

Reuters from entering into any agreement with FNS that prevents Reuters from competing in the production, marketing, or sale of news transcripts. Finally, the proposed consent order prohibits Reuters from entering into any agreements with any news transcript competitor or reseller that fix the resale prices for news transcripts.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the terms of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,
Secretary.

[FR Doc. 95-24758 Filed 10-4-95; 8:45 am]

BILLING CODE 6750-01-M

HARRY S. TRUMAN SCHOLARSHIP FOUNDATION

Scholarships: Closing Date for Nominations From Eligible Juniors at Four-Year Institutions of Higher Education

Notice is hereby given that, pursuant to the authority contained in the Harry S. Truman Memorial Scholarship Act, Public Law 93-642 (20 U.S.C. 2001), nominations are being accepted from eligible four-year institutions of higher education for Truman Scholarships. Procedures are prescribed at 45 CFR Part 1801, and where published in the Federal Register on September 23, 1991 (54 FR 48076).

In order to be assured of consideration, all documentation in support of nominations must be received by The Truman Scholarship Review Committee, Recognition Programs, Operations Division, 2255 North Dubuque Road, Iowa City, Iowa 52243 no later than December 1, 1995.

Louis H. Blair,

Executive Secretary.

[FR Doc. 95-24736 Filed 10-4-95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N-0314]

Professional Product Labeling; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an open public meeting to discuss

prescription drug product labeling designed for health care professionals.

The purpose of this meeting is to present background information and research concerning how approved prescription drug product labeling (package inserts) may be adapted to communicate more effectively to professional users, especially health care practitioners in clinical practice. FDA has developed an initial prototype of approved product labeling that summarizes the important information in drug product labeling and reorganizes existing sections. FDA is seeking comments on the value of these possible revisions to professional product labeling, and therefore FDA encourages interested individuals to attend this meeting to obtain relevant information on which to base their comments.

DATES: The public meeting will be held on Monday, October 30, 1995, from 9 a.m. to 3:30 p.m. Written comments will be accepted until January 19, 1996.

ADDRESSES: The public meeting will be held at the Gaithersburg Hilton Hotel, 620 Perry Pkwy., Gaithersburg, MD 20879. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the initial prototype can be obtained from the Center for Drug Evaluation and Research's (CDER's) FAX-on-Demand system, 301-827-0577 or 1-800-342-2722 (Document No. 0212). A transcript and summary of the meeting may be seen at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Kimberly Topper or Angie Whitacre, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

SUPPLEMENTARY INFORMATION: The major purpose of prescription drug product labeling is to help ensure that prescribing health care professionals have the information necessary to prescribe products in a safe and effective manner. When the agency determines that a sponsor has provided the requisite scientific data to allow marketing of a product in the United States, the approved labeling communicates the conclusions of FDA review of the data in the product's new drug application (NDA). Because the NDA review process provides access to

the raw data from clinical trials, the product labeling may provide the only comprehensive, independently reviewed source of medical/scientific information about newly approved products and new indications for older products.

The approved labeling also serves as the basis for product promotion. FDA regulations specify that all advertising claims made about a product be consistent with its approved labeling (21 CFR 202.1(e)(4)). The approved labeling serves as the basis for fulfilling the requirement of the Federal Food, Drug, and Cosmetic Act (the act) that prescription drug advertising include " * * * information in brief summary relating to side effects, contraindications, and effectiveness * * * ." (section 502(n) of the act (21 U.S.C. 352(n)).

The approved labeling's multiple purposes have contributed to its evolution. Product labeling has become increasingly detailed and lengthy over the past several years. FDA is concerned that these changes not undermine the usefulness of labeling for providing important information to prescribers. Recent research conducted by the agency evaluated physicians' perceptions of labeling's usefulness for their clinical practice. While the data were consistent with previous studies demonstrating that parts of labeling are extensively used, they also suggested potential areas where improvements could be made.

FDA has responded to these concerns and data by examining: (1) How important information in approved labeling could be more effectively accessed by prescribers, and (2) how a summary of important information could be designed and added to the approved product labeling. As a result, FDA has developed a new prototype for approved product labeling. A copy of this initial prototype can be obtained from CDER's FAX-on-Demand system (Document No. 0212) or from the information contact person (address above). This initial prototype represents a preliminary draft; it is being provided only for the purpose of helping to facilitate the public's preparation for the meeting. This initial prototype may change, even prior to the meeting. FDA is interested in receiving comments on the version of the prototype that will be presented at the public meeting.

Under 21 CFR 10.65(b), the Commissioner of Food and Drugs has concluded that it would be in the public interest to hold an open public meeting to discuss this initial prototype and the value of possible revisions to professional product labeling. This

public meeting is designed to give interested parties the necessary information to understand more fully the background, purpose, and process of prototype development.

The meeting will be informal, i.e., any interested person may attend and participate in the discussion without prior notice to the agency. The meeting will begin with presentations by FDA, followed by a panel discussion. The panel will be composed of representatives from industry and from medical and pharmaceutical information professional groups. The final part of the meeting will be devoted to questions and comments from meeting attendees.

A transcript and summary of the meeting will be available from the Dockets Management Branch (address above) approximately 10 business days after the meeting at a cost of 10 cents per page.

Interested persons may submit to the Dockets Management Branch (address above) comments on the initial prototype and the meeting. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Written comments will be accepted until January 19, 1996, to permit time for all interested persons to submit data, information, or views on this subject.

Dated: September 29, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-24815 Filed 10-4-95; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA), (Federal Register, Vol. 59, No. 60, pp. 14628-14630, dated Tuesday, March 29, 1994) is amended to reflect the separation of HCFA support staff from the Provider Reimbursement Review Board (PRRB). It should be noted that this change does not affect the PRRB as prescribed by the Social Security Act.

The specific amendments to Part F are as follows:

- Section F.10. (Organization) is amended by deleting F.10.A.1. in its entirety and replacing it with the following:

1. Office of Hearings (FA-5)

- Provides staff support to the Provider Reimbursement Review Board (PRRB) and the Medicare Geographic Classification Review Board (MGRB).

- Conducts Medicare and Medicaid hearings on behalf of the Secretary or the Administrator that are not within the jurisdiction of the Department Appeals Board, the Social Security Administration's Office of Hearings and Appeals, the PRRB, the MGRB, or the States.

- Facilitates and supports hearings and assists members of the Board(s) in the preparation of final decision documents.

Dated: September 27, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 95-24761 Filed 10-4-95; 8:45 am]

BILLING CODE 4120-01-M

National Institutes of Health

AIDS Research Program Evaluation Working Group; Notice of Meeting

Notice is hereby given of the meeting of the NIH AIDS Research Program Evaluation Working Group Area Review Panel on Vaccine Research and Development on October 16, 1995 from 9:00 am to 5:00 pm at the Days Inn Crystal City, 2000 Jefferson Davis Highway, Arlington, Virginia. The meeting will be open to the public from 2:00 pm to 5:00 pm, and the closed portion will be from 9:00 am to 1 pm.

The NIH Revitalization Act of 1993 authorizes the Office of AIDS Research (OAR) to evaluate the AIDS research activities of NIH. The NIH AIDS Research Program Evaluation Working Group was established by the OAR to carry out this major evaluation initiative, reviewing and assessing each of the components of the NIH AIDS research endeavor to determine whether those components are appropriately designed and coordinated to answer the critical scientific questions to lead to better treatments, preventions, and a cure for AIDS. Six area Review Panels were also established to address the following research areas: Natural History and Epidemiology; Etiology and Pathogenesis; Clinical Trials; Drug Discovery; Vaccines; and Behavioral and Social Sciences Research.

The purpose of the meeting is to seek input from individuals and organizations interested in the

evaluation of AIDS research in the areas of vaccine research and development. Examples of areas under consideration by the panel include identification of potential vaccine approaches, design and preclinical testing of candidate AIDS in animals—both small laboratory animals and nonhuman primates, clinical testing of candidate vaccines in human volunteers in phase I and II (safety and immunogenicity studies) and preparation for large scale testing in populations at high risk of acquiring HIV-1 infection. The NIH AIDS Research Program Evaluation Working Group will develop recommendations to be made to the Office of AIDS Research Advisory Council that address the overall NIH AIDS research initiatives, both intramural and extramural, and identify long-range goals in the relevant areas of science. These recommendations will provide the framework for future planning and budget development of the NIH AIDS research program.

There will be a closed session from 9:00 am to 1 pm to update the Panel members on privileged information on institute and center grant and contract portfolios.

The open session from 2 pm to 5:00 pm will begin with a brief overview of panel activities by members of the panel. The remainder of the meeting will be devoted to presentations from individuals and organizations. The session is open to the public; however, attendance may be limited by seat availability.

Comments should be confined to statements related to the current status of NIH AIDS research in the areas of AIDS vaccine research and development and recommendations for consideration by the panel in assessing and reviewing the relevant research in these areas.

Only one representative of an organization may present oral comments. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations must submit a letter of intent to present comments and three (3) typewritten copies of the presentation, along with a brief description of the organization represented, to the attention of Dr. Bonnie J. Mathieson, Office of AIDS Research, NIH, 31 Center Drive, MSC 2340, Building 31, Room 4C06, Bethesda, MD 20892-2340, (301) 496-4564, FAX: (301) 402-8638. Letters of intent and copies of presentations must be received no later than 4:00 pm EDT on Friday, October 13.

Any person attending the meeting who does not request an opportunity to speak in advance of the meeting will be