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.

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.


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.

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 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

ADRESSES: 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/ohrms/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
and private-sector providers of written medication information for patients that
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
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/odckeystone/pdf/.

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

³ Public Law 104–100, Title VI, Sec 601 Effective
• 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 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 average usefulness of the information was 62 percent for medications. However, the average usefulness of the information was only about 50 percent.

The report findings were presented at an FDA Drug Safety and Risk Management 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/ohrms/dockets/ default.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/ohrms/dockets/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...