

written information disseminated during 2001 with four widely-used prescription drugs reported the average "usefulness" of the information was only about 50 percent. The statute's goal for 2006 is that 95 percent of individuals receiving new prescriptions would receive useful written information. FDA is soliciting comments on and convening a public meeting to discuss what steps can be taken to improve the usefulness of such written prescription drug information in order to meet the year 2006 goal. FDA is posing four specific questions, and the agency is interested in responses to these questions and any other pertinent information stakeholders would like to share.

**Date and Time:** The public meeting will be held on July 31, 2003, from 9 a.m. to 5 p.m. Registration to speak at the meeting must be received by June 30, 2003. Written or electronic comments will be accepted to the docket until September 2, 2003.

**Location:** The public meeting will be held at the National Transportation Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594. (Phone: 202-314-6421; Metro: L'Enfant Plaza station on the green, yellow, blue, and orange lines). See: <http://www.nts.gov/events/newlocation.htm>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

**For Information Regarding This Notice Contact:** Christine Bechtel, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5458, email [bechtelc@cder.fda.gov](mailto:bechtelc@cder.fda.gov). If you need special accommodations due to a disability, please inform the contact person.

**Registration and Requests for Oral Presentation:** No registration is required if you only plan to attend the meeting. Seating will be on a first-come, first-served basis. If you wish to make an oral presentation during the open public comment period of the meeting, you must register to speak at the meeting by submitting your name, title, business affiliation, address, telephone number, fax number, and e-mail address and you must specify on your registration that you wish to make a presentation. You must also submit the following: (1) A written statement for each question addressed, (2) the names and addresses of all who plan to participate, and (3) the approximate time requested to make your presentation. Individuals who register to make an oral presentation

will be notified of the scheduled time for their presentation prior to the meeting. Depending on the number of presentations, FDA may have to limit the time allotted for each presentation. All participants are encouraged to attend the entire day. Presenters must submit two hard copies of each presentation given.

**For Registration Information Contact:** Christine Bechtel, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5458, email [bechtelc@cder.fda.gov](mailto:bechtelc@cder.fda.gov). Electronic registration for this meeting is available at: <http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm>, or, registration requests and materials can be sent to Christine Bechtel.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Access to useful written patient information is an important aspect of helping to ensure appropriate use of prescription medicines, thereby preventing serious personal injury and avoiding excess costs to consumers and the health care system. FDA telephone surveys have shown that the rate of distribution of written prescription drug information has increased over the past 20 years.

Historically, written patient information has either been required by regulation for particular prescription drug products or product classes, or has been distributed on a voluntary basis by the manufacturer. Since 1968, FDA has occasionally required that prescription drug labeling written specifically for patients in nontechnical language be distributed to patients whenever certain prescription drugs, or classes of prescription drugs, are dispensed. In the 1970s, FDA began evaluating the usefulness of patient labeling for prescription drug products generally, and published a proposed rule to require written patient information for prescription drugs in 1979 (44 FR 40016, July 6, 1979). In 1980, FDA published a final rule establishing requirements and procedures for the preparation and distribution of FDA-approved patient labeling for a large number of prescription drugs (45 FR 60754, September 12, 1980). FDA revoked those regulations in 1982 based, in part, on assurances by the private sector that the goals of the final rule would be met (47 FR 39147, September 7, 1982). A decision was made to allow voluntary private sector initiatives to proceed before a determination was

made whether to impose a mandatory program.

In 1995, FDA published a proposed rule entitled "Prescription Drug Product Labeling; Medication Guide Requirements" that would have required manufacturers to prepare and distribute "Medication Guides" to accompany a limited number of prescription drug products that posed a serious or significant public health concern, and set forth the requirements for the Medication Guide program (the 1995 proposed rule) (60 FR 44182, August 24, 1995). FDA's proposed goal for prescription drugs that did not require Medication Guides was that, by the year 2000, at least 75 percent of people receiving new prescriptions would receive useful written patient information, and that by 2006, 95 percent of people who receive new prescriptions would also receive useful written patient information. The 1995 proposed rule set criteria by which written information would be judged to determine whether it was "useful" and should therefore count toward accomplishment of the target goals. FDA defined "useful" as written in nontechnical language and containing a summary of the most important information about the drug. FDA also specified that the usefulness of written patient information would be evaluated according to its scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

On August 6, 1996, as FDA was reviewing the public comments on the 1995 proposed rule, Public Law 104-180 that adopted goals consistent with the 1995 proposed rule for the distribution of useful written patient information by the private sector, was enacted. The legislation also required that, no later than 30 days after its enactment, the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) would request that national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties collaborate to develop a long-range comprehensive action plan (Action Plan) to achieve goals consistent with the goals of the 1995 proposed rule. Required elements of the Action Plan included: an assessment of the effectiveness of the current private-sector approaches to providing consumer medication information; the development of guidelines for providing effective