DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0278]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 June 20, 2007.

ADDRESSES: 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. All comments should be identified with the OMB control number 0910–0518. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Liz Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–1482.

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.

Guidance for Industry on Continuous Marketing Applications: Pilot—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 one 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 one 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 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.

In the **Federal Register** of July 24, 2006 (71 FR 41819), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Pilot 2 Application	No. of Respondents	No. of Responsesper 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: May 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9709 Filed 5–18–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007E–0066]

Determination of Regulatory Review Period for Purposes of Patent Extension; NOXAFIL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NOXAFIL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions 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: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product NOXAFIL (posaconazole). NOXAFIL is indicated for prophylaxis of invasive *Aspergillus* and *Candida* infections in patients, 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant recipients with Graft versus Host Disease or those with hematologic malignancies with prolonged neutropenia from chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NOXAFIL (U.S. Patent No. 5,661,151) from Schering Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 12, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NOXAFIL represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NOXAFIL is 3,650 days. Of this time, 3,382 days occurred during the testing phase of the regulatory review period, while 268 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: September 19, 1996. The applicant claims November 6, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 19, 1996, which was 30 days after FDA receipt of the first IND.