

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.*

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## 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 be 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