II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: September 23, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–21873 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0438]

Guidance for Industry: Use of Material from Bovine Spongiform Encephalopathy-Positive Cattle in Animal Feed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#174) entitled ''Use of Material from BSE-Positive Cattle in Animal Feed.'' This guidance document describes FDA's current thinking regarding the use in all animal feed of all material from cattle that test positive for BSE (bovine spongiform encephalopathy).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: 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 on the guidance via the Internet at *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Burt Pritchett, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6860, e-mail: *burt.pritchett@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

BSE belongs to a family of animal and human diseases called transmissible spongiform encephalopathies (TSEs). These include BSE or ''mad cow'' disease in cattle; scrapie in sheep and goats; and classical and variant Creutzfeldt-Jakob diseases (CJD and vCJD) in humans. There is no known treatment for these diseases, and there is no vaccine to prevent them. In addition, although validated postmortem diagnostic tests are available, there are no validated diagnostic tests for BSE or other TSEs that can be used to test for the disease in live animals or humans.

Under FDA's BSE feed regulation (21 CFR 589.2000) any protein-containing portion of mammalian animals is prohibited for use in feed for ruminant animals with the exception of certain products. FDA took this action to minimize the potential for any undetected BSE infectivity in animal feed to spread to ruminants via their feed. This guidance document describes FDA's recommendations regarding the use in all animal feed of all material from cattle that test positive for BSE.

II. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation in § 10.115(21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because FDA believes that, in light of the increased BSE testing activities by the U.S. Department of Agriculture, it is of public health importance to clarify that cattle that test positive for BSE are adulterated and are not to be used in any animal feed.

This guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance. The public will be notified of any such amendments through a document in the **Federal Register**.

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.

V. Electronic Access

Copies of this guidance document may be obtained from the Center for Veterinary Medicine home page (*http://www.fda.gov/cvm*) and from the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: September 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22014 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0385]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus; 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: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus.'' This draft guidance document describes a means by which in vitro diagnostic devices for the laboratory diagnosis of Hepatitis A Virus 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 these device types from class III into class II (special controls).

DATES: Submit written or electronic comments on this draft guidance by December 29, 2004.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus'' 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 information on electronic access to the 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: Sally Hojvat, 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

This draft document was developed as a special control to support the classification of in vitro diagnostic devices for the laboratory diagnosis of Hepatitis A Virus (HAV) into class II (special controls). Hepatitis A Virus Tests, Product Code LOL, are devices that detect immunoglobulins M, (IgM), immunoglobulin G (IgG), and total antibodies (IgM and IgG) reactive to HAV. The detection of HAV-specific antibodies in human serum or plasma is laboratory evidence of HAV infection, with the presence of IgM type antibodies differentiating an acute infection from past infection.

This draft guidance document identifies the classification regulation and product code for HAV-specific IgM, IgG, and total antibody assays. In addition, other sections of this guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these assays and lead to a timely premarket notification (510(k)) review and clearance. This document supplements other FDA documents regarding the specific content of a premarket notification submission.

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 Class II special controls for in vitro diagnostic devices for the laboratory diagnosis of Hepatitis A Virus. 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: Hepatitis A Serological Assays for the Clinical Laboratory Diagnosis of Hepatitis A Virus'' by 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 1536 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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 (44 USC 3501–3520) (the PRA). The collections of information addressed in the 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 No. 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB No. 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 copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–22010 Filed 9–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0412]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Sirolimus Test Systems; 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 ''Class II Special Controls Guidance Document: Sirolimus Test Systems.'' This guidance document describes a means by which sirolimus test systems 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 to classify sirolimus test systems into class II (special controls). This guidance document is immediately in effect as the special control for sirolimus test systems but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Sirolimus Test Systems'' 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 information on electronic access to the guidance.

Submit written comments concerning this 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://*