device industries, professional societies, laboratory professionals, healthcare providers, and other stakeholders, which discussed the criteria that are important in the analytical and clinical validation of multiplex assays. These discussions also explore the kind of information the industry might submit to the agency to achieve the least burdensome means of demonstrating substantial equivalence or evaluating effectiveness. FDA is issuing the draft guidance document in an effort to continue this dialogue. FDA believes the draft guidance document represents a summary of the discussions that have taken place.

FDA recognizes, however, that the discussions to this point have been introductory. Therefore, following review of the comments we receive on this draft guidance document, FDA intends to issue a new draft guidance document for additional discussion. FDA is taking this approach because we believe the public health will benefit from dialogue with the industry about appropriate ways to review this new and important technology.

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns.'' 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 the approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act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). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E,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 and/or premarket approval applications (21 CFR part 814, OMB Control Number 0910–0231)).

IV. Comments

Interested persons may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two hard copies of any mailed comments. Identify comments with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

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 Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

To receive a copy of ''Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns'' 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 (1210) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance document may also do so by using the Internet. CDRH maintains a site 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 submissions, Mammography Matters, and other device-oriented information.

Dated: April 3, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–9661 Filed 4–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Meeting of the Advisory Committee on Organ Transplantation.

SUMMARY: Pursuant to Pub. L. 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the fourth meeting of the Advisory Committee on Organ Transplantation (ACOT), Department of Health and Human Services (HHS). The meeting will be held from approximately 9 a.m. to 5:30 p.m. on May 22, 2003, and from 9 a.m. to 5 p.m. on May 23, 2003, at the Marriott Washington, 1221 22nd Street NW., Washington, DC 20037. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (*see* below).

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), the ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. The ACOT is composed of 41 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

The ACOT will hear and discuss reports from the following ACOT subcommittees: Organ Supply Concerns, Recipient Concerns, Public Concerns, and Allocation Concerns.

The draft meeting agenda will be available on May 1 on the Division of Transplantation's Web site *http://*

www.hrsa.gov/osp/dot/whatsnew.htm or the Department's donation Web site at *http://www.organdonor.gov/acot.html.*

A registration form is available on the Division of Transplantation's Web site: *http://www.hrsa.gov/osp/dot/whatsnew.htm* or the Department's donation Web site at *http://www.organdonor.gov/acot.html.* The completed registration form should be submitted by facsimile to McFarland and Associates, Inc., the logistical support contractor for the meeting, at Fax number (301) 589–2567. Individuals without access to the Internet who wish to register may call Paulette Wiggins with McFarland and Associates, Inc., at 301–562–5337. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACOT Executive Director, Jack Kress, in advance of the meeting. Mr. Kress may be reached by telephone at 301–443–8653, by e-mail at: *jkress2@hrsa.gov*, or in writing at the address of the Division of Transplantation provided below. Management and support services for ACOT functions are provided by the Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 16C–17, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentation of the subcommittee reports, members of the public will have an opportunity to provide comments on the subcommittee reports. Because of the Committee's full agenda and the time frame in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting.

Dated: April 10, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–9665 Filed 4–18–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Proposed Information Collection; Request for Comments

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 30-day proposed information collection: ''IHS Forms to Implement the Privacy Rule (45 CFR parts 160 and 164).

SUMMARY: The Indian Health Service (IHS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. As required by section 3507(a)(1)(D) of the Act, the proposed information collection has been submitted to the Office of Management and Budget (OMB) for review and approval. The IHS received comments in response to the 60-day **Federal Register** notice (67 FR 67411) published on November 5, 2002. The public comments received in response to the notice and the Agency responses are summarized and addressed below.

Comment: One comment questioned the readability of the forms. The commentor suggested that the Flesch Reading Ease score be raised to 50–75 percent from the 27.9 percent–47.3 percent readability score that the forms received. The commentor also noted that the Flesch-Kincaid Grade level for the forms required a reading level of 11½ to 12 years of education. The commentor also suggested decreasing the required education level for the forms.

Agency Response: The data collection instruments were field tested at the Fort Duchesne IHS Health Center, Fort Duchesne, Utah to determine whether the data collection instruments and instructions were clear and user friendly. They were found to be user friendly, clear and understandable. Changes suggested during the field testing were incorporated into the forms. Since the forms are generally filled in by the patient at an IHS facility, questions regarding understandability will be answered by IHS staff who will be trained on the correct and proper use of each form.

Comment: The only other comment received concerned the proposed IHS Form 911 (renumbered 917), the Request for Correction/Amendment of Protected Health Information. The commentor requested that the IHS eliminate the word ''Correction'' from the title and the word ''corrected'' in the body of the form. The commentor believed that the word ''correction'' implies a deletion of information. The commentor points out that the word ''correction'' was deleted from § 164.526 of the Privacy Rule for the same reason. In addition the commentor also states that the Privacy Act of 1974 (5 USC 552a) in section (d)(2) Access to Records does not reference ''correction/amendment.'' This last point is not correct. If one continues to read section (d)(2) further to subsection (d)(2)(B)(i) the Privacy Act states that the agency is required to ''make any correction of any portion thereof which the individual believes is not accurate, relevant, timely or complete; * * *'' The Privacy Act clearly uses the word ''correction'' regarding the corrective action that the Agency is required to take. Furthermore, the Department of Health and Human Services (DHHS) Privacy Regulations at 45 CFR 5 b.7 and 5 b.8 also use the terms ''correction or amendment'' in either the titles of the subsections or in the body of the subsection. Section 5 b.7 is titled ''Procedures for correction or amendment of records'' and § 5 b.8 is titled ''Appeals of refusals to correct or amend records.'' Furthermore, the DHHS Privacy Regulation also clearly states in section 5 b.7 when an actual deletion would occur. Section 5 b.7 states that ''The record will be deleted without regard to its accuracy, if the record is not relevant or necessary to accomplish the Department functions for which the record was provided or is maintained.'' Therefore we believe that the Privacy Act and the DHHS regulations in this regard are quite clear. As an added note, the IHS Manual at Chapter 3–3.14(c)(6) describes the method for correcting entries in a medical record. The manual states that no erasure or other obliteration shall be made and also required that incorrect data shall be lined out with a single line.

Therefore, the IHS has decided not to follow the suggestions submitted by the commentor.

The purpose of this notice is to allow an additional 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 09–17–NEW, ''IHS Forms to implement the Privacy Rule (45 CFR parts 160 and 164)''. *Type of Information Collection Request:* New collection. *Form Number(s):* IHS–810 Authorization for Use or Disclosure of Health Information, IHS–917 Request for Correction/Amendment of Protected Health Information, IHS–912–I Request for Restriction(s), IHS 912–2 Terminating a Restriction, and IHS 913 Request For an Accounting of Disclosures. *Need and Use of Information Collection:* This collection of information is made necessary by the Department of Health