

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 FDA is issuing the draft guidance document in an effort to continue this dialogue. FDA believes the draft guidance document represents a summary of the discussions that have taken place.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 Therefore, following review of the comments we receive on this draft guidance document, FDA intends to issue a new draft guidance document for additional discussion.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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on "Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns."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This draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act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 The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E,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Interested persons may submit to the Dockets Management Branch (*see ADDRESSES*) written or electronic comments on the draft guidance.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.

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Deputy Director, Center for Devices and Radiological Health.

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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://>