

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]

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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.

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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