fda.hhs.gov](mailto:emily.smith2@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of draft guidance for industry #217 entitled "Evaluating the Effectiveness of Anticoccidial Drugs In Food-Producing Animals." The draft guidance discusses general considerations for the evaluation of the efficacy of anticoccidial drugs in poultry, minor species and food-producing mammals. Draft guidance for industry #217 supersedes the CVM draft guidance for industry #40, entitled "Draft Guideline for the Evaluation of The Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry," dated April 1992.

This draft guidance discusses general considerations regarding protocol development, study conduct, animal welfare, substantial evidence of effectiveness, feed preparation, drug assays, and combination approvals.

This draft guidance discusses CVM considerations for studies used to substantiate effectiveness of anticoccidial drugs in poultry, including battery studies and commercial field studies. In addition, the draft GFI discusses CVM considerations for studies used to substantiate effectiveness of anticoccidial drugs in food-producing mammals, in minor species, and for minor uses.

##### II. Significance of Guidance

This level 1 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 evaluating the effectiveness of anticoccidial drugs in food-producing animals. 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 draft 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 this guidance have been approved under OMB control nos. 0910-0032 and 0910-0117.

##### IV. 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.

##### V. Electronic Access

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

Dated: November 17, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Tobacco Products Scientific Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Tobacco Products Scientific Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 18, 2012, from 8 a.m. to 5 p.m., on January 19, 2012, from 8 a.m. to 5 p.m., and on January 20, 2012, from 8 a.m. to 4 p.m.

*Location:* Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1 (877) 287-1373.

*Contact Person:* Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-(877) 287-1373 (choose option 4), *email:* [TPSAC@fda.hhs.gov](mailto:TPSAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-(800) 741-8138 ((301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* As part of the Tobacco Products Scientific Advisory Committee's required report to the Secretary of Health and Human Services, the committee will continue discussing issues related to the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. Discussion will include such topics as the composition and characteristics of dissolvable tobacco products, product use, potential health effects, and marketing.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* On January 18, 2012, from 2 p.m. to 5 p.m., on January 19, 2012, from 8 a.m. to 5 p.m., and on January 20, 2012 from 8 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 4, 2012. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. on January 19, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the

evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 27, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 28, 2011.

*Closed Committee Deliberations:* On January 18, 2012, from 8 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). This portion of the meeting must be closed because the Committee will be discussing trade secret and/or confidential data regarding products provided by the tobacco companies.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caryn Cohen at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 16, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-30163 Filed 11-22-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0780]

#### **Bridging the Idea Development Evaluation Assessment and Long-Term Initiative and Total Product Life Cycle Approaches for Evidence Development for Surgical Medical Devices and Procedures; Public Workshop; Correction**

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

**ACTION:** Notice of public workshop; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Monday, November 7, 2011 (76 FR 68769). The document announced a public workshop entitled "Bridging the Idea Development Evaluation Assessment and Long-Term Initiative and Total Product Life Cycle Approaches for Evidence Development for Surgical Medical Devices and Procedures." The document was published with an incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3208, Silver Spring, MD 20993-0002, (301) 796-9148.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011-28722, appearing on page 68769, in the **Federal Register** of Monday, November 7, 2011, the following correction is made:

On page 68769, in the first column, in the Docket No. heading, "[Docket No. FDA 2011-N-0002]" is corrected to read "[Docket No. FDA-2011-N-0780]".

Dated: November 17, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### **Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information