visually impaired, to polling places, including the path of travel, entrances, exits and voting facilities. The Office also administers a training and technical assistance grant program under the Help America Vote Act that provides technical assistance to Protection and Advocacy Systems in their mission to promote the full participation in the electoral process for individuals with the full range of disabilities, including registering to vote, casting vote, and accessing polling places.

The Office of Innovation originates and manages cross-cutting research, demonstration and evaluation initiatives with other components of ADD, ACF, HHS and other government agencies. The Office also coordinates information sharing and other activities related to national Developmental Disability program trends with other ACF programs and HHS agencies; and studies, reviews and analyzes other Federal programs providing services applicable to persons with developmental disabilities for the purpose of integrating and coordinating program efforts.

III. Continuation of Policy

Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within the Administration for Children and Families, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

IV. Delegation of Authority

All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

V. Funds, Personnel, and Equipment

Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Dated: November 10, 2011.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2011–30176 Filed 11–22–11; 8:45 am]

BILLING CODE 4184–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0439]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 23, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* (202) 395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0249. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Recall Regulations—(OMB Control Number 0910–0249)—Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7 (21 CFR part 7), subpart C set forth the recall regulations (guidelines) and provide guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA regulated products (*i.e.,* food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; biological products intended for human use; and tobacco). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluation return reply cards, effectiveness checks, and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55(b)).

A search of the FDA database was performed to determine the number of recalls, and terminations that took place during fiscal years (FYs) 2008 to 2010. The resulting number of total recalls (9,303) and terminations (2,858) from this database search were then averaged over the 3 years, and the resulting per year average of recalls (3,101) and terminations (953) are used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the previous information to be 443,820 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary reporting requirements of FDA's recall regulations recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products.

The annual reporting burdens are explained as follows:

I. Total Annual Reporting

A. Recall Strategy

Request firms develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of information, the Agency estimates it will receive 3,101 responses annually based on the average number of recalls over the last 3 FYs.

B. Firm Initiated Recall and Recall Communications

Request firms voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices,

biologics, and tobacco to immediately notify the appropriate FDA district office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy, and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the Agency estimates it will receive 3,101 responses annually based on the average number of recalls over the last 3 FYs.

C. Recall Status Reports

Request that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This request only applies to firms with active recalls, and is estimated to be reported every 2 to 4 weeks. This collection of information will generate approximately 27,924 responses annually, based on the average number of recalls over the last 3 FYs (3,101), less the average number of terminations over the last 3 FYs (953), multiplied by the conservative frequency of reporting per year (13).

D. Termination of a Recall

Provide the firms an opportunity to request in writing that FDA end the recall. The Agency estimates it will receive 953 responses annually based on the average number of terminations over the past 3 FYs.

II. Hours per Response Estimates

FDA has no information that would allow it to make a calculated estimate on the hours per response burden to FDA regulated firms to conduct recalls. Variables in the type of products, the quantity and level of distribution, and the various circumstances of recall notifications could cause the hours per response to vary significantly. The best guesstimate of average burden hours per response from previous information collection request reports are utilized again for the current estimates on burden hours per response.

In the **Federal Register** of June 29, 2011 (76 FR 38184), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received and was PRA related.

(Comment) One comment noted that the FDA Average Burden per Response (ABPR) are low. The commenter's estimates are double the estimates provided by FDA.

(Response) FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. From FYs 2008 to 2010, FDA classified approximately 9,303 recalls of FDA-regulated products. Further, FDA notes that not all recall events reported to the Agency are similar in nature and may entail different information and volume of information on a case-by-case basis. Therefore, FDA could not calculate or determine an estimate for the average burden per response for a particular or specific product type or area and has based its estimates for all industries that it regulates.

(Comment) One comment questioned the validity of the methodology and assumption used by FDA, citing that data ranges are not given. The comment encouraged FDA to provide data ranges for industry to assess better the accuracy of the Agency's estimates.

(Response) As stated in the prior response, FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. From FY 2008 to 2010, FDA classified approximately 9,303 recalls of FDA-regulated products. Further, FDA notes that not all recall events reported to the Agency are similar in nature where complexity and size of the recall can dictate the amount of recall information and data to be submitted. Therefore, FDA could not provide ranges of the burden for data collection for industry and based its estimates across the entire scope of recalls of FDA-regulated products.

(Comment) One comment suggests that the Agency develop an electronic tool for recall reporting or ''eRecall'' tool, and ask, that industry be able to provide input to any developer of user requirements for such a tool before implementations.

(Response) FDA will consider the suggestion of an electronic recall tool for reporting. However, because of the many types of industries that FDA regulates, such a tool may not be able to accommodate the variety of information specific to many of these industries.

(Comment) One comment suggests that recall requirements should apply only to finished goods that are consumable and that FDA's entire recall program, not just information collection, be reviewed to determine if the program serves the purpose originally intended to protect consumers.

(Response) FDA disagrees with the comment. FDA believes that violative products in the marketplace should be recalled from consignees and customers who received them even if they are not finished goods that are consumables. For example, a recall of a violative product which is used for further manufacture and that poses a health risk would also serve as notification to consignees and customers to remove the recalled product from further use or distribution, including providing instructions for additional recall of products that may have been manufactured using the recalled products.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Recall Strategy (§ 7.42)	3,101	1	3,101	20	62,020
Firm Initiated Recall and Recall Communications (§§ 7.46 & 7.49)	3,101	1	3,101	30	93,030
Recall Status Reports and Followup (§ 7.53)	2,148	13	27,924	10	279,240
Termination of a Recall (§ 7.55(b))	953	1	953	10	9,530
Total					443,820

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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.