educational measures in the Head Start Program. This includes the Head Start National Reporting System (NRS). The Committee is to provide recommendations for integrating NRS with other ongoing assessments of the effectiveness of the program. The Committee will make recommendations as to how NRS and other assessment data can be included in the broader Head Start measurement efforts found in the Family and Child Experiences Survey (FACES), the national Head Start Impact Study, Head Start's Performance Based Outcome System and the ongoing evaluation of the Early Head Start program.

Date: November 1, 2005, 8:30 a.m.–5:30 p.m. (Dinner Recess). November 2, 2005, 8:30 a.m.–4:30 p.m.

Place: The Beacon Hotel, 1615 Rhode Island Ave, NW., Washington, DC 20036.

Agenda: The Committee will hear presentations related to existing Head Start evaluations and NRS implementation and will continue the discussions begun at the first meeting in June 2005.

SUPPLEMENTARY INFORMATION: This, the second meeting of the Committee, is open to the public. Persons wishing to bring written statements or papers focused on relevant, existing research with Head Start populations or on measures appropriate for low-income four- and five-year-old children are welcome to do so. Individuals may e-mail such documents to *Secretaryadvisory-hs@esi-dc.com* or mail to: ESI, ATTN: Xzavier Wright, Head Start Bureau—Secretary's Advisory Committee, 7735 Old Georgetown Road, Suite 600, Bethesda, Maryland 20814.

Documents received shall be presented to the Committee.

The Committee meeting records shall be kept at the Aerospace Center located at 901 D Street, SW., Washington, DC 20447. The Head Start Bureau will also make material related to this meeting available on the Head Start Web site *http://www2.acf.dhhs.gov/programs/hsb/*.

An interpreter for the deaf and hard of hearing will be available upon advance request by contacting *xzavier@esi-dc.com*.

Naomi Goldstein,

Director, Office of Planning, Research and Evaluation.

[FR Doc. 05–20758 Filed 10–17–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0410]

Prescription Drug User Fee Act; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on the Prescription Drug User Fee Act (PDUFA). The legislative authority for PDUFA expires in September 2007. Without further legislation, we will no longer be able to collect user fees for the prescription drug program and resources critical to running the program would become unavailable to us. We invite public comment on the PDUFA program and suggestions regarding what features we should propose for the next PDUFA program.

DATES: The public meeting will be held on November 14, 2005, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by October 31, 2005. You may register electronically at *CBERTraningSuggestions@cber.fda.gov*. Walk-in registration at the meeting site will also be accepted. Submit written comments by December 14, 2005.

ADDRESSES: The meeting will be held at the Natcher Conference Center, National Institutes of Health, Bldg. 45, Center Dr., 9000 Rockville Pike, Bethesda, MD 20815. Parking is limited, and there may be delays entering the NIH campus due to increased security. All visitors' vehicles will be inspected, and visitors must show one form of identification (ID) (such as a government-issued photo ID, driver's license, passport, etc.) We recommend arriving by subway (Metrorail) if possible. NIH is accessible from the Metrorail's ''Red Line'' at the Medical Center/NIH station.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice: Patricia A. Stewart, Office of Policy and Planning (HFP–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2647, FAX: 301–594–6777, e-mail: *Patricia.Stewart@oc.fda.gov*.

For information regarding registration: Melanie Whelan or Kathy Eberhart, Office of Communication, Training and Manufacturers Assistance (HFM–49), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–2000, FAX: 301–827–3079.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing its intention to hold a public meeting on PDUFA. The authority for PDUFA expires in September 2007. Without further legislation, FDA would no longer be able to collect user fees for the prescription drug program. Resources critical to running the program would become unavailable to FDA. We are now considering what features we should propose for the next PDUFA program. We are convening a public meeting to hear stakeholder views on this subject. We are offering the following two general questions for consideration, and we are interested in responses to these questions and any other pertinent information stakeholders would like to share:

1. What is your assessment of the overall performance of the PDUFA program thus far?

2. What aspects of PDUFA should be retained, or what should be changed to further strengthen and improve the program?

We provide the following background on the PDUFA program so potential participants can better understand the history and evolution of the PDFUA program and its current status.

II. What is PDUFA? What Does It Do?

PDUFA, in broad terms, is a series of laws that have authorized us to collect fees from companies that produce certain human drug and biological products. The original PDUFA (PDUFA I) was enacted in 1992 (as the Prescription Drug User Fee Act, Public Law 102–571) and had a 5-year life. In 1997, as PDUFA I expired, Congress passed the FDA Modernization Act (FDAMA, Public Law 105–115). FDAMA included, among other things, an extension of PDUFA (PDUFA II) for an additional 5 years. In 2002, Congress extended PDUFA again for 5 years (PDUFA III) through the Public Health Security and Bioterrorism Preparedness and Response Act (Public Law 107–188).

PDUFA's original intent was to provide additional revenues to us so that we could hire more staff to improve the process for the review of human

drugs to make important drug therapies available to patients sooner without compromising review quality.

Under PDUFA, the industry provided additional funds through user fees that would be available to FDA, in addition to appropriated funds, to spend on the process for the review of human drugs. Our authority to collect user fees is ''triggered'' only when a base amount of appropriated funds, adjusted for inflation, is spent.

In conjunction with PDUFA, we set review performance goals that became more stringent each year. These goals applied to the review of original new human drug and biological product applications, resubmissions of original applications, and supplements to approved applications. During the first few years of PDUFA I, we eliminated backlogs of original applications and supplements that had formed in earlier years when the program had fewer resources. Phased in over the 5 years of PDUFA I, the goals were to review and act on 90 percent of priority new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements (i.e., submissions for products providing significant therapeutic gains) within 6 months of submission of a complete application; to review and act on 90 percent of nonpriority original NDAs, BLAs, and efficacy supplements within 12 months, and on resubmissions and manufacturing supplements within 6 months. Over the course of PDUFA I, we exceeded all of these performance goals.

Under PDUFA II, some review performance goals continued to shorten. For example, by 2002, the PDUFA II goals called on us to review and act on 90 percent of the following:

- Standard new drug and biological product applications and efficacy supplements within 10 months;
- Chemistry and Manufacturing Control supplements requiring prior FDA approval within 4 months; and
- Class 1 resubmissions (that respond to relatively minor deficiencies such as labeling changes) within 2 months.

In addition, PDUFA II added a new set of procedural goals intended to improve our interactions with industry sponsors during the early years of drug development. For example, these goals called for us to meet with sponsors and provide followup meeting minutes within a certain number of days, and provide responses to questions on industry submitted special study protocols within a certain number of days.

We met or exceeded nearly all of our goals for application review and for these other procedures under PDUFA II.

Under PDUFA III, additional money from user fees was authorized, and a mechanism placed in the act to annually account for increases in workload associated with the process for the review of human drugs. For the first time, PDUFA III also authorized us to spend user fee funds on certain aspects of postmarket risk management. The review performance and procedural goals associated with PDUFA III were similar to those under PDUFA II for fiscal year (FY) 2002 performance levels, but the PDUFA III program addressed drug safety issues and established several new initiatives to improve application submissions and agency-sponsor interactions during drug development and application review.

The goals under PDUFA III also included new provisions, for example, to develop guidance for industry on good risk assessment, risk management, and pharmacovigilance practices, to fund outside expert consultants to help evaluate and improve review management processes, and to centralize accountability and funding for all PDUFA information technology initiatives and activities.

Furthermore, in conjunction with PDUFA's reauthorization in 2002, we committed to the creation of a guidance for our review staff and industry on good review management principles and practices as they apply to the first cycle review of NDAs, BLAs, and efficacy supplements, and we announced the guidance's availability in the **Federal Register** of March 31, 2005 (70 FR 16507). We also set a goal of testing whether providing early review of selected applications and additional feedback and advice to sponsors during drug development for selected products can shorten drug development and review times. There were two continuous marketing application (CMA) pilot programs; CMA Pilot 1 provides for the review of a limited number of presubmitted portions of NDAs and BLAs. Under CMA Pilot 2, FDA and applicants can enter into agreements to engage in frequent scientific feedback and interactions during the investigational new drug phase of product development. The first-cycle and CMA initiatives are currently being evaluated to determine their impact on the effectiveness and efficiency of FDA-sponsor communications, product development, and regulatory review.

We have published a number of reports that may help inform the public about PDUFA and its implementation. Key **Federal Register** documents, such as, PDUFA-related guidances, legislation, performance reports, and financial reports, can be found at *http://www.fda.gov/oc/pdufa/* and *www.fda.gov/cder/pdufa*. We may make additional information about PDUFA available on our Web site at *http://www.fda.gov/oc/pdufa*. Additional information about the activities of the involved FDA product centers can be found in the Center for Drug Evaluation and Research 2004 Report to the Nation (*http://www.fda.gov/cder/reports/rtn/2004/rtn2004.htm*), and the Center for Biologics Evaluation and Research FY 2004 Annual Report (*http://www.fda.gov/cber/inside/annrpt.htm*).

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will We Use?

Through this notice, we are announcing that we will convene a public meeting to hear stakeholder views on what features we should advance in proposing the PDUFA IV program.

We will conduct the meeting on November 14, 2005, at the Natcher Conference Center, National Institutes of Health (NIH) (see **ADDRESSES**). In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (such as patient advocates, consumer protection, industry, health professionals, and academic researchers). We will also provide an opportunity for individuals to make presentations at the meeting, and for organizations and individuals to submit written comments to the docket after the meeting

B. What Questions Would We Like the Public to Consider?

Please consider the following questions for this meeting:

1. What is your assessment of the overall performance of the PDUFA program thus far?

2. What aspects of PDUFA should be retained, or what should be changed to further strengthen and improve the program?

C. How Do You Register for the Meeting or Submit Comments?

If you wish to attend and/or make a presentation at the meeting, please send an e-mail message to: *CBERTrainingSuggestions@cber.fda.gov* by October 31, 2005. Your e-mail should include the following information: Name, company, company address, company phone number, and e-mail address. You will receive a confirmation within 2 business days.

We also will accept walk-in registration at the meeting site, but

space is limited, and we will close registration when maximum seating capacity (approximately 500) is reached.

We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

If you require special accommodations due to a disability, please contact Patricia A. Stewart at least 7 days in advance.

If you would like to submit comments regarding PDUFA IV, please send your comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

D. Will Meeting Transcripts Be Available?

We will prepare a meeting transcript, and we will make the transcript available on our Web site (*http://www.fda.gov*) after the meeting. We anticipate that transcripts will be available approximately 30 working days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management (see **ADDRESSES**), between 9 a.m. and 4 p.m. Monday through Friday.

Dated: October 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20875 Filed 10–14–05; 8:57 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review, Comment Request; 5 A Day Customized Survey

SUMMARY: In compliance with the requirement of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), 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. The proposed information collection below was previously published in the **Federal Register** on May 18, 2005, page 28544–28545 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 after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: *Title:* 5 A Day Customized Survey. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of the 5 A Day Customized Survey is to further the development of standardized measures of consumer knowledge, attitudes, and behaviors regarding the consumption of fruits and vegetables. Specifically, the Customized Survey will allow for validation of the new ''cup'' portion sizes (consistent with the 2005 Dietary Guidelines) and identify the most efficacious short screener methods of fruit and vegetable intake. In addition, the Customized Survey will measure established predictors of fruit and vegetable consumption at the national level and explore new predictors and constructs not previously examined for fruit and vegetable consumption. The sample will be drawn from a consumer opinion panel methodology using balancing techniques to mirror the U.S. general population on a set of key demographic variables. A separate sample of African Americans will be drawn from the panel.

Prior to fielding the Customized Survey, two pilot studies will be completed as the first phase of this research. Pilot respondents will be drawn from the same consumer panel and have similar demographics as respondents in the main study. A brief description of the two pilot studies follows. In pilot study 1, respondents will initially complete a brief screener questionnaire, three 24-hour dietary recalls over the phone, followed by the Customized Survey by mail. To account for diversity in eating habits, dietary recalls will be obtained for 2 weekdays and 1 weekend per respondent. The recalls will be conducted via phone by trained interviewers using the University of Minnesota's Nutrition Data System (NDS). After completing the dietary recalls pilot respondents will be mailed the Customized Survey within 2 weeks. Fruit and vegetable consumption as assessed by the average of the three 24-hour recalls will be compared with the fruit and vegetable consumption measures from the Customized Survey. In pilot study 2, respondents will complete the Customized Survey by mail at two points in time, six to eight weeks apart. The analysis in pilot study 2 will focus on a rigorous evaluation of the psychometric properties of the Customized Survey instrument to ensure that item-level and instrument-level reliability and validity has been achieved before proceeding to the main data collection phase of the study. Based on the findings of the pilot studies, minor modifications may be made to the Customized Survey prior to the implementation of the main study. *Frequency of response:* Main study, one time response (5 A Day Customized Survey). Pilot study 1, five times (screener, three 24-hour dietary recalls, 5 A Day Customized Survey). Pilot study 2, two times (5 A Day Customized Survey at two points in time). *Affected Public:* Individuals. *Type of Respondents:* U.S. adults. The annual reporting burden is as follows: *Estimated Number of Respondents:* 5,875; *Estimated Number of Responses per Respondent:* 1, 2 or 5; *Average Burden Hours per Response:* .416; and *Estimated Total Annual Burden Hours Requested:* 2,467.90. The annualized cost to respondents is estimated at: $46,384.28. The annual reporting burden is summarized in exhibit 1 below. There are no Operating or Maintenance Costs to report.

EXHIBIT 1

Type of respondents *	Number of respondents	Frequency of response	Average burden hours	Annual hour burden
Pilot Study 1:				
Screener	480	1	.08	38.4
Dietary Recall 1	380	1	.50	190
Dietary Recall 2	325	1	.50	162.5