[Federal Register Volume 59, Number 42 (Thursday, March 3, 1994)]
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[FR Doc No: 94-4802]

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[Federal Register: March 3, 1994]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 93E-0327]

Determination of Regulatory Review Period for Purposes of Patent Extension; Imagent GI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Imagent GI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period 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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner 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 Imagent GI. Imagent GI (perflubron) is indicated

for oral use with magnetic resonance imaging to enhance delineation of the bowel in order to distinguish it from adjacent organs and areas of suspected pathology. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Imagent GI (U.S. Patent No. 3,975,512) from the Board of Trustees of the University of Illinois, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated September 23, 1993, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Imagent GI represented the first 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 Imagent GI is 7,493 days. Of this time, 6,469 days occurred during the testing phase of the regulatory review period, while 1,024 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 became effective: February 8, 1973. The applicant claims February 9, 1973, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 8, 1973, which was 30 days after FDA's 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 Federal Food, Drug, and Cosmetic Act: October 25, 1990. The applicant claims June 18, 1990, as the date the new drug application (NDA) for Imagent GI (NDA 20-091) was initially submitted. FDA refused to file this application and notified the applicant of this fact by a letter dated August 16, 1990. The completed NDA 20-091 was resubmitted on October 25, 1990, the initially submitted date.

3. The date the application was approved: August 13, 1993. FDA has verified the applicant's claim that NDA 20-091 was approved on August 13, 1993.

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 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 2, 1994, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 30, 1994, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 (address above) in three copies (except that individuals may submit single copies) and 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: January 28, 1994.
Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 94-4802 Filed 3-2-94; 8:45 am]
BILLING CODE 4160-01-F