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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. FDA–2008–N–0281]

Pilot Program to Evaluate Proposed Name Submissions; Concept Paper; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) are announcing a public technical meeting in preparation for a pilot program to enable pharmaceutical firms to evaluate proposed propriety names and submit the data generated from those evaluations to FDA for review. The purpose of the public technical meeting is to discuss a concept paper that 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 plans to formally issue the concept paper by the end of fiscal year (FY) 2008 and expects to begin enrollment in the pilot program in FY 2009.

DATES: The public meeting will be held on June 5 and 6, 2008, from 8:30 a.m. to 5 p.m. each day. Register to make a presentation at the meeting by May 23, 2008. See section III of this document for information on how to attend or present at the meeting. Submit any written or electronic comments regarding the concept paper and pilot program by July 7, 2008.

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ADDRESSES: The public meeting will be held at the Crowne Plaza Hotel, 877 Georgia Ave., Silver Spring, MD 20910 (Metro: Silver Spring Station on the Red Line). Submit written or electronic requests to make a presentation at the meeting to Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**). A draft concept paper will be available soon.

Comment Submissions: Submit written comments 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.*

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.*

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Medicine (IOM) in its 2006 report "Preventing Medication Errors" 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.*

FDA reviews proprietary names from both promotional and safety perspectives. The promotional review of proposed names considers whether the name functions to overstate the efficacy, minimize the risk, broaden the indication, make unsubstantiated superiority claims for the product, or is overly fanciful. The safety review of a proposed name is based on the findings of a Failure Modes and Effects Analysis of the proprietary name, and is focused on the avoidance of medical errors. FDA not only considers the potential for a name to be spelled similarly and/or sound similar to a currently marketed product or one that is in the approval pipeline, but also considers the potential for the proposed name to inadvertently function as a source of error for reasons other than look and sound-alike name confusion, for instance whether the abbreviation for the drug would be similar to the abbreviation of another drug product.

Consideration also is given to the proposed product's characteristics including its intended use, dosage form and strength, and route of administration, because the product characteristics provide a context for communication of the product name and ultimately determine the use of the product in the usual clinical practice setting. In addition, because product-name confusion can occur at any point in the medication use process, FDA considers the potential for confusion throughout the process, including

product procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.

Currently, the data generated to access this information is internal to FDA. However, there have been a number of calls for industry to become involved in the name testing process including IOM's 2006 report, IOM's 1999 report "To Err is Human," Recommendation #238 from the HHS Advisory Committee on Regulatory Reform's November 21, 2002 report, and, most recently, in the Prescription Drug User Fee Act (PDUFA IV) performance goals.

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 FY 2008 through FY 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 intends the concept paper to provide transparency to the FDA review processes, as well as to provide a consistent, scientific approach to the review of proprietary names data. FDA agreed to conduct a public meeting to discuss the content of the concept paper, which will describe 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 is developing the concept paper, which contains its current thinking on the

logistics of the pilot and name testing and evaluation under the pilot. The concept paper will be available at the Division of Dockets Management and on the Internet prior to the meeting (see **ADDRESSES**). FDA welcomes written and electronic comments on the draft concept paper before and after the public meeting (see section IV of this document).

II. Scope of Public Meeting

At the public meeting, FDA will present its current thinking on proprietary name review testing and the proposed pilot program, and will solicit feedback from industry, patient safety groups, academics, health care professionals, other governmental agencies, and the public. The meeting will include panel discussions and individual and/or joint presentations. Some of the key questions that will be considered at the meeting include, but are not limited to, the following:

1. What are best practices in safety and promotional testing of proprietary names? What are the limitations of current methods and how may they be overcome?

2. What combination of tests should be undertaken and what data should be submitted by sponsors participating in the pilot? Discussion of testing procedures should focus on advances in the field of name testing since the 2003 public meetings (e.g., improvements in test design, accuracy, and validation, as well as use of practitioner input in the range of clinical settings in which drugs are procured, prescribed, prepared/dispensed, administered, and monitored).

3. How should testing be standardized to achieve valid, reliable results across studies?

4. What criteria should FDA consider in evaluating the testing done and the data submitted?

5. How should the pilot program be structured and evaluated?

6. Are there any public health concerns raised by the pilot program and how should they be addressed?

Speakers who wish to present material in the public meeting must register before the meeting (see section III of this document). Time will be allowed for questions and answers after each panel discussion.

Information gathered from the meeting and from comments submitted to the docket will be used to develop the final concept paper. FDA intends to publish the final concept paper by the end of FY 2008 and expects to begin enrollment in the pilot in FY 2009.

III. Attendance and Registration

There is no fee to attend the meeting, and attendees who do not wish to make an oral presentation do not need to register. Seating will be on a first-come, first-served basis.

If you would like to make an oral presentation during the meeting, you must register and provide an abstract of your presentation by close of business on May 23, 2008. You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, and e-mail address to Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**). You should identify the topic or section of the draft concept paper you wish to address in your presentation, whether you wish to address comments on day one or day two, and the approximate time requested for your presentation. FDA has identified topics of special interest in section II of this document and is posting a draft concept paper and agenda on the Internet (see **ADDRESSES**). The Centers may change the time allotted depending on the number of people requesting to present. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation.

Persons registered to make an oral presentation should check in before the meeting. If you need special accommodations because of disability, please contact Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding issues and questions presented in the concept paper or at the meeting. 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.*

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division

of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: MAY 06 2008

May 6, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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