TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Interviews/Surveys	19,822	1	19,822	14/60	4,757

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

Annually, FDA projects about 45 communication studies using the variety of test methods listed previously in this document. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: May 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13812 Filed 6–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0433] (formerly FDA–2003D–0474)

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Revised Guidance for Industry on "Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish a Microbiological ADI" (VICH GL–36(R)); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft revised guidance for industry (#159) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI" (VICH GL36(R)). This draft revised guidance, which updates a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of February 11, 2005, has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised VICH guidance was revised to include Appendix D—Supplement to Section 2 Regarding the Determination of the Fraction of Oral Dose Available to Microorganisms. This draft VICH guidance document is intended to provide guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora.

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 revised guidance before it begins work on the final version of the revised guidance, submit either electronic or written comments on the draft revised guidance by August 2, 2011.

ADDRESSES: Submit written requests for single copies of the draft revised 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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft revised guidance document.

Submit electronic comments on the draft revised 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: Silvia A. Pineiro, Center for Veterinary Medicine, (HFV–157), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–276–8227, *Silvia.Pineiro@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH) for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also

participates in the VICH Steering Committee meetings.

II. Guidance on Microbiological Acceptable Daily Intake

In February 2011, the VICH Steering Committee agreed that a draft revised guidance entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI (Revision)" (VICH GL36(R)) should be made available for public comment. This draft revised VICH guidance is a revision of a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of February 11, 2005 (70 FR 7278). This draft revised guidance was revised to include Appendix D–Supplement to Section 2 Regarding the Determination of the Fraction of Oral Dose Available to Microorganisms. This VICH guidance provides guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora. The objectives of this guidance are to: (1) Outline the recommended steps in determining the need for establishing a microbiological acceptable daily intake (ADI); (2) recommend test systems and methods for determining no-observable adverse effect concentrations (NOAECs) and no-observable adverse effect levels (NOAELs) for the endpoints of health concern; and (3) recommend a procedure to derive a microbiological ADI. It is recognized that different tests may be useful. The experience gained with the recommended tests may result in future modifications to this guidance and its recommendations.

The draft revised guidance is a product of the Quality Expert Working Group of the VICH. Comments about this draft will be considered by FDA and the VICH Quality Expert Working Group.

III. Paperwork Reduction Act of 1995

This draft revised 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 revised guidance have been approved under OMB control number 0910–0032.

IV. Significance of Guidance

This draft revised guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." In addition, guidance documents must not include mandatory language such as "must," "shall," "require" or "requirement" unless FDA is using these words to describe a statutory or regulatory requirement.

This draft revised VICH guidance when finalized, will represent the Agency's current thinking on this 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 applicable statutes and regulations.

V. 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.

VI. Electronic Access

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

Dated: May 31, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13821 Filed 6–2–11; 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 July 21, 2011, from 9 a.m. to 5 p.m., and on July 22, 2011, from 8 a.m. to 5 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), e-mail: *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: On the morning of July 21, 2011, the committee will discuss changes proposed by committee members to the Tobacco Products Scientific Advisory Committee (TPSAC) Menthol Report submitted to the Agency on March 18, 2011. The committee will consider additional oral and written comments from the public on the Menthol Report and the proposed changes to the report, as submitted according to the instructions in the *Procedure* portion of this document. The committee will consider and deliberate on proposed changes to the report and adopt amendments that constitute the advice of the committee. Redacted versions of the document, reflecting the changes to the report proposed by the committee members, will be made available on the FDA Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm,* no later than June 22, 2011. On the afternoon of July 21, 2011, and on July 22, 2011, the TPSAC will initiate discussions on the issue of the nature and impact of the use of dissolvable tobacco products on the