Agenda: At the workshop, FDA will hear presentations and receive comments from stakeholders likely to be affected by FDA policies or procedures regarding the review and approval of innovative medical products. Stakeholders include, but are not limited to device, drug, and biological product manufacturers; members of the academic and clinical communities; and consumer and patient advocacy groups.

Registration: Preregistration is required by July 1, 2003, and will be accepted on a first-come, first-served basis; however, notwithstanding attendance at the workshop, interested persons are encouraged to provide comments (see the *Request for Comments* section of this document). There will be no onsite registration. FDA is pleased to provide the opportunity for interested persons to listen from a remote location to the live proceedings of the public workshop. In order to ensure that a sufficient number of call-in lines are available, please register to listen to the meeting at *http://www.fda.gov/cdrh/meetings/070803.html*. Persons without Internet access may call 1-888-203-6161. The registration deadline is July 1, 2003. For technical reasons, persons wishing to make an oral presentation at the public workshop must do so in person. Those who wish to make presentations should submit written notification including: (1) The specific issue related to the topic you intend to address; (2) the names and addresses of all individuals that will participate in your presentation; (3) the approximate amount of time your presentation will require; and (4) two copies of all presentation materials to Cynthia Benson by June 27, 2003. Presentations will be limited to the topics outlined in the **SUPPLEMENTARY INFORMATION** section of this document and, depending on the number of speakers, FDA may limit the time allotted for each presentation. If you need special accommodations due to a disability, please contact Anne Marie Williams at 301–594–1283 at least 7 days in advance.

Request for Comments: Regardless of attendance at the workshop, interested persons may submit written or electronic comments to the Dockets Management Branch (see the *Addresses* section of this document). You should annotate and organize your comments to identify the specific issues to which they refer. Submit two paper copies of any mailed comments. Individuals may submit one copy. Identify comments with the docket number found in brackets in the heading of this document. The comments that FDA receives will be made available at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Transcripts: Following the workshop, transcripts will be available for review at the Dockets Management Branch (see the *Addresses* section of this document).

SUPPLEMENTARY INFORMATION: FDA believes that innovative and novel medical technologies have the potential to greatly improve the public health in many different areas. By addressing and clarifying regulatory uncertainty, the agency believes that the development of these technologies will be expedited and the predictability in product development will be increased, thus allowing more of these products to reach the marketplace in a timely manner. As part of a broad effort to increase the development of novel medical technologies, FDA is seeking information on how to expedite the review and approval of innovative devices for the delivery of drugs and biologics. For this effort, these products will be broadly defined. We are including any combination of drug and device or biologic and device products in which the two components work together to have a desired effect on the patient. Some examples of the innovative products to be included in this effort are:

- Novel, specialized catheters to permit localized delivery of drugs or biologics (*e.g.*, chemotherapeutic agents, thrombolytics, cells/biologics);
- Lasers or other energy delivery devices for delivery or enhancement of drug or biologic effectiveness (*e.g.*, electroporetic or laser systems to enhance the transport of drugs to the target site);
- Device/drug or device/biologic combinations that permit new routes of administration for drugs (*e.g.*, devices for inhalation of drugs formerly administered intravenously);
- Devices that activate drugs in the body (*e.g.*, photodynamic therapy);
- Drug-eluting stents designed to prevent restenosis; and
- Orthopedic repair products containing bone morphogenic proteins or other cytokines.

The lead for review of the products to be discussed in the workshop may be in any of the FDA medical products centers (the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health, *i.e.*, CDER, CBER or CDRH) and the products may reach the market through several different regulatory pathways (*e.g.*, investigational device exemption/premarket approval applications (IDE/PMA), investigational new drug application/new drug application (IND/NDA), IND/biological license application (BLA), IDE/510(k), or a combination of these). This workshop is being held to provide a forum for the academic and clinical communities, industry, consumer and patient advocacy groups and FDA to discuss the latest scientific and clinical developments for these products as well as any regulatory concerns and challenges. In addition to increasing our understanding of the latest technological developments in this field, FDA is seeking input to specifically address the following:

1. What are the most critical challenges in developing and bringing to market a novel, innovative technology for delivery of drugs or biologics?
2. Which areas are most important for the agency to provide guidance to developers of these novel products?
3. How can the agency best collaborate with industry, academia, other government agencies, and other scientific bodies in this area of rapidly evolving technology?

The agency hopes to use the information from the workshop to guide the future development of guidance documents, memoranda of understanding, or other position papers.

Dated: May 27, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–14209 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0168]

Current Status of Useful Written Prescription Drug Information for Consumers: 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 a public meeting to discuss the current status of the private sector's efforts to provide useful written prescription drug information to consumers. Public Law 104–180 adopted a goal that useful written information would be distributed to 75 percent of individuals receiving new prescriptions by the year 2000. An FDA-commissioned study of

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.ntsb.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*. 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*. 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

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

and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 days after the meeting at a cost of 10 cents per page. You may also examine the transcript Monday through Friday between 9 a.m. and 4 p.m. in the Dockets Management Branch or on the Internet at *http://www.fda.gov/ohrms/dockets/dockets/dockets.htm* (select docket # 03N–0168). The transcript will be available 4–6 weeks after the meeting.

V. Electronic Access

Persons with access to the Internet may obtain a copy of the commissioned study report at *http://www.fda.gov/cder/reports/prescriptioninfo/default.htm*, the Action Plan at *http://www.keystone.org,* and a transcript of FDA's July 17, 2002, Drug Safety and Risk Management Advisory Committee meeting at *http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874T1.htm*.

Dated: May 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14212 Filed 6–4–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0359]

Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2004. As part of its annual planning, budgeting, and resource allocation process, CFSAN is reviewing its programs to set priorities and establish work product expectations. This notice is being published to give the public an opportunity to provide input into the priority-setting process.

DATES: Submit written or electronic comments by August 4, 2003.

ADDRESSES: Submit written comments concerning this document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Donald J. Carrington, Center for Food Safety and Applied Nutrition (HFS–666), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1697, or e-mail: *Dcarring@cfsan.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 10, 2003, CFSAN released a document entitled ''2003 CFSAN Program Priorities.'' The document, a copy of which is available on CFSAN's Web site (*www.cfsan.fda.gov*), constitutes the center's priority work plan for FY 2003, i.e., October 1, 2002, through September 30, 2003. (Copies also are available from the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section.) The 2003 work plan is based on input we received from our stakeholders as well as input generated internally. Throughout the priority-setting process, we focus on one central question: ''Where do we do the most good for consumers?''

The FY 2003 work plan focuses heavily on ensuring the security of our country's food supply as a primary goal. With the enactment in June 2002 of the Public Health Security and Bioterrorism Preparedness and Response Act (Public Law 107–188), much of our effort during the current fiscal year will focus on issuing the necessary regulations to implement this statute. We will also continue to enhance our level of emergency preparedness, particularly our laboratory preparedness.

The FY 2003 work plan continues to place a high priority on food safety, food additives, and dietary supplements, and also highlights our desire to revitalize our nutrition program. In December 2002, FDA announced a major initiative to enhance ''Consumer Health Information for Better Nutrition.'' Accordingly, this year's plan includes the steps needed to implement that initiative, including increased enforcement against unsubstantiated claims on food and dietary supplement products.

Outside of these priorities, the FY 2003 work plan identifies eight other program areas and cross-cutting areas that need emphasis: (1) Cosmetics; (2) enhancing the science base; (3) international activities; (4) food biotechnology; (5) enhancing internal processes; (6) focused economic-based regulations; (7) equal employment opportunity/diversity initiatives; and (8) management initiatives.

The FY 2003 work plan contains two lists of activities—the ''A-list'' and the ''B-list.'' Our goal is to fully complete at least 90 percent of the 145 ''A-list'' activities by the end of the fiscal year, September 30, 2003. Activities on the ''B-list'' are those we plan to make progress on, but may not complete, before the end of the fiscal year.

CFSAN intends to issue a mid-year progress report on what program priority activities already have been completed to date in FY 2003 as well as any adjustments in the work plan (i.e., additions or deletions) for the balance of the fiscal year.

CFSAN has responsibility for many important ongoing activities that are not identified in the work plan. For example, the center's base programs in data collection, research, and enforcement are important and ongoing. Rather, the work plan addresses primarily those initiatives representing something new or different that we need to address in 2003 as well as priority initiatives that are being continued from the 2002 work plan. In addition, the work plan does not address the myriad of unanticipated issues that often require a substantial investment of CFSAN resources (e.g., response to outbreaks of foodborne illness).

II. 2004 CFSAN Program Priorities

FDA is requesting comments concerning the establishment of program priorities in CFSAN for FY 2004, and the input will be used to develop CFSAN's 2004, work plan. The work plan will set forth the center's program priorities for October 1, 2003, through September 30, 2004. FDA intends to make the 2004 work plan available in the fall of 2003.

The format of the 2004 work plan will be similar to last year's work plan. FDA expects there will be considerable continuity and followthrough between the 2003 and 2004 work plans. For example, new initiatives aimed at increasing the security of our country's food supply and revitalizing our nutrition program will continue to be a high priority in FY 2004.

FDA is in the process of developing a major strategic plan and has identified the following five top priority areas for the agency: (1) A strong FDA; (2) efficient risk management; (3) patient and consumer safety; (4) better informed consumers; and (5) counter-terrorism. Action items implementing the strategic plan will be incorporated into CFSAN's priorities for FY 2004.

As noted in the previous paragraphs, many of the ''B-list'' activities are 2-year projects that we are positioning to be candidates for the ''A-list'' next year.