

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0385]

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Signature	<i>J. Coole</i>

**Guidance for Industry and Food and Drug Administration Staff; Class II
Special Controls Guidance Document; Hepatitis A Virus Serological Assays;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays." The guidance document describes a means by which these in vitro diagnostic devices for the laboratory diagnosis of hepatitis A virus (HAV) may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying these devices from class III (premarket approval) into class II (special controls). HAV serological assays are in vitro diagnostic devices used to test for specific antibodies to support the clinical laboratory diagnosis of HAV.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays"

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 for 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>.

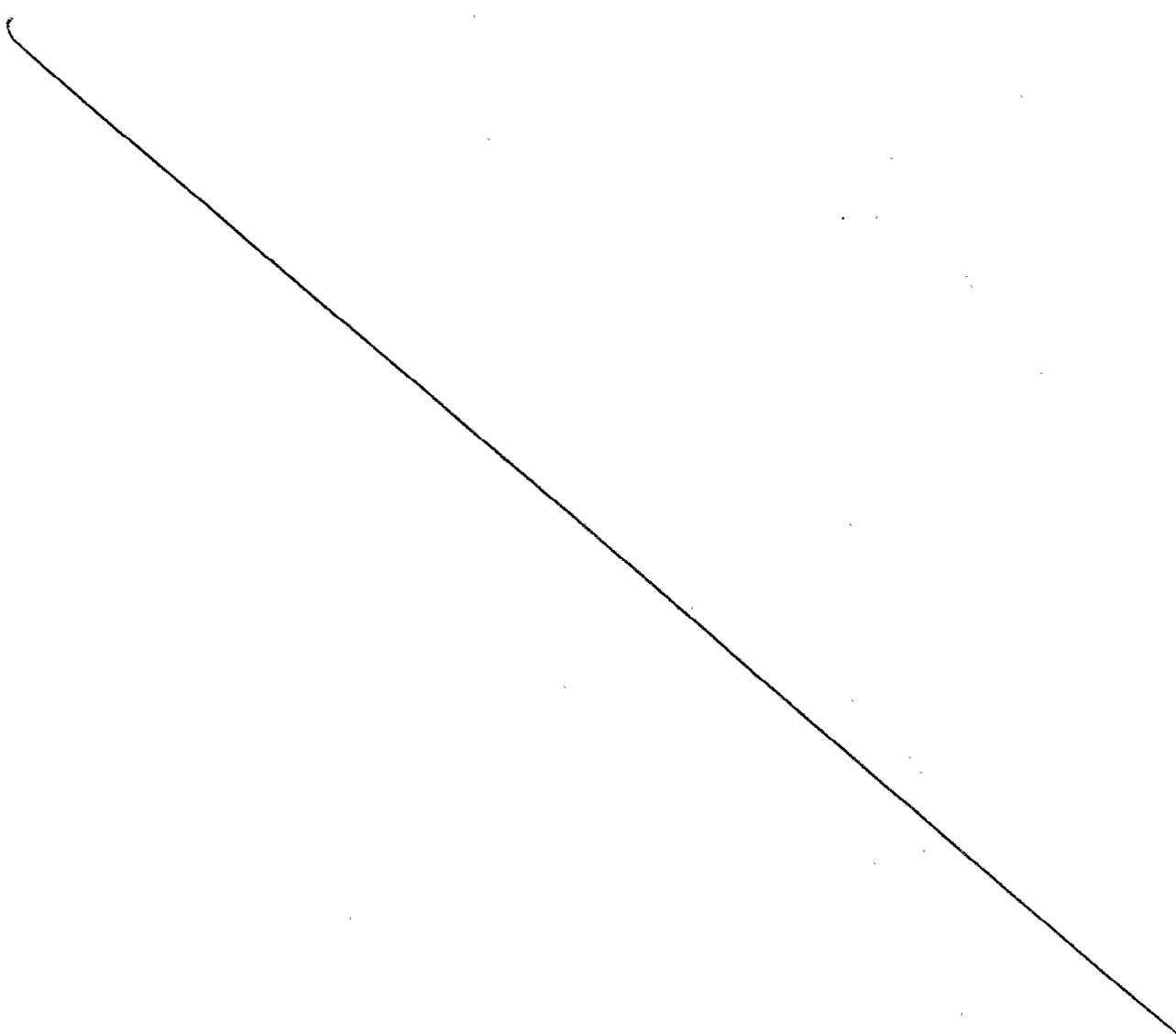
IV. Paperwork Reduction Act

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: 2/1/06

February 1, 2006.

Linda S. Kahan

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