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

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Oluchi Elekwachi, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6381.

SUPPLEMENTARY INFORMATION:

I. Background

Weight-loss medications approved by FDA before the 1990s, such as phentermine and diethylpropion, are indicated for the short-term (a few weeks) treatment of obesity. The short-term indication reflects the now rejected belief that drug-induced weight loss will be maintained after the medication is stopped. In recent years, it has become clear that the successful treatment of obesity, with or without pharmacologic intervention, requires long-term, if not chronic, therapy.

In 1995, FDAs Division of Metabolic and Endocrine Drug Products convened an expert advisory panel to discuss the development of weight-loss drugs indicated for the long-term treatment of obesity. The discussions at this meeting formed the basis for a draft guidance document entitled ''Guidance for the Clinical Evaluation of Weight-Control Drugs,'' which was made available on September 24, 1996. Two of the more important recommendations made in the draft guidance relate to the duration of the phase 3 trials and the criteria used to define efficacy.

FDA is interested in incorporating the latest scientific advances in the field of obesity and drug development into an amended obesity guidance document. Once the draft has been revised, it will be issued again for comment before finalization. To that end, interested parties are encouraged to submit comments on the 1996 draft obesity guidance.

This request for comments on the 1996 draft guidance is being issued consistent with FDAs good guidance practices (GGPs) regulation (21 CFR 10.115). The draft 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. You can use an alternative approach if the approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft 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 docket number found in the brackets in the heading of this document. A copy of received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: January 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1496 Filed 1–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4903–N–01]

Notice of Submission of Proposed Information Collection to OMB: Single Family Premium Collection Subsystem-Upfront

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

The Single Family Premium Collection Subsystem-Upfront (SFPCS–U) is used by lenders to remit Upfront Mortgage Insurance Premiums using funds obtained from the borrower during the closing of the mortgage transaction at settlement.

DATES: *Comments Due Date:* February 25, 2004.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and OMB approval number (2502–0423) and should be sent to: Melanie Kadlic, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395–6974; E-mail *Melanie_Kadlic@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins or on HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm.*

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Single Family Premium Collection Subsystem-Upfront.

OMB Approval Number: 2502–0423.

Form Numbers: None.

Description of the Need for the Information and Its Proposed Use: The Single Family Premium Collection Subsystem-Upfront (SFPCS–U) is used by lenders to remit Upfront Mortgage Insurance Premiums using funds obtained from the borrower during the closing of the mortgage transaction at settlement.