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In the **Federal Register** of June 17, 2003 (68 FR 35901), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection.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**

Register on May 6, 2003, page 24007 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

Proposed Collection: Title: Re-contacting Participants in the Observing Protein and Energy Nutrition (Re-OPEN) Study. *Type of Information Collection Request:* Reinstatement with change (OMB #0925–0465, expiration 07/31/02). *Need and Use of Information Collection:* The agency conducts and funds studies examining the relationship between diet and chronic diseases. The study will collect food intake and physical activity data and body weight measurements on a cohort of approximately 482 free-living men and women, 43 to 72 years of age, who have participated in the 1999 Biologic Specimen-Based Study of Dietary Measurement Error for Nutritional Epidemiology and Surveillance. Participants will complete a food frequency questionnaire, two 4-day food intake records, one 7-day food intake checklist, a physical activity questionnaire, and a body weight measurement. The data will be used to assess the magnitude and structure of dietary measurement error in dietary assessment instruments for dietary surveillance and nutritional epidemiologic studies.

Frequency of Response: One-time study. *Affected Public:* Individuals or households. *Type of Respondents:* U.S. adults 43–72 years. The annual reporting burden is as follows:

Data collection task	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total hour burden	Estimated total annual burden hours requested
Enrollment Form	482	1	0.083	40	13
Food frequency questionnaire	482	1	1	482	161
4-Day food record 1	482	1	1.332	642	214
4-Day food record 2	482	1	1.332	642	214
Food Checklist	482	7	.117	395	132
Physical activity questionnaire	482	1	.25	120	40
Weight measurement	482	1	.25	120	40
Total	482			2443	814

The annualized cost to respondents is estimated at $13,024. There are no Capital Costs to report. There are no Operating and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Amy Subar, Ph.D., Project Officer, National Cancer Institute, EPN 313, 6130 Executive Blvd MSC 7344, Bethesda, MD 20892–7344, or call non-toll-free number (301) 496–8500, or FAX your request to (301) 435–3710, or E-mail your request, including your address, to: *subara@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: September 2, 2003.

Reesa Nichols,

NCI Project Clearance Liaison.

[FR Doc. 03–22828 Filed 9–8–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; the National Diabetes Education Program Comprehensive Evaluation Plan

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The National Diabetes Educations Program Comprehensive Evaluation Plan. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The National Diabetes Education Program (NDEP) is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private organizations. The long-term goals of the NDEP are to improve the treatment and health outcomes of people with diabetes, to promote early diagnosis, and, ultimately, to prevent the onset of diabetes. The NDEP objectives are: (1) To increase awareness of the seriousness of diabetes, its risk factors, and strategies for preventing diabetes and its complications among people at risk for diabetes; (2) to improve understanding about diabetes and its control and to promote better self-management behaviors among people with diabetes; (3) to improve health care providers' understanding of diabetes