

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0281]

PDM

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Certifier	D. Hawkins

Pilot Program To Evaluate Proposed Name Submissions; Concept Paper

AGENCY: Food and Drug Administration, HHS.

73 FR 58604
10/7/08

ACTION: Notice; availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a concept paper entitled "PDUFA Pilot Project Proprietary Name Review." The concept paper provides information to pharmaceutical firms about how to evaluate proposed propriety names and submit the data generated from those evaluations to FDA for review under an anticipated pilot program. FDA plans to begin enrollment in the pilot program in fiscal year (FY) 2009.

DATES: Submit written or electronic comments on the pilot program at any time.

ADDRESSES: Submit written requests for single copies of the concept paper to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD, 20852-1448. The concept paper may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket

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number found in brackets in the heading of this document. Submit written comments on the pilot program 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.regulations.gov>. See I. **BACKGROUND** of the **SUPPLEMENTARY INFORMATION** section for electronic access to the concept paper.

FOR FURTHER INFORMATION CONTACT:

Lana Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg, 51, rm. 6196, Silver Spring, MD 20993, 301-796-0518, FAX: 301-847-8753, e-mail: lane.pauls@fda.hhs.gov, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In its 2006 report “Preventing Medication Errors,” the Institute of Medicine noted that “[i]n particular, drug names that look or sound alike increase the risk of medication errors.” FDA also has determined that many of the medication errors reported to the agency result from proprietary names that look or sound like the names of other medical products. Reducing the potential for medication errors due to proprietary name confusion is part of FDA’s ongoing medical product risk management effort. In 2003, FDA held two public meetings that explored many of the issues involved in proprietary name review:

- The June 26, 2003, public meeting on “Minimizing Medication Errors—Methods for Evaluating Proprietary Names for Their Confusion Potential,” (Docket No. 2002N–0201) (68 FR 32529; May 30, 2003); information about the meeting is available at <http://www.fda.gov/cder/meeting/drugNaming.htm>.
- The December 4, 2003, meeting of the Drug Safety and Risk Management Advisory Committee (68 FR 65075; November 18, 2003); transcripts, presentations, and materials from the meeting are available at <http://www.fda.gov/ohrms/dockets/ac/cder03.html#DrugSafetyRiskManagement>.
- On June 5 and 6, 2008, FDA held a public technical meeting to discuss a draft concept paper (see meeting notice at 73 FR 27001; May 12, 2008) describing the pilot and FDA’s thinking about how pharmaceutical firms could participate in the pilot to evaluate proposed proprietary names and submit the data generated to FDA for review. Transcripts, presentations, and materials from the meeting are available at http://www.fda.gov/cder/drug/MedErrors/meeting_2008.htm.

In title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), Congress reauthorized and expanded the Prescription Drug User Fee program for FYs 2008 to 2012 (PDUFA IV). As part of the performance goals and procedures set forth in an enclosure to the letter from the Secretary of the Health and Human Services referred to in section 101(c) of FDAAA, FDA agreed to publish a concept paper on and implement a pilot program to enable pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and submit the data generated from those evaluations to FDA for review. This process is consistent with other areas of drug review in which FDA evaluates data generated by firms rather than producing such data independently. FDA agreed to conduct a public meeting

to discuss the content of the concept paper, which describes the logistics of the pilot program, proposed recommendations for carrying out a proprietary name review, and the way FDA intends to review submissions made under the pilot program. FDA issued the draft concept paper for discussion at the June 5 and 6, 2008, meeting, and after considering comments received at the meeting and to the public docket, FDA finalized the concept paper. Changes made to the final concept were editorial and primarily clarifying. There were two substantive changes: (1) Participation in the portion of the pilot addressing review of promotional aspects of proposed proprietary names has been made optional for applicants who choose to participate in the pilot, so that they may choose to submit only safety-related assessments and (2) additional information has been provided to explain how the agency recommends reviews be undertaken for names intended for over-the-counter drugs.

FDA expects to begin enrollment into the pilot program no later than the end of FY 2009. At the end of FY 2011, or subsequent to accruing 2 years of experience with pilot program submissions, FDA intends to evaluate the pilot program to determine whether to have applicants perform their own name analysis and submit resulting data to FDA for review. The results of this pilot program and recommended additions and/or changes to methods based on the reported results will be discussed in a future public meeting. Following that meeting, a draft guidance will be published describing the best test methods for proprietary name evaluation.

II. Comments

FDA welcomes suggestions for and comments regarding the pilot program. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the pilot program.

Submit a single copy of electronic comments or two paper copies of any mailed 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.

Dated: 10/1/08
October 1, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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