SUPPLEMENTARY INFORMATION: A Web address for the meeting will be available at: *http://www.hhs.gov/healthit.*

Dated: February 1, 2006.

Dana Haza,

Office of Programs and Coordination, Office of the National Coordinator.

[FR Doc. 06–1180 Filed 2–8–06; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 70 FR 72842–72843, dated December 7, 2005) is amended to reflect the title change for the Division of Injury and Disability Outcomes, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title for the *Division of Injury and Disability Outcomes (CE6)* and insert the *Division of Injury Response (CTCE).*

Dated: January 27, 2006

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 06–1199 Filed 2–8–06; 8:45 am]

BILLING CODE 4160–18—M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee); Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary of Health and Human Services (the Secretary) and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand study by the U.S. Air Force and provide scientific oversight of the Department of Veterans Affairs Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the committee is desirable.

Date and Time: The meeting will be held on February 27, 2006, from 8:30 a.m. to 4 p.m.

Location: Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD.

Contact Person: Leonard Schechtman, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512560. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the following items: (1) Update on the Institute of Medicine's Air Force Health Study Disposition Study and related closure activities; (2) updates from the Air Force on the Viability Study, Compliance Study, Comprehensive Study, Mortality Update, Technical Reports, and External Collaborations.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 17, 2006. Oral presentations from the public will be scheduled on February 27, 2006, between approximately 11:30 a.m. and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 17, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Leonard Schechtman at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 2, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1737 Filed2–8–06; 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 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: 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