actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product EXELON (rivastigmine tartrate). EXELON is indicated for the treatment of mild to moderate dementia of the Alzheimer's type. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EXELON (U.S. Patent No. 4,948,807) from Novartis, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 2, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EXELON represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for EXELON is 3,424 days. Of this time, 2,313 days occurred during the testing phase of the regulatory review period, while 1,111 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: December 8, 1990. The applicant claims November 7, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 8, 1990, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 7, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for EXELON (NDA 20–823) was initially submitted on April 7, 1997.

3. *The date the application was approved*: April 21, 2000. FDA has verified the applicant's claim that NDA 20–823 was approved on April 21, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments and ask for a redetermination by June 20, 2003. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 20, 2003. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (*See* H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (*see* **ADDRESSES**). Three copies of any information are to be submitted, 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 and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 31, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–9663 Filed 4–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0120]

Medical Devices: Draft Guidance for Industry and FDA Reviewers; Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled ''Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns.'' FDA has received many inquiries pertaining to multiplex test submissions (including microarray submissions). This draft guidance document represents the Center for Devices and Radiological Health's (CDRH) attempt to continue the dialogue with stakeholders regarding the basic framework for the types of data that should be included in a submission. FDA is anxious to provide the best guidance possible to assist sponsors in developing multiplex text submissions that will support timely review and marketing of safe and effective products using this technology. This draft guidance document is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance document by July 21, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns'' 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 two self-addressed adhesive labels 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 draft guidance document.

Submit written comments on this draft guidance to the Dockets Management Branch (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: Elizabeth Mansfield or Michele Schoonmaker, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background

FDA anticipates that multiplex tests, including such as microarrays, using DNA and ribonuclei acid samples will are anticipated to have a number of clinical purposes, including genotyping, haplotype analysis, and categorization by expression profile, etc. FDA has received many inquiries pertaining to possible regulatory strategies for submitting and reviewing data from assays yielding multiple, simultaneous results. Over the past 24 months, FDA has participated in a number of seminars and workshops with representatives from the drug and

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://*