

consumer medication information consistent with the findings of such assessment; the identification of components necessary to ensure the transmittal of useful information to the public expected to use the product, including the criteria identified in the 1995 proposed rule; and the development of a mechanism to periodically assess the quality of prescription information and the frequency with which it is provided to consumers.

Under subsection (d) of section 601 of Public Law 104–180, FDA could not implement the portion of the proposed rule, or any other regulation or guideline, that specified a uniform, FDA-approved content or format for written information voluntarily provided to consumers about prescription drugs, if private sector organizations met the requirements of the long-range Action Plan within the timeframe provided by the law.

The law also required DHHS to review the status of the private sector initiatives designed to achieve the goals of the action plan by January 1, 2001. Public Law 104–180 required that if 75 percent of individuals receiving new prescriptions did not receive useful written information by the year 2000, the limitation in subsection (d) of section 601 would not apply and the Secretary was required to seek public comment on other initiatives that could meet the goals.

Initially following the enactment of Public Law 104–180, the Secretary asked the Keystone Center to convene a Steering Committee to collaboratively develop the Action Plan. The Action Plan accepted by the Secretary in January 1997 reiterated the target goals specified in Public Law 104–180. The Action Plan endorsed the criteria specified in Public Law 104–180 for defining the usefulness of medication information. Specifically, the Action Plan stated that such materials should be: (1) Scientifically accurate; (2) unbiased in content and tone; (3) sufficiently specific and comprehensive; (4) presented in an understandable and legible format that is readily comprehensible to consumers; (5) timely and up to date; and (6) useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm. [The Action Plan, including descriptions of the criteria, is available on the Internet at <http://www.keystone.org>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after the document publishes in the **Federal Register**.)

Consistent with Public Law 104–180, the Action Plan called for the development of a mechanism to periodically assess the quality of written prescription information provided to patients. To test a methodology for collecting patient information materials and assessing their usefulness, FDA contracted with the National Association of Boards of Pharmacy (NABP). The contract called for the selection of several State Boards of Pharmacy, which would arrange for collecting, from a sample of State pharmacies, written materials given to patients when new prescriptions for three commonly prescribed drugs were filled. The contract also called for the development of an expert panel to create evaluation materials to assess the usefulness of the information through application of the Action Plan criteria. The written prescription drug information was collected in 1999, and the final report from the pilot study was completed in December 1999 and presented by FDA at a public workshop on February 29–March 1, 2000.

In 2001, FDA commissioned NABP to subcontract a national study to assess the usefulness of written prescription drug information being distributed to patients. A professional shopper firm was hired to bring prescriptions for four widely prescribed drugs in different drug classes to 384 pharmacies selected in a statistically random fashion from a national list. All written materials received with the prescriptions were sent to an expert panel for evaluation against the criteria endorsed by the Action Plan. The results of the study were announced in 2002. The evaluation found that, on average, 89 percent of patients received some form of written medication information. However, the expert panel found that the average “usefulness” of the information was only about 50 percent. The report of the evaluation is available at <http://www.fda.gov/cder/reports/prescriptioninfo/default.htm>.

The report findings were presented at an FDA Drug Safety and Risk Management Advisory Committee (the Advisory Committee) meeting on July 17, 2002. The Advisory Committee recommended that FDA take a more active role in advising and encouraging the private sector to meet the 2006 goal. FDA accords the recommendations of all advisory committees significant weight, but such recommendations are not binding on the agency. A transcript of FDA’s Drug Safety and Risk Management Advisory Committee meeting on July 17, 2002, is available at <http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874T1.htm>.

II. Scope of Discussion

In view of the facts described in section I of this document, FDA is soliciting comments on several issues and is convening this public meeting on July 31, 2003, to discuss the current status of the private sector’s efforts to provide useful written prescription drug information to consumers. Interested persons are invited to submit comments to the docket and to attend the public meeting and present their views. Issues that we are asking interested parties to address in their comments, at the public meeting, or both, are as follows:

1. What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goal?

2. What barriers exist for the private sector to meet the Year 2006 goal, and what plans exist to overcome these barriers?

3. What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?

4. What other initiatives should FDA consider for providing patients with useful written information about prescription drugs as endorsed by Public Law 104–180? Such initiatives could include the possibility of FDA requiring manufacturers to provide authorized dispensers with the means to distribute useful written information approved by FDA.

III. Comments

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments on or before September 2, 2003. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document. Submit electronic comments by September 2, 2003, to fdadockets@oc.fda.gov or at <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. You should annotate and organize your comments to identify the specific questions to which they refer. Comments to the docket can be reviewed in the Dockets Management Branch, Monday through Friday between 9 a.m. and 4 p.m. or on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/dockets.htm> (select docket # 03N–0168).

IV. Transcripts

You may request a copy of the transcript in writing from the Freedom of Information Office (HFI–35), Food