We believe the estimate, 177,165 hours per year (38,514 responses × 4.6 hours per response) accurately reflects the burden. We recognize that companies who are less familiar with the data entry system and the Clinical Trials Data Bank will require greater than 4.6 hours per response. However, as sponsor familiarity with the system increases, the hourly estimate will decrease.

Dated: August 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21624 Filed 8–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0200]

Agency Information Collection Activities; Submission for OMB Review; 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 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: Submit written comments on the collection of information by September 24, 2003.

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: Peggy Robbins, Office of Management Programs (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.

Export of Medical Devices—Foreign Letters of Approval (OMB Control Number 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.

In the **Federal Register** of June 3, 2003 (68 FR 33161), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801(e)(2)	20	1	20	2.5	50

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

Dated: August 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21625 Filed 8–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0038]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Device User Fee Cover Sheet; Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device User Fee Cover Sheet; Form FDA 3601'' 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 Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 21, 2003 (68 FR 27818), 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 0910–0511. The approval expires on August 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: August 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21627 Filed 8–22–03; 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). At least one portion of the meeting will be closed 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 September 29, 2003, from 8 a.m. to 5 p.m.; and on September 30, 2003, from 8 a.m. to 1 p.m.

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

Contact Person: Kimberly Topper, 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, or e-mail: topperk@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 both days, the committee will discuss the proposed systemic lupus erythematosis (SLE) concept paper, a preliminary discussion for creating a guidance document for the development of drugs, biologics, and devices for the treatment of SLE.

On September 29, 2003, the committee will discuss the proposed sections regarding the current state of the art, the claims for treatments, and clinical markers. On September 30, 2003, the meeting will be open to the public from 8 a.m. to 11 a.m., and the committee will discuss the section concerning clinical trial design. From 11 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

Procedure: On September 29, 2003, from 8 a.m. to 5 p.m.; and on September 30, 2003, from 8 a.m. to 11 a.m., the meeting will be 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 September 19, 2003. Oral presentations from the public will be scheduled on September 29, 2003, between approximately 12:30 p.m. and 1 p.m., on the topic of claims; between approximately 2:45 p.m. and 3:15 p.m., on the topic of clinical markers; and on September 30, 2003, between approximately 9 a.m. and 9:30 a.m., on the topic of trial design. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 19, 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 desiring to speak who have not registered in advanced may be recognized from the floor by the Chair.

Closed Committee Deliberations: On September 30, 2003, from 11 a.m. to 1 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)).

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 Trevelin Prysock 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: August 18, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–21626 Filed 8–22–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Reproductive Health Drugs; 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: Advisory Committee for Reproductive Health Drugs.

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 September 29 and 30, 2003, from 8:30 a.m. to 5 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Shalini Jain, 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, e-mail: *jains@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12537. Please call the Information Line for up-to-date information on this meeting. Background materials for this meeting when available will be posted on the Web site 1 business day before the meeting at: *www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

Agenda: On September 29, 2003, the committee will discuss issues relevant to the conduct of clinical trials and outcome measures for consideration of approval of drug products for the indications of induction of ovulation and pregnancy in anovulatory, infertile women and development of multiple follicles, and pregnancy in ovulatory women participating in assisted reproductive technology (ART) programs. On September 30, 2003, the committee will discuss new drug application (NDA) 21–322, Luveris (lutropin alfa for injection) Serono, Inc., a recombinant human luteinizing