

version published in the **Federal Register** on December 16, 1999 (64 FR 70264). The comment period for the draft guidance ended on March 15, 2000. A meeting of the Obstetrics and Gynecology Devices Panel was held on January 25, 2000, to discuss the draft version of this guidance.

Comments received on the draft guidance generally addressed the use of adhesion reduction as a surrogate endpoint for clinical endpoints such as fertility, pelvic pain, and small bowel obstruction. Several respondents stated that adhesion reduction itself should be considered an endpoint that provides a clinical benefit to the patient irrespective of other clinical outcomes such as those mentioned above. The agency believes that whether adhesion reduction is considered a surrogate or clinical endpoint, it is valid as a study endpoint so long as the adhesion reduction measured provides some reasonable assurance that the adhesion barrier will provide clinically significant results.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on resorbable adhesion barrier devices used in abdominal and/or pelvic surgery. 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 statute and regulations.

## III. Electronic Access

In order to receive "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1356) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may obtain a copy of the guidance from the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small

manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. You may access the CDRH home page at <http://www.fda.gov/cdrh>. You may search for all CDRH guidance documents at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets>.

## IV. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 31, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02-15209 Filed 6-17-02; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Solicitation of Information and Recommendations for Revising the Compliance Program Guidance for the Hospital Industry

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice.

**SUMMARY:** This **Federal Register** notice seeks the input and recommendations of interested parties as the OIG revises the compliance program guidance (CPG) for hospitals, especially those serving Medicare, Medicaid and other Federal health care program beneficiaries. The hospital industry has experienced a number of changes since the first CPG was published in early 1998. Additionally, the subsequent 4 years of compliance activity in the hospital industry has allowed the OIG to more fully address the various risk areas in hospital compliance.

With the implementation of the Hospital Outpatient Prospective Payment System (OPPS), as well as other significant changes in the hospital

industry, the OIG is reevaluating the contents of the hospital CPG. As part of this process, the OIG is soliciting comments, recommendations and other suggestions from concerned parties and organizations on how best to revise the hospital CPG to address relevant compliance issues. Specifically, the OIG seeks comments addressing any changes to existing risk areas, and introduction of any new risk areas related to OPPS implementation or industry changes.

**DATES:** To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on August 19, 2002.

**ADDRESSES:** Please mail or deliver your written comments, recommendations and suggestions to the following address: Department of Health and Human Services, Office of Inspector General, Attention: OIG-12-CPG, Room 5527 A, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to the file code OIG-12-CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, SW., Washington, DC 20201 on Monday through Friday of each week from 8:00 A.M. to 4:30 P.M.

**FOR FURTHER INFORMATION CONTACT:** Paul M. Johnson, Office of Counsel to the Inspector General, (202) 619-2078; or Joel Schaer, Office of Counsel to the Inspector General, (202) 619-0089.

**SUPPLEMENTARY INFORMATION:** The development of compliance program guidances has become a major initiative of the OIG in its effort to engage the private health care industry in addressing and combating fraud and abuse. Over the past several years, the OIG has developed and issued compliance program guidances directed at various segments of the health care industry. These guidances are designed to provide clear direction and assistance to specific sections of the health care industry that are interested in addressing compliance with Federal health care program requirements.

The guidances have represented the culmination of the OIG's suggestions on how providers can most effectively establish internal controls and implement monitoring procedures to identify, correct and prevent potentially fraudulent conduct. The suggestions contained in the guidances are not mandatory for providers, nor do they

represent an exclusive discussion of the advisable elements of a compliance program.

Through this **Federal Register** notice, the OIG is seeking input from interested parties as the OIG considers revising the CPG for the hospital industry. The OIG will consider all comments, recommendations and suggestions received within the time frame indicated above. The OIG would appreciate specific comments, recommendations and suggestions on (1) risk areas for the hospital industry, and (2) aspects of the seven elements contained in the previous CPGs that may need to be modified in light of recent developments in the hospital industry and changes in Federal health care program systems. Detailed justifications and empirical data supporting any suggestions would be appreciated.

We request that any comments, recommendations or suggestions be submitted in a format that address the topics outlined above in a concise manner, rather than in the form of a comprehensive draft guidance that mirrors previous CPGs.

Dated: May 29, 2002.

**Janet Rehnquist,**

*Inspector General.*

[FR Doc. 02-15349 Filed 6-17-02; 8:45 am]

**BILLING CODE 4152-01-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, "Growth Factor Receptor Signaling in Breast Cancer Progression".

*Date:* July 10-12, 2002.

*Time:* 5:00 PM to 1:00 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Radisson AstroDome Convention Center, 8686 Kirby Drive, Houston, TX 77030.

*Contact Person:* Shakeel Ahmad, PhD, Scientific Review Administrator, Grants Review Branch, National Cancer Institute, National Institutes of Health, 8th Floor, Room 8137, 6116 Executive Boulevard, Bethesda, MD 20892, (301) 594-0114, [amads@mail.nih.gov](mailto:amads@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: June 11, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02-15261 Filed 6-17-02; 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, Review of Tobacco Industry Documents.

*Date:* July 11, 2002.

*Time:* 2 pm to 8 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Radisson Hotel, 1901 University Blvd. SE, Albuquerque, NM 87106.

*Contact Person:* Gerald G. Lovinger, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8101, Rockville, MD 20892-7405, 301/496-7987.

(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: June 11, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02-15266 Filed 6-17-02; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Cancer Institute.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and meet special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Advisory Committee to the Director, National Cancer Institute.

*Date:* July 10, 2002.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* The purpose of the meeting will be to discuss the Kidney/Bladder Progress Review Group Report.

*Place:* National Cancer Institute, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 11A03, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Lisa Stevens, PhD, Executive Secretary, National Institute of Health, Building 31, Room 3A30, Bethesda, MD 20892, 301/496-1458.

Information is also available on the Institute's/Center home page: [deainfo.nci.gov/advisory/joint/htm](http://deainfo.nci.gov/advisory/joint/htm), where an agenda and any additional information for the meeting will be posted when available.

(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)