

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5199]

DMB

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Certifier	SNK Reese

**Medical Devices; Draft Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled, "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery." This draft guidance is not final nor is it in effect at this time. This draft guidance is being issued because of the increasing interest on the part of sponsors in developing adhesion barrier products and increasing questions regarding the study requirements for development of these products. In addition, because two review groups evaluate these products for use in abdominal and/or pelvic surgery, this draft guidance was developed to encourage consistency between the two review groups when they evaluate investigational device exemption (IDE) and premarket approval application (PMA) applications for these products.

**DATES:** Submit written comments concerning this guidance by [*insert date 90 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written requests for single copies on a 3.5' diskette of the draft guidance entitled, "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 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. Written comments concerning this guidance must be submitted to the

Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fisher Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** David B. Berkowitz, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This draft guidance is being issued because of the increasing interest on the part of sponsors in developing adhesion barrier products and in answering questions regarding the study requirements for development of these products. In addition, because two branches and divisions are evaluating these products for use in abdominal and/or pelvic surgery, this guidance was developed to encourage consistency between the two review groups when they evaluate IDE and PMA applications for these products.

**II. Significance of Guidance**

This draft guidance document represents the agency's current thinking on resorbable adhesion barrier devices for use 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

### 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 (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (1356) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the draft guidance entitled “Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery,” 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. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

### IV. Comments

Interested persons may, on or before [*insert date 90 days from date of publication in the Federal Register*], submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that

individuals may submit one 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 12/7/99  
December 7, 1999

*Linda S. Kahan*

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Center for Devices and Radiological Health

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**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

*Suzette Reese*