Dated: November 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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

BILLING CODE 4160–01–P

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Draft Guidance for Industry on Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry #217 entitled ''Evaluating the Effectiveness of Anticoccidial Drugs in Food-Producing Animals.''

The draft guidance, when finalized, is intended to provide guidance to industry for designing and conducting clinical effectiveness studies, and describes criteria that the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 The draft guidance also suggests times during the evaluation of effectiveness when sponsors may wish to consult with CVM.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 23, 2012.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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.*

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FDA is announcing the availability of draft guidance for industry #217 entitled ''Evaluating the Effectiveness of Anticoccidial Drugs In Food-Producing Animals.'' The draft guidance discusses general considerations for the evaluation of the efficacy of anticoccidial drugs in poultry, minor species and food-producing mammals.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.

[FR Doc. 2011–30149 Filed 11–22–11; 8:45 am]

BILLING CODE 4160–01–P

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.