Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–22437, appearing on page 55114 in the **Federal Register** of Wednesday, September 24, 2008, the following correction is made:

1. On page 55114, in the third column, in the *Procedure* section, the fourth sentence is corrected to read ''Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m.''

There are no other changes to the document.

Dated: October 1, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–23718 Filed 10–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0525]

Draft Guidance for Industry on New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products; Availability

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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.'' As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures, FDA agreed to publish draft guidance by September 30, 2008, for medical imaging devices with ''contrast agents or radiopharmaceuticals.'' FDA intends this draft guidance to assist developers of medical imaging devices and imaging drug/biological products that provide image contrast enhancement. Particularly this guidance focuses on approaches in developing new contrast indications for imaging devices for use with already approved imaging products. FDA intends for the recommendations in this guidance to promote timely and effective review of, and consistent and appropriate regulation and labeling for imaging drugs and devices.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 5, 2009.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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 the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products (HFG–3), Office of the Commissioner, Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.'' This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products. 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.

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807 have been approved under 0910–0120. The collections of information in 21 CFR part 814 have been approved under 0910–0231. The collections of information in 21 CFR part 314 have been approved under 0910–0001.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: September 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–23712 Filed 10–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0281]

Pilot Program To Evaluate Proposed Name Submissions; Concept Paper

AGENCY: Food and Drug Administration, HHS.

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 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: *lana.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: October 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–23715 Filed 10–6–08; 8:45 am]

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