forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device GENESIS NEUROSTIMULATION SYSTEM. GENESIS NEUROSTIMULATION SYSTEM is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GENESIS NEUROSTIMULATION SYSTEM (U.S. Patent No. 4,793,353) from Advanced Neuromodulation Systems, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 31, 2002, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of GENESIS NEUROSTIMULATION SYSTEM represented the first permitted commercial marketing or use of the product. 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 GENESIS NEUROSTIMULATION SYSTEM is 469 days. Of this time, 292 days occurred during the testing phase of the regulatory review period, while 177 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: August 11, 2000. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on June 16, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on August 11, 2000, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: May 29, 2001. The applicant claims April 3, 2001, as the date the premarket approval application (PMA) for GENESIS NEUROSTIMULATION SYSTEM (PMA P010032) was initially submitted. However, FDA records indicate that PMA P010032 was submitted on May 29, 2001.

3. *The date the application was approved*: November 21, 2001. FDA has verified the applicant's claim that PMA P010032 was approved on November 21, 2001.

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 840 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 May 23, 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 September 22, 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. Three copies of any information are to be submitted, except that individuals may submit one copy 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: February 7, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–6892 Filed 3–21–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92–463, the fiscal year 2002 annual report for the following Health Resources and Services Administration's Federal advisory committee has been filed with the Library of Congress: Maternal and Child Health Research Grants Review Committee.

Copies are available to the public for inspection at the Library of Congress, Newspaper and Current Periodical Reading Room in the James Madison Memorial Building, Room LM–133 (entrance on Independence Avenue, between First and Second Streets, SE., Washington, DC).

Copies may be obtained from: Kishena C. Wadhwani, Ph.D., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Parklawn Building, Room 18A–55, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone 301–443–2340.

Dated: March 17, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–6858 Filed 3–21–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program Guidance for Ambulance Suppliers

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Federal Register notice sets forth the recently issued Compliance Program Guidance for Ambulance Suppliers developed by the Office of Inspector General (OIG). The OIG has previously developed and published voluntary compliance program guidance focused on several different areas of the health care