

Notices

Federal Register

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

Display Date: 8-4-03 Publication Date: 8-5-03

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 19, 2003, from 8 a.m. to 2 p.m.

Location: Holiday Inn, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Shalini Jain, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, e-mail at: jains@cder.fda.gov, or FDA Advisory Committee Information Line, 1 800-741-8138 (301-443-0572 in the Washington, DC area), code 12535. Please call the information line for up to date information on this meeting. Background materials for this meeting, when available, will be posted on the Web site 1 business day before the meeting at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>.

Agenda: The committee will discuss current screening methods to assess sound alike and look alike proprietary drug names, in order to reduce the incidence of medication errors resulting from look-alike and sound-alike names. This advisory committee meeting is in followup to FDA, Institute for Safe Medication Practices, and the Pharmaceutical Research and Manufacturers of America public meeting on the same subject, held on June 26, 2003.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written

submissions may be made to the contact person by September 12, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 12, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability; please contact Kimberly Topper at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 25, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-??-?? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

[Federal Register: May 30, 2003 (Volume 68, Number 104)]
[Notices]
[Page 32529-32530]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr30my03-88]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0201]

Minimizing Medication Errors--Methods for Evaluating Proprietary
Names for Their Confusion Potential; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in cooperation with the Pharmaceutical Research and Manufacturers Association (PhRMA) and the Institute for Safe Medication Practices (ISMP), is announcing a public meeting to explore current methods being used to evaluate proprietary drug names to reduce medication errors due to similarity in drug names. The goal of the meeting is to solicit views on a recommendation by the Department of Health and Human Services (HHS) that drug manufacturers perform proprietary name testing prior to submitting new

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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 S 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 meet 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 [numsign]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 [numsign]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.
[FR Doc. 03-13591 Filed 5-28-03; 11:17 am]

BILLING CODE 4160-01-S

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DISPLAY DATE: 08-05-03
PUBLICATION DATE: 08-06-03

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0201]

Minimizing Medication Errors—Methods for Evaluating Proprietary Names for their Confusion Potential; Public Meeting; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) held a public meeting on June 26, 2003, to discuss current methods and approaches used to evaluate proprietary drug names for similarities. In the document that published in the **Federal Register** of May 30, 2003 (68 FR 32529), announcing the June 26, 2003, meeting, the agency requested comments by July 15, 2003, on questions relating to the issues discussed at the meeting. FDA is reopening the comment period until [insert date 30 days after date of publication in the **Federal Register**], on issues discussed at that meeting in response to a request that the agency allow interested parties additional time to review and to submit comments on this issue.

ADDRESSES: 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 questions to <http://www.fda.gov/ohrms/dockets>.

DATES: Submit written or electronic comments by [insert date 30 days after date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT:

Mary C. Gross, Center for Drug Evaluation and Research (HFD-400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7849, FAX: 301-443-9664.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 30, 2003, FDA published a document announcing a public meeting, which was to be held on June 26, 2003, in cooperation with the Institute for Safe Medication Practices and the Pharmaceutical Research and Manufacturers of America. The purpose of the meeting was to encourage discussion among representatives from industry, the health care professions, consumer groups, academia, and others on how best to minimize the potential for medication errors due to similarities in drug names, including a discussion of current methods and approaches. The Department of Health and Human Services (DHHS), Office of the Secretary published a recommendation (from the November 21, 2002, report from the DHHS Advisory Committee on Regulatory Reform) that called for FDA to shift, in most cases, from performing drug name safety testing to reviewing data submitted by sponsors. At the June 26, 2003, meeting, several tools with the potential to minimize naming errors resulting from look alike and sound alike drug names were considered. Potential tools included sampling, questionnaire construction, handwriting and voice recognition models, expert

committees, computer assisted decision analysis, failure modes and effects analysis and premarketing risk management programs. In the document announcing that meeting, the agency requested information in response to FDA questions that had been posted at <http://www.fda.gov/cder/workshop.htm> (choose Minimizing Medication Errors—Evaluating the Drug Naming Process; Public Meeting). Comments were to be received by July 15, 2003. However, in response to a request that the agency allow interested parties additional time to review and to submit comments on this issue, FDA is reopening the comment period on issues discussed at that meeting until [insert date 30 days after date of publication in the **Federal Register**].

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 individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the document 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. Electronic Access

Persons with access to the Internet may obtain the issues on which comments are requested at <http://www.fda.gov/cder/workshop.htm>. Paper copies of the questions may be obtained by contacting Mary Gross (see **FOR FURTHER INFORMATION CONTACT**).

Dated: July 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S