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 This draft guidance is not final, nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by May 10, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Intervertebral Body Fusion Device'' to the Division of Small Manufacturers, International, and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 See the **SUPPLEMENTARY INFORMATION** section of this document for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 This document announces the draft guidance that is based on these recommendations.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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on intervertebral body fusion devices.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

guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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:

Robert Becker, Center for Devices and Radiological Health (CDRH) (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0493, ext. 212.

For use of the guidance in relation to applications to CBER, contact: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

For use of the guidance in relation to applications to the Center for Drug Evaluation and Research (CDER), contact: Allen Rudman, Office of Clinical Pharmacology and Biopharmaceutics (HFD–850), Food and Drug Administration, 10903 New Hampshire Ave., W021, rm. 3666, Silver Spring, MD 20993–0002, 301–796–1597.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document provides recommendations on preparing and reviewing PMAs and 510(k) submissions for pharmacogenetic and other human genetic tests, whether testing is for single markers or for multiple markers simultaneously (multiplex tests). Tests of gene expression and tests for non-heritable (somatic) mutations are not specifically addressed, although many of the same principles may apply. Likewise, this draft guidance specifically addresses only nucleic-acid based analysis, but some of the principles may be applied to other matrices (e.g., protein), when the purpose is to provide genetic information.

FDA issued an earlier version of this draft guidance on February 27, 2003, entitled ''Draft Guidance for Industry and FDA Reviewers; Multiplex Tests for Heritable DNA Markers, Mutations and Expression Patterns.'' The notice of availability for the February 27, 2003, draft guidance was published in the **Federal Register** of April 21, 2003 (68 FR 19549) and the comment period closed on July 21, 2003. As explained in the February 27, 2003, draft guidance and April 21, 2003, document, we recognized that discussions on this topic had been introductory. Because of this, we explained that the February 2003 draft guidance would be followed by another draft guidance that would provide an opportunity for additional discussion. As stated in the April 2003 document, we believe the public health will benefit from this dialogue with industry about appropriate ways to review this technology.

We received several comments on the 2003 draft guidance, which included comments suggesting that the draft guidance was too broad in scope. The 2003 draft guidance document addressed both gene expression and genetic tests. The draft guidance announced in this **Federal Register** document, ''Pharmacogenetic Tests and Genetic Tests for Heritable Markers,'' instead focuses on genetic tests.

In developing the draft guidance announced in this document, FDA considered the comments received on the 2003 draft guidance and also information we received through our participation at seminars and workshops with representatives from the drug and device industries, professional societies, laboratory professionals, healthcare providers, and other stakeholders. These seminars and workshops included discussions of the criteria that are important in the analytical and clinical validation of multiplex tests, including pharmacogenetic and genetic assays. These discussions also explored the kind of information the industry might submit to the agency to achieve the least burdensome means of demonstrating substantial equivalence or evaluating safety and effectiveness.

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 ''Pharmacogenetic Tests and Genetic Tests for Heritable Markers.'' 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 ''Pharmacogenetic Tests and Genetic Tests for Heritable Markers'' 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 (1549) 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*. CBER's guidance documents are available at *http://www.fda.gov/cber/guidelines.htm*. 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 refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB Control No. 0910–0120; 21 CFR part 814 have been approved under OMB Control No. 0910–0231; 21 CFR part 801 and 21 CFR part 809 have been approved under OMB Control 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 paper 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: February 1, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–1787 Filed 2–8–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 9, 2006, 9 a.m.–3:30 p.m., EST.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, March 9, from 9 a.m. to 3:30 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–800–369–6048 on March 9 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the March meeting will include, but are not limited to: An overview of compensation programs in other countries; results of the National Vaccine Injury Compensation Program's (VICP) Program Assessment Rating Tool; a discussion of the Division of Vaccine Injury Compensation's (DVIC) communication strategies; a report from the ACCV Workgroup looking at proposed guidelines for future changes to the Vaccine Injury Table; and updates from DVIC, Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics and Evaluation Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail *clee@hrsa.gov.* Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–2124 or e-mail *clee@hrsa.gov.*

Dated: February 2, 2006.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–1733 Filed 2–8–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Privacy Act System of Records Notice 09–17–0001, ''Medical, Health and Billing Records'': Correction

AGENCY: Indian Health Service (IHS), HHS.

ACTION: Notice: correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on December 30, 2005. The document contained an error.

FOR FURTHER INFORMATION CONTACT: Contact Ms. Patricia Gowan, IHS Lead Health Information Management (HIM) Consultant (Acting), Office of Health Programs, Phoenix Area Office IHS, Two Renaissance Square, Suite 606, 40 North Central Avenue, Phoenix, AZ 85004 or via the Internet at *Patricia.Gowan@ihs.gov.*

Correction

In the **Federal Register** of December 30, 2005, in FR Doc 05–24644, on page 77407, in the second column, correct number 5 to read: ''Records may be disclosed to the Bureau of Indian Affairs (BIA) or its contractors under an agreement between IHS and the BIA relating to disabled AI/AN children for the purposes of carrying out its functions under the Individuals with Disabilities Education Act (IDEAS), 20 U.S.C. 1400, *et seq.*''

Re-number 5 to number 6 and so forth for a total of twenty-four routine uses instead of twenty-three.

Dated: February 2, 2006.

Robert G. McSwain,

Deputy Director, Indian Health Service.

[FR Doc. 06–1188 Filed 2–8–06; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: January 2006

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of January 2006, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.