Description of Respondents: Businesses or other for-profit organizations.

FDA estimates the 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 Respondent	Total Hours
101.93	2,500	1	2,500	.75	1,875

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

The agency believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or in labeling of dietary supplements. The agency is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. This estimate is based on the average number of notification submissions received by the agency in the preceding 12 months.

Dated: July 17, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11642 Filed 7–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0278]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act.

DATES: Submit written or electronic comments on the collection of information by September 22, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Elizabeth Berbakos, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 **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 these topics: (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.

Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act—(OMB Control Number 0910–0518)— Extension

FDA is requesting OMB approval under the PRA (44 U.S.C. 3507) for the reporting and recordkeeping requirements contained in the guidance for industry entitled ''Continuous Marketing Applications (CMA): Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA.'' This guidance discusses how the agency will implement a pilot program for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of the development of certain Fast Track drug and biological products. Applicants are asked to apply to participate in the Pilot 2 program.

In conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA), FDA agreed to meet specific performance goals (PDUFA Goals). The PDUFA Goals include two pilot programs to explore the CMA concept. The CMA concept builds on the current practice of interaction between FDA and applicants during drug development and application review and proposes opportunities for improvement. Under

the CMA pilot program, Pilot 2, certain drug and biologic products that have been designated as Fast Track (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) are eligible to participate in the program. Pilot 2 is an exploratory program that allows FDA to evaluate the impact of frequent scientific feedback and interactions with applicants during the investigational new drug application (IND) phase. Under the pilot program, a maximum of 1 Fast Track product per review division in FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) is selected to participate. This guidance provides information regarding the selection of participant applications for Pilot 2, the formation of agreements between FDA and applicants on the IND communication process, and other procedural aspects of Pilot 2. FDA began accepting applications for participation in Pilot 2 on October 1, 2003.

The guidance describes 1 collection of information: Applicants who would like to participate in Pilot 2 must submit an application (Pilot 2 application) containing certain information outlined in the guidance. The purpose of the Pilot 2 application is for the applicants to describe how their designated Fast Track product would benefit from enhanced communications between FDA and the applicant during the product development process.

FDA's regulation at § 312.23 (21 CFR 312.23) states that information provided to the agency as part of an IND must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs. 21 CFR part 312 and FDA Form 1571 have a valid OMB control number: OMB control number 0910–0014, which expires May 31, 2009.

In the guidance document, CDER and CBER ask that a Pilot 2 application be submitted as an amendment to the application for the underlying product under the requirements of § 312.23; therefore, Pilot 2 applications should be submitted to the agency in triplicate with Form FDA 1571. The agency recommends that a Pilot 2 application be submitted in this manner for two reasons: (1) To ensure that each Pilot 2 application is kept in the administrative file with the entire underlying application, and (2) to ensure that pertinent information about the Pilot 2 application is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the agency to monitor progress on activities.

Under the guidance, the agency asks applicants to include the following information in the Pilot 2 application:

- Cover letter prominently labeled ''Pilot 2 application;''
- IND number;
- Date of Fast Track designation;
- Date of the end-of-phase 1 meeting, or equivalent meeting, and summary of the outcome;
- A timeline of milestones from the drug or biological product development program, including projected date of new drug application (NDA)/biologics license application (BLA) submissions;
- Overview of the proposed product development program for a specified disease and indication(s), providing information about each of the review disciplines (e.g., chemistry/manufacturing/controls, pharmacology/toxicology, clinical, clinical pharmacology and biopharmaceutics);
- Rationale for interest in participating in Pilot 2, specifying the ways in which development of the subject drug or biological product would be improved by frequent scientific feedback and interactions with FDA and the potential for such communication to benefit public health by improving the efficiency of the product development program; and
- Draft agreement for proposed feedback and interactions with FDA.

This information is used by the agency to determine which Fast Track products are eligible for participation in Pilot 2. Participation in this pilot program is voluntary.

Based on the number of Pilot 2 applications submitted to CDER and CBER during fiscal year 2004 and 2005, we estimate that the number of applications received annually for Pilot 2 is 7 for products regulated by CDER and 1 for products regulated by CBER. FDA anticipates that approximately 7 applicants (respondents) will submit these Pilot 2 applications annually to CDER and approximately 1 applicant (respondent) will submit these Pilot 2 applications annually to CBER. 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 use approximately 640 hours annually to submit the Pilot 2 applications.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Pilot 2 Application	No. of Respondents	No. of Responses per Response	Total Responses	Hours per Response	Total Hours
CDER	7	1	7	80	560
CBER	1	1	1	80	80
Total					640

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

Dated: July 17, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11643 Filed 7–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0486]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Public Health Notification (formerly known as Safety Alert/Public Health Advisory) Readership Survey

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: Fax written comments on the collection of information by August 23, 2006.

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: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472

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.

FDA Public Health Notification (formerly known as Safety Alert/Public Health Advisory) Readership Survey (OMB Control Number 0910–0341)—Extension.

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The Public Health Notification (PHN) and (2) the Preliminary Public Health Notification (PPHN). The PHN is published when CDRH has information or a message to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type, and that information may not be readily available to the affected target audience in the health care community, and CDRH can make recommendations that will help the health care practitioner mitigate or avoid the risk.

The PPHN is also published when CDRH has information to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type. However, two additional conditions exist that make the use of this type of notification preferable. First, CDRH's understanding of the problem, its cause(s), and the scope of the risk is still evolving, and in order to minimize the risk, the center believes that health care practitioners need the information they have, however incomplete, as soon as possible. Second, the problem is being actively investigated by the center, the industry, another agency, or some other reliable entity, so that the center expects to be able to update the PPHN when definitive new information becomes available.

Notifications are sent to organizations affected by the risks discussed in the notification, such as hospitals, nursing homes, hospices, home health care agencies, retail pharmacies, and other health care providers. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to publish notifications.

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly notifications for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future notifications electronically, as well as how the PHN program might be improved.

The information collected will be used to shape FDA's editorial policy for the PHN and PPHN. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

In the **Federal Register** of December 22,2005 (70 FR 76054), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	.17	157

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

Based on the history of the PHN program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: July 17, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11644 Filed 7–21–06; 8:45 am]

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