the role of amplification; models of early intervention; and the need for future research.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Marcus Gaffney, M.P.H., National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, NE., M/S E–88, Atlanta, Georgia 30333. Telephone: (404) 498–3031.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 20, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–10541 Filed 5–25–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health, Safety and Occupational Health Study Section

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–5 p.m., June 21, 2005. 8 a.m.–5 p.m., June 22, 2005.

Place: Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, Virginia, 22314, telephone 703/684–5900, fax 703/684–1403.

Status: Open 8 a.m.–8:15 a.m., June 21, 2005. Closed 8:15 a.m.–5 p.m., June 21, 2005. Closed 8 a.m.–5 p.m., June 22, 2005.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters to be Discussed: The meeting will convene in open session from 8–8:15 a.m. on June 21, 2005, to address matters related to the conduct of Study Section business. The remainder of the meeting will proceed in closed session. The purpose of the closed sessions is for the study section to consider safety and occupational health-related grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Pub. L. 92–463.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Price Connor, Ph.D., NIOSH Health Scientist, 1600 Clifton Road, NE., Mailstop E–74, Atlanta, Georgia 30333, telephone 404/498–2511, fax 404/498–2569.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 20, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–10542 Filed 5–25–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0169]

Draft Guidance on Useful Written Consumer Medication Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Useful Written Consumer Medication Information (CMI).'' CMI is written information developed for consumers about prescription drugs that is distributed to consumers when they have prescriptions filled. The guidance discusses general issues and makes recommendations on the content of useful written CMI.

DATES: Submit written or electronic comments on the draft guidance by July 25, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ellen Tabak, Center for Drug Evaluation and Research (HFD–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7843.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Useful Written Consumer Medication Information (CMI).'' This draft guidance is intended to assist individuals or organizations (e.g., pharmacies, private vendors, healthcare associations) in developing useful written CMI. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to ensure that their CMI is useful to consumers.

Traditionally, FDA has believed that when people are well-informed about the medications they take, they are able to make better decisions about their healthcare and better use of the prescription medications available to them. Access to useful written information about prescription medications is important to ensuring appropriate use of these products. In 1996, a steering committee comprised of interested stakeholders (including healthcare professionals, consumer organizations, voluntary health agencies, pharmaceutical manufacturers, prescription drug wholesalers, drug information database companies, CMI developers, and

others), facilitated by the Keystone Center, collaboratively developed a report entitled ''Action Plan for the Provision of Useful Prescription Medicine Information'' (the Action Plan).[1] The Action Plan outlined criteria for evaluating whether a particular piece of written medical information is useful to consumers. It represented the culmination of a long history of efforts aimed at ensuring that consumers receive useful information regarding their prescription medications.

A. Regulatory History Preceding the Action Plan

Since 1968, FDA regulations have required that patient package inserts, written specifically for patients, be distributed to patients when certain prescription drugs, or classes of prescription drugs, are dispensed (see 21 CFR 310.501 for oral contraceptives and 310.515 for estrogens). FDA regulations also require pharmaceutical manufacturers to develop and distribute written patient labeling called Medication Guides for prescription drug products that pose a serious and significant public health concern (21 CFR 208.1(c)). These Medication Guides are required to be written in nontechnical language (21 CFR 208.20(a)(1)). In addition, drug manufacturers have voluntarily agreed with FDA to produce and distribute patient labeling for many other prescription drugs and classes. A description of how the FDA regulations evolved is provided in the following paragaraphs.

1. The First Proposed Rule That Required Written Patient Information

In the 1970s, FDA began evaluating the general usefulness of patient labeling for prescription drugs and, in 1979, published a proposed rule to require written patient information for all prescription drugs (44 FR 40016, July 6, 1979). In 1980, FDA published a final rule establishing requirements and procedures for the preparation and distribution of manufacturer-prepared and FDA-approved patient labeling for a limited number of prescription drugs (45 FR 60754, September 12, 1980). In 1982, FDA revoked those regulations, in part based on assurances by pharmaceutical manufacturers, healthcare professional associations, and private-sector providers of written medication information for patients that the goals of the final rule would be met more effectively and with greater innovation without regulation (47 FR 39147, September 7, 1982). FDA committed itself to monitor the progress of this private-sector effort.

2. The Medication Guide Rule

Periodic FDA surveys showed that although the distribution of written prescription drug information increased, the usefulness of the information was highly variable. Consequently, in 1995, FDA published a proposed rule entitled ''Prescription Drug Product Labeling; Medication Guide Requirements'' (60 FR 44182, August 24, 1995). The proposal was designed to aid patients in receiving useful written information about the prescriptions they were given by setting specific distribution and quality goals and time frames for achieving them. The goals that FDA proposed in the rule were that, by the year 2000, 75 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions; by 2006, 95 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions. The proposed rule also described criteria for usefulness to permit evaluation of whether the information met the target goals.[2] In addition to setting these goals, the proposed rule was designed to require manufacturers to prepare and distribute Medication Guides for a limited number of prescription drug products that posed a serious and significant public health concern.

3. Medication Guide Legislation

On August 6, 1996, as FDA was reviewing the public comments on the 1995 proposed rule, Public Law 104–180 was enacted.[3] It adopted goals and time frames consistent with the 1995 proposed rule. The legislation also required the Secretary of HHS (the Secretary) to request that a representative group of interested stakeholders collaborate to develop a long-range comprehensive action plan (the Action Plan) to achieve the goals specified in the statute. Required elements of the Action Plan included the following items:

- An assessment of the effectiveness of the current private-sector approaches to providing CMI;
- Development of guidelines for providing effective CMI consistent with the findings of such assessment;
- 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
- Development of a mechanism to periodically assess the quality of prescription information and the frequency with which that information is provided to consumers.

The law prohibited FDA from taking further regulatory steps specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs if private-sector initiatives met the goals of the plan within the specified time frames. However, if evaluations showed that the goals were not met, the limitation would not apply, and the Secretary would be required to seek public comment on other initiatives that could meet the goals.

B. The Development and Implementation of the Action Plan

As mentioned previously in this document, a steering committee comprised of interested stakeholders, facilitated by the Keystone Center, collaboratively developed the Action Plan, which the Secretary accepted in January 1997. 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 ''[p]rescription medicine information shall be useful to consumers'' and provided criteria that are intended to define useful CMI. As stated in the Action Plan, useful written information is that which ''* * * is sufficiently comprehensive and communicated [in] such [a way] that consumers can make informed decisions about how to receive the most benefit from medicines and protect themselves from harm. Both the substance and presentation of the information are important.'' Specifically, the Action Plan stated that such materials should meet the following criteria:

- Scientifically accurate;
- Unbiased in content and tone;
- Sufficiently specific and comprehensive;
- Presented in an understandable and legible format that is readily comprehensible to consumers;

[1] Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, unpublished report submitted to The Honorable Donna E. Shalala, Secretary of Health and Human Services (HHS), December 1996, available on the Internet at *http://www.fda.gov/cder/offices/ods/keystone.pdf.*

[2] FDA also specified that the usefulness of written patient information would be evaluated based on its scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

[3] Public Law 104–180, Title VI, Sec 601 Effective Medication Guides, 110 Stat 1593 (1996).

- Timely and up-to-date; and
- Useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm.

The Action Plan includes descriptions of the criteria.

1. The Pilot Study That Applied the Action Plan Usefulness Criteria

To test a methodology for assessing the usefulness of CMI in relation to the requirements of the law, FDA contracted with the National Association of Boards of Pharmacy (NABP) to conduct a pilot study. In 1998, NABP arranged for the collection of written materials given to patients who filled new prescriptions for three commonly prescribed drugs from a sample of State pharmacies. An expert panel developed assessment tools, applying the Action Plan criteria, and used them to evaluate the usefulness of the collected CMI materials. The pilot study report[4] was presented by the director of the expert panel and discussed by stakeholders at an FDA public workshop from February 29 to March 1, 2000 (65 FR 7022, February 11, 2000).

2. The National Study That Applied the Action Plan Usefulness Criteria

In 2001, FDA commissioned NABP to conduct a national study to assess the extent to which the year 2000 goals specified in the law had been achieved. A random sample of pharmacies across the continental United States was selected. Patients submitted prescriptions at each pharmacy for four commonly prescribed drugs and collected any written materials given to them when the medications were dispensed. The materials 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.

On average, 89 percent of the patients received some form of written medication information. However, the average usefulness of the information was only about 50 percent. The evaluation report[5] is available on the Internet at *http://www.fda.gov/cder/reports/prescriptioninfo/default.htm*.

[4] Svarstad, B. L. and D. C. Bultman, ''Evaluation of Written Prescription Information Provided in Community Pharmacies: An 8-State Study,'' interim report to HHS and FDA, December 1999, available on the Internet at *http://www.fda.gov/cder/calendar/meeting/rx2000/report1.htm*.

[5] Svarstad, B. L. and J. K. Mount, ''Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001,'' final report to HHS and FDA, December 2001.

3. The Advisory Committee Meeting That Led to the Development of This Guidance

The report findings were presented at an FDA Drug Safety and Risk Management Advisory Committee (Advisory Committee) meeting on July 17, 2002 (67 FR 45982, July 11, 2002). In addition, public comments were requested about the steps the private sector was taking to meet the target goals of Public Law 104–180, possible barriers to meeting the goals and plans to overcome those barriers, the role FDA should take in assuring full implementation of the Action Plan, and other initiatives FDA should consider in facilitating achievement of the goals (68 FR 33724, June 5, 2003). The Advisory Committee recommended that FDA take a more active role in advising and encouraging the private sector to meet the next target goal set for 2006. A transcript of FDA's Drug Safety and Risk Management Advisory Committee meeting on July 17, 2002, is available on the Internet at *http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874t1.htm*. Subsequent to the Advisory Committee meeting, FDA stated its belief that the voluntary approach to improving the distribution of useful CMI could still work to meet the legislatively mandated 2006 level if efforts to improve began immediately. FDA considered the Advisory Committee recommendations, the public comments, and the findings of strong CMI distribution rates but clear deficiencies in quality, and identified three specific areas in need of consensus and action by the relevant stakeholders to meet the 2006 goal. The following areas were identified: (1) Implementation (identifying roles and responsibilities among the stakeholders and methods for overcoming barriers to meeting the goals); (2) evaluation (determining how quality improvements can be made in areas of CMI deficiencies); and (3) education (implementing procedures so that all CMI developers, pharmacists, and professional associations are aware of the statutory requirements).

The agency met with various groups and held a public meeting in 2003 (see *http://www.fda.gov/cder/offices/ods/writtenprescripinfo.htm*). In these meetings, the agency was asked to provide clarification on how the Action Plan should be interpreted and implemented. This guidance is a result of that request. Specifically, this guidance is intended to provide recommendations to developers of CMI regarding how best to evaluate current CMI and develop future CMI to ensure that all CMI meet the usefulness criteria provided in the Action Plan. FDA welcomes comments on all the topics addressed by the guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on useful written CMI. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10445 Filed 5–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning