

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. FDA-2006-N-0178] (formerly Docket No. 2006N-0362)

**Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Absorbable Hemostatic Device; Availability; Reopening of Comment Period**

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

**ACTION:** Notice; reopening of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening until *[insert date 30 days after date of publication in the Federal Register]*, the comment period for a draft guidance entitled “Class II Special Controls Guidance Document: Absorbable Hemostatic Device.” The draft guidance describes a means by which the absorbable hemostatic device may comply with the requirements of special controls if it is reclassified. FDA is reopening the comment period to update comments and to receive any new information. Elsewhere in this issue of the **Federal Register**, FDA is reopening the comment period on a proposed rule to reclassify the absorbable hemostatic device from class III (premarket approval) into class II (special controls).

**DATES** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance *[insert date 30 days after date of publication in the Federal Register]*.

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**ADDRESS:** Submit written comments 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3638.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 31, 2006 (71 FR 63728), FDA published a proposed rule to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket) into class II (special controls). In the same issue of the **Federal Register** (71 FR 63774), FDA published a notice of availability of a draft guidance document entitled "Class II Special Controls Guidance Document: Absorbable Hemostatic Device." FDA invited interested persons to comment on the draft guidance document by January 29, 2007. In the **Federal Register** of May 8, 2007 (72 FR 26134), FDA published a notice reopening the comment period for 30 days.

On July 2, 2007, FDA received a petition under 21 CFR 10.30 and 10.35 requesting that the agency refrain from issuing a final regulation for the proposed reclassification and the draft special controls guidance for the absorbable hemostatic device until an updated and complete administrative record is made available to the public. The petitioner also requested that FDA reopen the rulemaking for the proposed reclassification to allow submission of comments based on the administrative record. Elsewhere in this issue of

the **Federal Register**, FDA is reopening the comment period on the proposed rule for 30 days. Because the issues presented by the guidance document are intertwined with those presented by the proposed rule, FDA is reopening the comment period on the guidance document for the same period.

## II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive the draft guidance document entitled “Class II Specials Controls Document: Absorbable Hemostatic Device,” you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document, or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1558 to identify the guidance you are requesting.

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 Internet access. 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 manufacturer’ assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

## III. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance document. Submit a single copy of electronic comments or two paper copies of any 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments submissions will be accepted by FDA through FDMS only.

Dated: 9/4/08  
September 4, 2008.

  
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Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

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