

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-3028]

DMB

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Certifier	<i>[Signature]</i>

Draft Guidance for Industry; Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV); Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA."

FDA is issuing this draft guidance to provide current recommendations about the design, data collection, and data analysis of studies that are important to the premarket approval application (PMA) process for in vitro diagnostic (IVD) devices pertaining to HCV. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological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. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Doria DuBois, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2096.

SUPPLEMENTARY INFORMATION:

I. Background

On February 12, 1998, FDA called a meeting of the Microbiology Devices Advisory Panel to obtain recommendations from the panel regarding scientific information necessary for premarket approval of tests for hepatitis viruses. Following the panel meeting and subsequent discussions between FDA and industry, FDA developed and published a draft guidance (See 64 FR 54902, October 8, 1999). FDA accepted public comments regarding the draft guidance until January 6, 2000. This second draft guidance incorporates those comments and replaces the October 8, 1999, draft guidance document.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on assays for detecting evidence of infection with HCV. 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 statutes and regulations.

The agency has adopted good guidance practices (GGPs) and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive "Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA" 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 (1353) 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 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. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. "Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection or HCV-Associated Disease; Draft Guidance for Industry and FDA," will be available at <http://www.fda.gov/cdrh/ode/guidance/1353.pdf>. Updated on a regular basis, the CDRH home page also includes the civil money penalty guidance documents package, 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.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by [insert date 90 days after date of publication in the **Federal Register**]. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 4/18/01
April 18, 2001.

Linda S. Kahan

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[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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