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.

DATES: Submit written comments on the collection of information by November 13, 2001.

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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Reports of Corrections and Removals—21 CFR Part 806 (OMB Control No. 0910–0359)—Extension

Section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)) directs FDA to issue regulations to require device manufacturers and importers to report promptly to FDA any correction or removal of a device undertaken by such manufacturers and importers if the correction or removal was undertaken to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health. Under 21 CFR 806.10 and 806.20(a), FDA requires that each device manufacturer and importer shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the act caused by the device which may present a risk to health within 10 working days of initiating such correction or removal. In addition, each manufacturer and importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that dangerous and defective devices are removed from the market, assuring that FDA has current and complete information regarding these corrections and removals and whether recall action is adequate. Failure to collect this information prevents FDA from receiving timely information about devices that may have a serious effect on the health of the users of the devices.

Respondents to this information collection are businesses or other for-profit manufacturers or importers of medical devices who must remove or correct medical devices that cause public health risk to the general public.

In the **Federal Register** of July 6, 2001 (66 FR 35644), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
806.10	880	1	880	10	8,800

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20(a)	440	1	440	10	4,400

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

The following is an explanation of the burden estimate:

Reporting Burden

FDA estimates that it would take 10 staff hours to prepare and assemble a written report. For the estimated 880 reports, FDA estimates that respondents will spend 8,800 hours to prepare, assemble, and send the reports.

Recordkeeping Burden

FDA estimates that it would take 10 staff hours to prepare a written record. For the estimated 440 records, the total recordkeeping burden is estimated at 4,400 hours per recordkeeper.

Dated: October 5, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–25660 Filed 10–11–01; 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). At least one portion of the meeting will be closed 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 October 25, 2001, from 8 a.m. to 3:30 p.m., and on October 26, 2001, from 8 a.m. to 4:30 p.m.

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

Contact: 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 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 25, 2001, the committee will discuss FDA's draft document entitled ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products'' (published in the **Federal Register** on August 29, 2001 (66 FR 45683), http://www.fda.gov/cber/gdlns/cjdvcjd.pdf). Later that morning the committee will discuss amino acid sourcing and production, and the theoretical risk of transmission of the BSE agent through their use in vaccines, other biologicals and human drugs. On October 26, 2001, the committee will discuss the risk of bovine brains and other neurological tissue for human use.

Procedure: On October 25, 2001, from 8 a.m. to 1:10 p.m. and from 1:40 p.m. to 3:30 p.m., and on October 26, 2001, from 8 a.m. to 4:30 p.m., the meeting is open to the public. 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 October 18, 2001. Oral presentations from the public will be scheduled between approximately 9 a.m. to 9:30 a.m., and 1:40 p.m. to 2:10 p.m. on October 25, 2001; and between 1 p.m. to 1:30 p.m. on October 26, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 18, 2001, 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.

Closed Committee Deliberations: On October 25, 2001, from 1:10 p.m. to 1:40 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

Dated: October 4, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–25607 Filed 10–11–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: September 2001

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of September 2001, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject City, State	Effective date
PROGRAM-RELATED CONVICTIONS	
Aragones, Concepcion N ..... Newmarket, NH	10/18/2001
Brocuglio, Steven J ..... Devens, MA	10/18/2001
Butt, Atiq Amad ..... Elizabeth, NJ	10/18/2001
Carlton, Edward D ..... Gainesville, VA	10/18/2001
Columbia Management Cos, Inc ..... Nashville, TN	07/01/2001
Connell, Debra A ..... Lancaster, OH	10/18/2001
Covone, Dominick ..... Fort Dix, NJ	10/18/2001
Cragen, Kenneth Russell ..... Los Angeles, CA	10/18/2001
Ekpo, Asuquo Eyo ..... Sugarland, TX	10/18/2001
Espinoza, Maria Aura ..... Southgate, CA	10/18/2001
Fenster, Robert H ..... Denver, CO	10/18/2001
Galstyan, Arutyun ..... Glendale, CA	10/18/2001
Gevorkyan, Arman ..... North Hollywood, CA	10/18/2001
Glass, Ted Alan ..... Fredericksburg, VA	10/18/2001
Griffin, Brian Michael ..... Shatleigh, ME	10/18/2001
Grigoryan, Manouk ..... Los Angeles, CA	10/18/2001
Grossman, Gary ..... Dix Hills, NY	10/18/2001
Guerrero, Marta ..... Miami, FL	10/18/2001
Gutierrez, Orlando ..... Southgate, CA	10/18/2001
Hardister, Earnest Richard ..... Boise, ID	10/18/2001
Hertz, Bradley ..... Miami, FL	10/18/2001
Hicks, Ingrid D ..... Union Grove, WI	10/18/2001
Johnson, Lucy Young ..... Maplewood, MN	10/18/2001
Keating, Janadean ..... Salt Lake City, UT	10/18/2001
Keo, Channy ..... Long Beach, CA	10/18/2001
Kessler, James M ..... Lutherville, MD	10/18/2001
Khozak, Elizabeth A ..... Manchester, NH	10/18/2001
Kuyumdzhyan, Armen ..... Los Angeles, CA	10/18/2001
Lagasse, Joy A ..... South Casco, ME	10/18/2001
Larson, Jeannine C ..... Portland, ME	10/18/2001
Leach, Debra ..... Danbury, CT	10/18/2001
Lee, Salvacion ..... Bell Canyon, CA	10/18/2001
Leiti, John ..... Roswell, GA	10/18/2001
Levias, Percy L ..... Starks, LA	10/18/2001
Linscott, Terry L ..... Alderson, WV	10/18/2001
Lovett, Gareth ..... Marietta, GA	10/18/2001
Lyall, Chelsea Damaris ..... Durango, CO	10/18/2001
Maury, Maricela ..... Surfside, FL	10/18/2001
McKeown, James Lee Jr ..... Clearwater, FL	10/18/2001
Men, Yen ..... Kent, WA	10/18/2001
Miller, Nival Rizk ..... Tuscaloosa, AL	10/18/2001
Mkhitaryan, Ashot ..... Van Nuys, CA	10/18/2001
Munguia, Carlos ..... Pinkerington, OH	10/18/2001
Nguyen, Ly Quang ..... Escondido, CA	10/18/2001
Oilschlager, Gerald Albert ..... Long Beach, CA	10/18/2001
Pacher, Catherine Jean ..... Gulfport, MS	10/18/2001
Pak, John Won Chai ..... Fresno, CA	10/18/2001
Pakhanyan, Hakob	10/18/2001