requirements met or exceeded the Medicare conditions of participation for hospices. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between JCAHO and Medicare's Conditions and Survey Requirements

We compared the standards contained in JCAHO's ''Comprehensive Accreditation Manual for Home Care'' (CAMHC) and its survey process in the ''Request for Continued Deeming for Hospice Handbook'' with the Medicare hospice conditions for participation and our State and Regional Operations Manual. Our review and evaluation of JCAHO's deeming application, which were conducted as described in section III of this notice yielded the following:

- In order to meet the requirements of § 488.4(a)(4)(v), JCAHO provided a copy of their Conflict of Interest and Financial Integrity policy that is required to be signed by all JCAHO surveyors.
- JCAHO provided a list of all full and partial hospice accreditation surveys scheduled to be performed by the organization in 2002 and 2003 to satisfy our requirements at § 488.4(a)(10).
- To satisfy the requirements of § 488.4(b)(3)(v), JCAHO provided documentation that allows its surveyors to serve as witnesses if we take an adverse action based on accreditation findings.
- In order to comply with § 418.100(k)(2)(i), JCAHO agreed to add to its ''intent'' statement that Medicare certified hospice, facilities require that a physician must order all medications for the patient.
- To comply with § 418.22(b), JCAHO agreed to add to their ''intent'' statement that in a Medicare certified hospice ''terminally ill'' means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the terminal illness runs its normal course.

B. Term of Approval

Based on the review and observations described in section IV of this final notice, we have determined that JCAHO's requirements for hospices meet or exceed our requirements. Therefore, we recognize the JCAHO as a national accreditation organization for hospices that request participation in the Medicare program, effective June 19, 2003 through June 19, 2009.

V. Collection of Information Requirements

This final notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with granting and withdrawal of deeming authority to national accreditation organizations, specified in 42 CFR part 488, ''Survey, Certification, and Enforcement Procedures,'' are currently approved by OMB under OMB approval number 0938–0690.

VI. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 98–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes JCAHO as a national accreditation organization for hospices that request participation in the Medicare and Medicaid programs. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in hospices already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem hospices accredited by JCAHO as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this notice will not significantly affect the rights of States, local, or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: April 18, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–13471 Filed 5–29–03; 8:45 am]

BILLING CODE 4163–18–P

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

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@cder.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.

[FR Doc. 03–13591 Filed 5–28–03; 11:17 am]

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