

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date 8-5-03

Publication Date 8-6-03

Certifier N. Hawkins

[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:

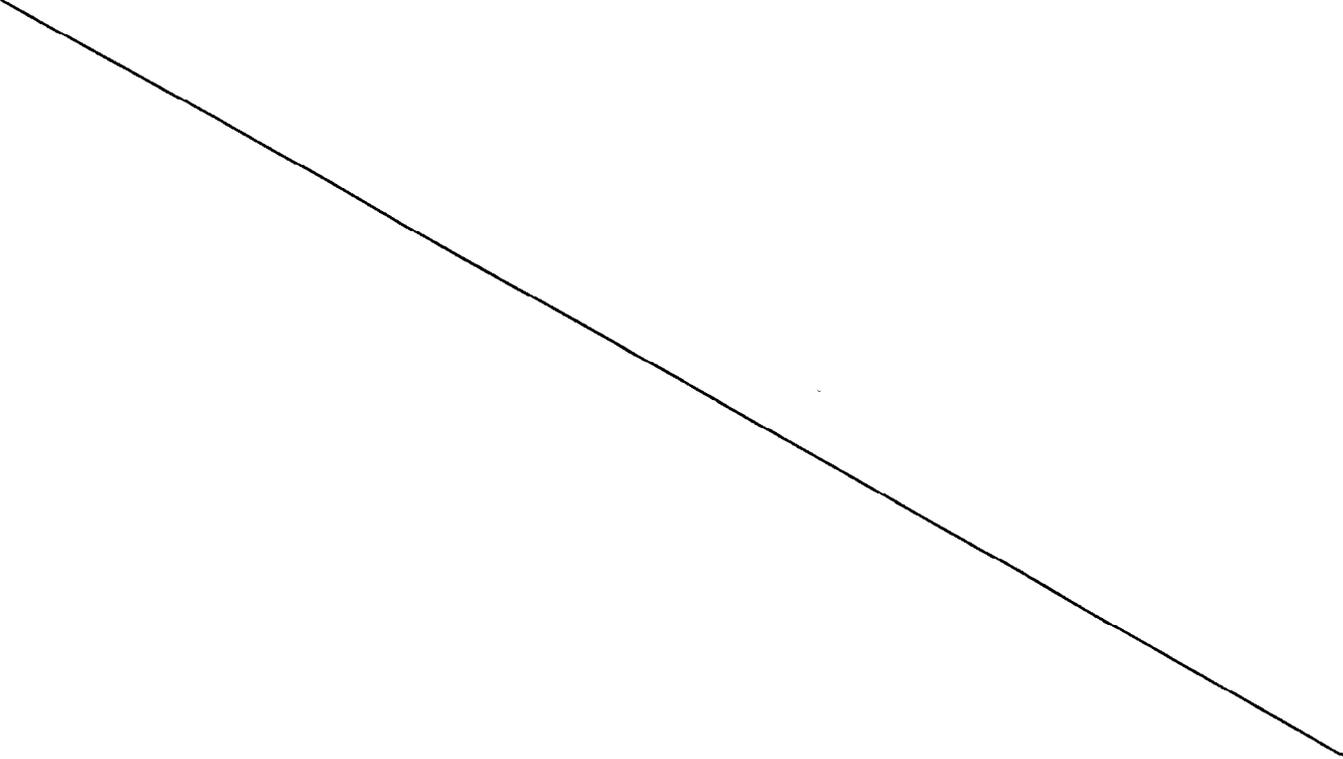
I. Background

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

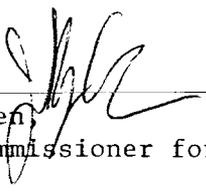
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified 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: 7/31/03
July 31, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Dawn P. Hawkins