estimates that in fiscal year (FY) 2002, 109 drug product applications and 46 biological products had Fast Track designation. FDA anticipates that approximately 85 drug product applicants (respondents) and approximately 29 biological product applicants (respondents) will submit at least one Pilot 2 application. Based on information collected from offices within CDER and CBER, the agency further anticipates that the total responses, i.e., the total number of applications received for Pilot 2, will be 90 for drug products and 35 for biological products. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted in a Pilot 2 application in accordance with the guidance, is estimated to be approximately 80 hours. Based on FDA's experience, we expect it will take respondents this amount of time to obtain and draft the information to be submitted with a Pilot 2 application. Therefore, the agency estimates that applicants will use approximately 10,000 hours to complete the Pilot 2 applications.

In the **Federal Register** of June 17, 2003 (68 FR 35901), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection. Four comments were received that did not pertain to the information collection estimates.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Pilot 2 Application | Number of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| CDER | 85 | 1.06 | 90 | 80 | 7,200 |
| CBER | 29 | 1.20 | 35 | 80 | 2,800 |
| Total | | | | | 10,000 |

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

Dated: September 4, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03–22949 Filed 9–4–03; 3:01 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Ophthalmic Devices Panel of the Medical Devices 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*: Ophthalmic Devices Panel of the Medical Devices 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 3, 2003, from 8:30 a.m. to 4 p.m.

*Location*: Gaithersburg Marriott, Salons E, F, and G, 9751 Washingtonian Blvd., Gaithersburg, MD.

*Contact Person*: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, ext. 127, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an implantable contact lens for the correction of moderate to high myopia between -3.0 diopters (D) to -20D with or without astigmatism up to 2.5D and is intended for placement in the posterior chamber of the phakic eye. Background information, including the attendee list, agenda, and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

*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 September 25, 2003. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. Near the end of the committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 25, 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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: September 2, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 03–22790 Filed 9–8–03; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; Re-Contacting Participants in the Observing Protein and Energy Nutrition (Re-Open) Study

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal**