Dated: June 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–15429 Filed 6–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0505]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Protein Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 20, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (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.

Title: Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR Part 589—(OMB Control No. 0910–0339)—Extension

Description: This rule (§ 589.2000 (21 CFR 589.2000)) provides that protein derived from mammalian tissue (with some exceptions) for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348). Proteins derived from animal tissues contained in such feed ingredients in distribution cannot be readily identified (i.e., species), by recipients engaged in the manufacture, processing and distribution, and use of animal feeds and feed ingredients.

Thus, under the agency's authority in section 701(a) of the act (21 U.S.C. 371(a)), to issue regulations for the efficient enforcement of the act, this rule places three general requirements on persons that manufacture, blend, process, distribute, or use products that contain or may contain protein derived from mammalian tissues and feeds made from such products. The first requirement is for cautionary labeling of these products with direct language developed by FDA. This labeling requirement is exempt from the scope of the PRA because it is a ''public disclosure of information originally supplied by the Federal Government for the purpose of disclosure to the public'' (5 CFR 1329.3(c)(2)).

The second requirement is for establishments to maintain and make available to FDA, records that are sufficient to track any material that contains protein derived from mammalian tissues (as defined in § 589.2000(a)(1)), throughout the material's receipt, processing, and distribution. Based on available information, FDA believes that maintenance of these records is a usual and customary part of normal business practices for these firms. Therefore, this recordkeeping requirement creates no additional paperwork burden.

The third requirement is that individuals or firms that manufacture, blend, process, or distribute both mammalian and nonmammalian materials must maintain written procedures to prevent commingling and cross-contamination. An estimate of the burden resulting from this recordkeeping requirement is provided in table 1 of this document. The estimate is based on the time required to develop written procedures.

Respondents to this collection of information are individuals or firms that manufacture, blend, process distribute, or use feed or feed ingredients that contain or may contain protein that may be derived from mammalian tissue.

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

TABLE1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Response	Total Annual Records	Hours per Record	Total Hours
589.2000(e)(1)(iv)	1,030	1	1,030	14	14,420

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

The estimated number of respondents, persons that separate mammalian and nonmammalian materials, is derived from inspections of firms handling animal protein intended for use in animal feed. The estimate of the time required for this recordkeeping requirement is based on agency records and communication with industry.

Dated: June 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–15430 Filed 6–19–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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: Biological Response Modifiers 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 13, 2000, 8:30 a.m. to 6 p.m. and July 14, 2000, 8:30 a.m. to 3 p.m.

Location: Hilton Hotel, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Gail Dapolito or Rosanna Harvey (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 13 and 14, 2000, the committee will discuss product development issues related to human stem cells as cellular replacement therapies for neurological disorders.

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 June 30, 2000. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. on July 14, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 30, 2000, 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.

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

Dated: June 9, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–15431 Filed 6–19–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription Drugs 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: Nonprescription Drugs 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 12, 2000, 1 p.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sandra L. Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or e-mail: TitusS@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the remarketing and labeling of the Today® Vaginal Contraceptive Sponge, new drug application (NDA) 18–683, Allendale Pharmaceuticals. This product was approved by FDA in 1983, but has not been marketed since January 1995.

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 July 6, 2000. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 6, 2000, 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.

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

Dated: June 9, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–15428 Filed 6–19–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Phase I of the National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program (0930–0171—Extension, revision)—The core and comparison studies of the evaluation collect information on child and family demographics, child mental health status, and service system development. In the core study, data were collected from children and families at intake into services, 6 months later, and every 12 months thereafter while the children remain in services. In the comparison study component, information is collected at intake, 6 months, 12 months, 24 months, and annually thereafter. In both studies, data were collected annually from grantees' administrators and providers.

SAMHSA's Center for Mental Health Services (CMHS) is seeking OMB approval for a 4-month extension of approval for the comparison study of this evaluation of integrated child mental health service systems funded by CMHS to allow sufficient follow-up data to be collected. The comparison study of the evaluation collects information on child and family demographics, and child mental health status and social functioning. The table below summarizes burden for this extension.