

electronic access to the guidance document.

Submit written comments concerning this guidance to the Division of Dockets Management (HFZ-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0496.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 30, 2004 (69 FR 58371), FDA published a proposed rule to reclassify HAV serological assays from class III (premarket approval) into class II (special controls). FDA proposed this action after reviewing information contained in a reclassification petition submitted by Beckman Coulter Inc. In addition, FDA issued a draft class II special controls guidance document entitled "Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus" to support the proposed reclassification. HAV serological assays are in vitro diagnostic devices that test for specific antibodies. In conjunction with other clinical laboratory findings, the detection of these HAV-specific antibodies aids in the clinical laboratory diagnosis of an acute or past infection by HAV. The comments FDA received were supportive of the proposed reclassification, but made some suggestions on the guidance's content. FDA considered the suggestions and made appropriate revisions. FDA is now identifying the guidance document entitled "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays" as the guidance document that will serve as the special control for these devices.

The guidance document provides a means by which HAV serological assays may comply with the requirement of special controls for class II devices. Following the effective date of the final reclassification rule, any firm submitting a premarket notification (510(k)) for HAV serological assays will need to address the issues covered in the special controls guidance document. However, the firm need only show that

its device meets the recommendation of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

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 HAV serological assays. 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 and regulations.

III. Electronic Access

To receive "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays" by fax, 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 (1536) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the 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 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 manufacturers' assistance, information on video conferencing and electronic submission, 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 on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collection of information in part three of this guidance document has been submitted

to OMB for review and was approved under OMB control number 0910-0120. The collection of information in part ten of this guidance document has been submitted to OMB for review and was approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this 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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 1, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 06-1207 Filed 2-8-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0020]

Draft Guidance for Industry and Food and Drug Administration Staff; Draft Class II Special Controls Guidance Document: Intervertebral Body Fusion Device; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." It was developed as a special control to support the reclassification of intervertebral body fusion devices that contain bone grafting material from class III (premarket approval) into class II (special controls). This draft guidance document describes a means by which these intervertebral body fusion devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify the intervertebral body fusion device that contains bone grafting material from class III into class II (special

controls) and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III. This draft guidance is not final, nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by May 10, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section of this document for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance 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.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jodi N. Anderson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, ext. 186.

SUPPLEMENTARY INFORMATION:

I. Background

On December 11, 2003, the Orthopedic and Restorative Devices Panel (the panel) recommended that intervertebral body fusion devices that contain bone grafting material be reclassified from class III into class II. The panel also provided recommendations on the types of information the agency should include in a class II special controls guidance document for these devices. This document announces the draft guidance that is based on these recommendations. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify these devices.

II. Significance of 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 intervertebral body fusion devices. 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

To receive "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" by fax, call the Center for Devices and Radiological Health (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 (1540) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. 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's 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 on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910-0120). The labeling provisions addressed in the draft guidance have been approved by OMB under OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this 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.

Dated: February 1, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6-1735 Filed 2-8-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0012]

Draft Guidance for Industry and Food and Drug Administration Staff; Pharmacogenetic Tests and Genetic Tests for Heritable Markers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Pharmacogenetic Tests and Genetic Tests for Heritable Markers." This draft guidance document is intended to provide guidance on preparing and reviewing premarket approval applications (PMAs) and 510(k) submissions for pharmacogenetic and other genetic tests, whether testing is for single markers or for multiple markers simultaneously (multiplex tests).

DATES: Submit written or electronic comments on this draft guidance by May 10, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Pharmacogenetic Tests and Genetic Tests for Heritable Markers" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 or submit written requests for single copies of the