the data needed, and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Eligible State and Territory Applicants

1. Alabama
2. Arizona
3. California
4. Colorado
5. Connecticut
6. Delaware
7. Florida
8. Indiana
9. Iowa
10. North Dakota
11. Pennsylvania
12. South Dakota
13. Tennessee
14. Puerto Rico

Dated: May 19, 2003.

Patricia Morrissey,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 03–13871 Filed 6–2–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0514]

Agency Information Collection Activities; Announcement of OMB Approval; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Irradiation in the Production, Processing, and Handling of Food'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 28, 2003 (68 FR 15209), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0186. The approval expires on May 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: May 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13754 Filed 6–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0200]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Medical Devices—Foreign Letters of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for firms that intend to export certain unapproved medical devices.

DATES: Submit written or electronic comments on the collection of information by August 4, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Export of Medical Devices—Foreign Letters of Approval (OMB No. 0910–0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written

authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States.

FDA uses the written authorization from the foreign country or the certification from a responsible company official in the United States to determine whether the foreign country has any objection to the importation of the device into their country.

The respondents to this collection of information are companies that seek to export medical devices.

FDA estimates the reporting 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
801(e)(2)	20	1	20	2.5	50
Total					50

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

These estimates are based on the experience of FDA's medical device program personnel, who estimate that completion of the requirements of this collection of information should take approximately 2.5 hours to complete.

Dated: May 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13755 Filed 6–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis 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: Arthritis 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 June 23 and 24, 2003, from 8 a.m. to 5 p.m.

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

Contact Person: Johanna Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 23, 2003, the committee will discuss fibromyalgia, clinical trial design, including important disease endpoints in the study, and development of therapies and treatments. On June 24, 2003, the committee will discuss the safety and efficacy of submission tracking number 103795/5123, ENBREL (etanercept), Immunex, for reducing signs and symptoms of active ankylosing spondylitis.

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 13, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12 noon on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 13, 2003, 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 LaNise Giles at 301–827–7001, 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: May 24, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–13757 Filed 6–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Manufacturing Inspections; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of public workshops to discuss current good manufacturing practice (CGMP) issues, including quality subsystems, areas of change control, and quality management. There will also be a discussion of current compliance issues and trends and the status of the part 11 (21 CFR part 11) draft guidance. The first workshop will be held in June 2003, then repeated in July 2003 and August 2003 at different locations to enable as many people to attend as possible. Held in collaboration with the Consumer Healthcare Products Association (CHPA), the workshops are intended to update participants with respect to issues involving CGMP compliance. Participants will also hear from FDA and industry speakers on