

B. TABLE 1.—ADDRESSES FOR CURRICULUM VITAE AND NOMINATIONS—Continued

Advisory Committee	Type of Representative	Contact Person	Office/Center/ Mail Code	Addresses/ E-mail	Telephone
DGMPAC	Industry and government representatives	Sharon Kalokerinos	CDRH (HFZ-300)	2094 Gaither Rd., Rockville, MD 20850, or <a href="mailto:smk@cdrh.fda.gov">smk@cdrh.fda.gov</a>	301-594-4613 ext. 139
TEPRSSC	Industry and government representatives	Orhan Suleiman	CDRH (HFZ-240)	1350 Piccard Dr., Rockville, MD 20850, or <a href="mailto:ohs@cdrh.fda.gov">ohs@cdrh.fda.gov</a>	301-594-3533
NMQAAC, DGMPAC, TEPRSSC	Consumer and general public representatives	Linda A. Sherman	Office of the Senior Associate Commissioner for Office of External Relations (HF-4)	5600 Fishers Lane, Rockville, MD 20857, or <a href="mailto:lshearn@oc.fda.gov">lshearn@oc.fda.gov</a>	301-827-1220

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: June 10, 2002.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 02-15210 Filed 6-17-02; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Protection of Human Subjects in Clinical Trials; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Protection of Human Subjects in Clinical Trials. The topics to be discussed are the role of FDA, institutional review boards, and other stakeholders in the protection of human subjects in clinical trials as it relates to minority participation.

**Date and Time:** The meeting will be held on August 22, 2002, from 7:30 p.m. to 9 p.m.

**Location:** The meeting will be held at Meharry Medical School, West Basic Science Building Auditorium, rm. M001, 21st Avenue North at Meharry Blvd., Nashville, TN 37208.

**Contact:** Sandra S. Baxter, Southeast Region, New Orleans District Office, Food and Drug Administration, 297 Plus Park Blvd., Nashville, TN 37217, 615-781-5385, ext. 122, FAX 615-781-5383, e-mail: [sbaxter@ora.fda.gov](mailto:sbaxter@ora.fda.gov).

**Registration and Requests for Oral Presentations:** Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and

requests to make oral presentations, to the contact person by August 8, 2002.

If you need special accommodations due to a disability, please contact Sandra S. Baxter at least 7 days in advance.

**Transcripts:** Transcripts of the meeting may be requested 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 working days after the meeting at a cost of 10 cents per page.

Dated: June 10, 2002.

**John Marzilli,**

*Acting Senior Associate Commissioner for Regulatory Affairs.*

[FR Doc. 02-15279 Filed 6-17-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99D-5199]

#### Medical Devices; Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery." This guidance is intended to provide guidance on the preclinical testing recommended for resorbable adhesion barrier devices used in abdominal and/or pelvic surgery. This guidance is being issued to finalize the previous draft version issued on December 16, 1999.

**DATES:** Submit written or electronic comments concerning this guidance at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

#### FOR FURTHER INFORMATION CONTACT:

Joyce M. Whang, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180

#### SUPPLEMENTARY INFORMATION:

##### I. Background

This guidance document is intended to provide guidance on the preclinical and clinical testing recommended for resorbable adhesion barrier devices used in abdominal and/or pelvic surgery. It was developed jointly by the Division of General, Restorative and Neurological Devices, and the Division of Reproductive, Abdominal and Radiological Devices. The final version of this guidance supersedes the draft

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