- 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

individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, NO1–CM–57018–16.

Date: June 23–24, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Affairs, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8057, MSC 8329, Bethesda, MD 20892–8329, 301–496–7421, *kerwinm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 18, 2005.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–10525 Filed 5–25–05; 8:45 am]

BILLING CODE 4140–01–M

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 meetings 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 grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute Special Emphasis Panel, RFA: CA05–026.

Date: July 18–19, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Sherwood Githens, PhD, Scientific Review Administrator, Special Review and Logistics Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executive Blvd. Room 8053, Bethesda, MD 20892, 301/435–1822, *githenss@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 18, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–10526 Filed 5–10–25; 8:45 am]

BILLING CODE 4140–01–M

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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Special Emphasis Panel for K05s, K24s, and Two types of R25 Applications.

Date: June 28–29, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Suites Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Marvin L. Salin, PHD, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, 6116 Executive Boulevard, Room 7073, MSC8329, Bethesda, MD 20892–8329, 301–496–0694, *msalin@mail.nih.gov*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 18, 2005.

LaVerne Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–10527 Filed 5–25–05; 8:45 am]

BILLING CODE 4140–01–M

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 pubic in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Innovative Technologies for Molecular Analysis of Cancer.

Date: June 16–17, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Lalita D. Palekar, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8105, Bethesda, MD 20892–7405, (301) 496–7575.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399,