

reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Data submission is voluntary and is self reported by the health care provider.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 2003D-0229]

Draft Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA."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 being asked to apply to participate in the Pilot 2 program.

DATES: Submit written comments on the draft guidance by August 1, 2003. General comments on agency guidance documents are welcome at any time. Submit written or electronic comments on the collection of information by August 15, 2003.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communications, Training, and

Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist either office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidances.

Submit written comments on the draft guidance and on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD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. Submit electronic comments on the draft guidance and the collection of information to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: John Jenkins, Center for Drug Evaluation and Research (HFD-020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-3937, or Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION:**I. Description of the Guidance**

FDA is announcing the availability of a draft guidance for industry entitled "Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA." 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 continuous marketing application (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 this 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 Pilot 2. Pilot 2 is an exploratory program that will allow 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 CDER and CBER will be 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. The FDA will begin accepting applications for participation in Pilot 2 on October 1, 2003.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) written or electronic comments on the draft guidance and the information collection. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (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. 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 the **Federal Register** concerning each proposed 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: (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