

drug applications (NDAs) and abbreviated new drug applications (ANDAs) to FDA. The input received at the workshop and from comments received during and after the workshop may be considered in developing a draft guidance on this topic.

DATES: The public meeting will be held on June 26, 2003, from 8 a.m. to 5:30 p.m. Registrants must sign in beginning at 7:30 a.m. on June 26. Submit written or electronic requests to speak at the public meeting by June 13, 2003. Written or electronic comments on the questions will be accepted until July 15, 2003.

ADDRESSES: The public meeting will be held at the Renaissance Washington DC Hotel, 999 9th St. NW., Washington, DC 20001, 202-962-4470. The hotel may be reached by Metro using the Gallery Place/Chinatown Station on the red line. Seating will be limited to the first 300 people registered.

Submit written or electronic requests to speak and comments to Mary Gross (see **FOR FURTHER INFORMATION CONTACT**) by June 13, 2003. A transcript of the workshop will be available for review after the meeting at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and on the Internet at <http://www.fda.gov/ohrms/dockets>.

FOR FURTHER INFORMATION CONTACT:

Those wishing to speak should contact: Mary Gross, Office of Drug Safety (HFD-400), Center for Drug Evaluation and Research (CDER), 5600 Fishers Lane, Rockville, MD 20857, 301-827-7849, e-mail: grossm@cderr.fda.gov.

Those wishing to attend the meeting should contact: Elizabeth Scheiman, PhRMA, 1100 15th St. NW., Washington, DC 20005, 202-835-3533, FAX: 202-572-7797, e-mail: elizabeth.scheiman@phrma.org.

Those wishing to attend the meeting should preregister by June 20, 2003. You will be asked to provide your name, affiliation, and e-mail address to register.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has determined that many of the medication errors reported to the agency result from medical products having 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.

Recommendation #7.3 in the December 1999 Institute of Medicine report proposed that FDA "require pharmaceutical companies to test (using FDA approved methods) proposed drug names to identify and remedy potential sound alike and look alike confusion with existing drug names." Subsequently, the Office of the Secretary published Recommendation #238 (from the November 21, 2002, report from the HHS Advisory Committee on Regulatory Reform). This recommendation calls for FDA to shift, in most cases, from performing drug name safety testing to reviewing data submitted by sponsors who have followed protocols designed to evaluate their products' names for possible look-alike and sound-alike errors prior to FDA approval.

This meeting is intended to encourage an open public discussion with representatives from industry, the health care professions, consumer groups, academia, or other interested individuals on how best to minimize the potential for medication errors due to similarities in drug names, including discussion of current methods and approaches being used to evaluate the potential for name confusion.

This public meeting is being cosponsored by FDA, ISMP, and PhRMA. The meeting discussion will not address other factors that may contribute to medication errors such as poor handwriting, incomplete patient and drug information, the use of abbreviations, or working and staffing conditions. The meeting will also not cover the evaluation of proprietary names for their promotional implications. FDA will be developing questions to help facilitate discussion and obtain public feedback. Questions will be available on the CDER workshop Web site at <http://www.fda.gov/cder/workshop.htm> (choose Minimizing Medication Errors—Evaluating the Drug Naming Process; Public Meeting).

II. Scope of the Meeting

The meeting will include expert speakers from regulated industry, academia, health professional groups, and FDA. Independent experts will discuss the use of sampling, questionnaire design, handwriting and voice recognition models, expert committees, computer assisted decision analysis, and failure modes and effects analysis as a potential tool to minimize naming errors resulting from look-alike and sound-alike names. Panels will be assembled to stimulate discussion among the experts and with the audience. Time will be allowed for persons who wish to provide comments

on the questions posed in the **Federal Register**. Speakers who wish to participate in the open public hearing must register by June 2, 2003. Time will also be allowed for questions and answers after each panel discussion.

III. Registration and Requests for Oral Presentation

To speak at the meeting, you must preregister by June 2, 2003. Requests must be submitted electronically or in writing. In your request to speak, you should state the questions you will be addressing and the amount of time you wish to speak. Requests to speak will be accepted on a first-come, first-served basis. Individuals who register to speak will be notified of the scheduled time before the workshop and will have reserved seating. Depending on the number of speakers, FDA may need to limit the time allotted for each presentation. Speakers must submit two copies of each presentation by the registration date. If you need special accommodations due to a disability, please inform the registration contact person when you register. Presentations should be limited to the questions being made available on the Internet at <http://www.fda.gov/cder/workshop.htm>. Preregistration is necessary to attend this meeting, as seating is limited. Attendees should preregister by June 20, 2003.

IV. Request for Comments

Regardless of attendance at the meeting, interested persons may submit written or electronic comments on the issue of similarity in drug naming or questions posed on <http://www.fda.gov/ohrms/dockets> to the Dockets Management Branch (see **ADDRESSES**). You should annotate and organize your comments to identify the specific question or questions you are addressing. Two paper copies of any mailed comments are to be submitted, 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. Transcripts of the hearing also will be available for review at the Dockets Management Branch.

Dated: May 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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