TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form 3602A	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Sections I and II (completed by the business seeking "small business" status)	229	1	229	1	229
Section III (completed by the foreign national taxing authority)	33	7	229	1	229
Total Burden					458

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

This burden estimate is based on an examination of 510(k) premarket notifications received during FY 2006 and FDA's estimation of the time required to collect the required information to complete the form. The evidence supporting each 3602A must be reviewed by a foreign national taxing authority to complete Section III, the National Taxing Authority Certification, of each 3602A. Because this is a new activity, and neither FDA nor any foreign national taxing authority has any data that would provide an objective measure of the effort required to complete Section III, FDA is estimating that the burden will be the same as FDA experiences in reviewing the Form FDA 3602, approved under OMB control number 0910–0508.

FDA believes most entities that submit a Form FDA 3602A will not have any affiliates, and very few will have more than three or four affiliates. Based on our experience with Form FDA 3602, FDA believes each business will require 1 hour to complete Sections I and II. Because this is a new requirement, FDA does not have any data on the time that will be required to complete Section III, the National Taxing Authority Certification.

Dated: September 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19411 Filed 10–1–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration; 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). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Board shall provide advice primarily to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the Board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading it's scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on October 30, 2007, from 8 a.m. to 5:30 p.m.

Location: Washington DC North/ Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877, Salons A, B, and C.

Contact Person: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, carlos.Peña@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. 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: The Science Board will hear about and discuss the agency's critical path program. The Science Board will hear about and discuss updates on the National Antimicrobial Resistance Monitoring System (NARMS) Program and activities related to melamine from the March 31, 2006, and June 14, 2007, Science Board meetings. The Science Board will then hear about and discuss the subcommittee review of the agency's science programs. The Science Board will also hear about and discuss the agency's updates on drug safety.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/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: 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 October 15, 2007. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. Those desiring to make 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 October 5, 2007. 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 October 8, 2007.

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 Dr. Carlos Peña 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/oc/advisory/default.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: September 23, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–19349 Filed 10–1–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0138]

Guidance for Industry: Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims; 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 (#178) entitled ''Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims.'' This guidance provides recommendations to industry relating to study design and describes the criteria that the Center for Veterinary Medicine (CVM) intends to use to evaluate effectiveness studies for swine respiratory disease (SRD) claims.

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

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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Michelle L. Stull, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5058, e-mail: *michelle.stull@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 14, 2006 (71 FR 19526), FDA published a notice of availability of a draft guidance entitled ''Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims.'' The notice gave interested persons until June 28, 2006, to comment on the draft guidance. FDA received a few comments on the draft guidance. We considered those comments as we finalized the guidance. The guidance, announced in this document, finalizes the draft guidance that we announced on April 14, 2006.

The purpose of the guidance is to provide the Center for Veterinary Medicine's (CVM's) current thinking regarding the recommended design and evaluation of effectiveness studies for swine respiratory disease (SRD) claims. This guidance identifies specific, detailed recommendations for sponsors of new animal drug applications to consider when they design and write protocols for SRD effectiveness studies.

II. 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 514.1 have been approved under OMB Control Number 0910–0032.

III. 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.

IV. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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 full title of the guidance and the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination 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 from either the CVM home page (*http://www.fda.gov/cvm*) or the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: September 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19412 Filed 10–1 –07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered Species Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comment.

SUMMARY: We invite the public to comment on the following applications to conduct certain activities with endangered species.

DATES: Comments on these permit applications must be received on or before November 1, 2007.

ADDRESSES: Written data or comments should be submitted to the U.S. Fish and Wildlife Service, Endangered Species Program Manager, California/Nevada Operations Office (CNO), 2800 Cottage Way, Room W–2606, Sacramento, California, 95825 (telephone: (916) 414–6464; fax: (916) 414–6486). Please refer to the respective