Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

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.

Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine, 21 CFR 11.2—(OMB Control N0. 0910–0454)—Extension

The Center for Veterinary Medicine (CVM) is responsible for developing and administering guidances that explain how to adhere to the electronic records; electronic signatures regulations (part 11 (21 CFR part 11)). These regulations allow sponsors to submit part or all of records to FDA electronically in lieu of paper, unless the paper records are specifically required by regulation, if the requirements of part 11 are met, and the documents to be submitted electronically are identified in Public Docket No. 92S–0251. These regulations comply with the Government Paperwork Elimination Act (GPEA) (Public Law 105–277). The GPEA requires Federal agencies, by October 21, 2003, to give persons who are required to maintain, submit, or disclose information the option of doing so electronically when practicable as a substitute for paper.

This guidance document describes the procedures persons who submit information to CVM should follow, if they want to file submissions electronically. This guidance instructs those who wish to submit information to CVM by e-mail to first register with the center. Registration entails sending a letter, on paper or electronically, to CVM with a sponsor password and the names, phone numbers, mail and e-mail addresses of a sponsor coordinator and each person who will submit information electronically to CVM. Other information collection provisions relate to electronic submissions by individuals and electronic submissions to make changes to the sponsor's registration. CVM will use all the information submitted to process electronic submissions. The likely respondents to this collection of information are new animal drug sponsors.

In the **Federal Register** of August 7, 2003 (68 FR 47077), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

We estimate the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,538	70	2	140	.5	70

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

The estimate of the times required for record preparation is based on agency communication with industry. Other information needed to calculate the total burden hours are derived from agency records and experience.+

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–1494 Filed 1–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0327]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How To Use E-Mail To Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

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 February 25, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Guidance for Industry on How To Use E-Mail To Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation—(OMB Control Number 0910–0452)—Extension

Any person intending to file a new animal drug application or abbreviated application is entitled to request meetings and/or teleconferences to reach agreement regarding a submission or investigational requirement (21 U.S.C. 3606(b)(3)). Every person outside the Federal Government may request a meeting with representative(s) of FDA to discuss a matter (21 CFR 10.65(c)).

Sponsors often meet with scientists in the Center for Veterinary Medicine's (CVM) Office of New Animal Drug Evaluation to formulate a rational approach to studies to be conducted and to discuss how to meet the statutory requirements for new animal drug approval under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Requests for meetings and teleconferences are currently submitted on paper to CVM.

This guidance document describes the procedure for persons to submit a request for a meeting or teleconference electronically on FDA Form 3489. The information sponsors should include on the form includes the sponsor's name and address, a list of agency participants, an agenda, and notification of audio-visual equipment that will be

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