needed. The form has been updated to allow sponsors to indicate whether the request amends a previous request for a meeting and to allow for consistency across forms. The likely respondents to this collection of information are new animal drug sponsors.

In the **Federal Register** of August 7, 2003 (68 FR 47079), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
3489	12	14	168	0.69	116

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

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1502 Filed 1–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies 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). The meeting will be open to the public.

Name of Committee: Transmissible Spongiform Encephalopathies 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 February 12, 2004, from 8 a.m. to 5:30 p.m., and on February 13, 2004, from 8 a.m. to 3:30 p.m.

Location: Holiday Inn, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 12, 2004, the committee will hear an informational presentation on a presumptive transfusion-transmitted case of variant Creutzfeldt-Jakob Disease (vCJD) reported recently in the United Kingdom, and hear updates on related experimental studies in animals on transmission of transmissible spongiform encephalopathies (TSE) agents by blood, and relevant epidemiology of human TSEs. In the afternoon, the committee will receive an update on the case of bovine spongiform encephalopathy (BSE) recently recognized in the United States, and will have a general discussion about potential models of risk-based approaches to sourcing of bovine materials used to make medical products. On February 13, 2004, the committee will have a preliminary discussion about FDA's current recommendations on measures to minimize risk from TSE agents in various types of medical products.

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 by February 5, 2004. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12 noon, and 3 p.m. and 3:30 p.m. on February 12, 2004; and between 11 a.m. and 12 noon on February 13, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 9, 2004, 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.

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 William Freas or Sheila D. Langford at least 7 days in advance of the meeting.

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

Dated: January 16, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–1495 Filed 1–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0570]

Request for Comments on a Draft Guidance on the Clinical Evaluation of Weight-Control Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on a previously published draft guidance that has never been finalized. The draft guidance entitled ''Guidance for the Clinical Evaluation of Weight-Control Drugs'' was issued September 24, 1996. The draft guidance gives recommendations for the design and conduct of phase 1–3 clinical studies aimed at demonstrating the efficacy and safety of weight-loss medications. The agency would like to revise this document for republication as a draft. Before it does this, the agency would like interested persons to review and submit comments on the 1996 draft guidance document.

DATES: Submit written or electronic comments on the draft guidance by April 26, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Drug Information (HFD–240), Center for Drug Evaluation and