

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 374 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 20, 2007. 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 November 19, 2007. 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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2007.

**Jane A. Axelrad,**

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

[FR Doc. E7–9733 Filed 5–18–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2002E–0156]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; GALILEO INTRAVASCULAR RADIOTHERAPY SYSTEM

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for GALILEO INTRAVASCULAR RADIOTHERAPY SYSTEM 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 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, GALILEO INTRAVASCULAR RADIOTHERAPY SYSTEM. GALILEO INTRAVASCULAR RADIOTHERAPY SYSTEM is indicated to deliver beta radiation to the site of successful percutaneous coronary intervention (PCI) for the treatment of

in-stent restenosis in native coronary arteries with discrete lesions  $\leq 47$  millimeters (mm) in a reference vessel diameter 2.4 mm to 3.7 mm. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GALILEO INTRAVASCULAR RADIOTHERAPY SYSTEM (U.S. Patent No. 5,199,939) from Guidant Corp., 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 GALILEO INTRAVASCULAR RADIOTHERAPY 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 GALILEO INTRAVASCULAR RADIOTHERAPY SYSTEM is 1,523 days. Of this time, 1,203 days occurred during the testing phase of the regulatory review period, while 320 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective:* September 3, 1997. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective September 3, 1997.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e):* December 18, 2000. The applicant claims March 13, 2000, as the date the premarket approval application (PMA) for GALILEO INTRAVASCULAR RADIOTHERAPY SYSTEM (PMA P000052) was initially submitted. However, FDA records indicate that PMA P000052 was completely submitted on December 18, 2000.

3. *The date the application was approved:* November 2, 2001. FDA has verified the applicant's claim that PMA P000052 was approved on November 2, 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 1,062 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 20, 2007. 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 November 19, 2007. 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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2007.

**Jane A. Axelrad,**

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

[FR Doc. E7-9720 Filed 5-18-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0195]

#### Science Board to the Food and Drug Administration; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Science Board to the Food and Drug Administration (Science Board).

**General Function of the Committee:** The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally,

the Science Board provides advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency sponsored intramural and extramural scientific research programs.

**Date and Time:** The meeting will be held on June 14, 2007, from 8 a.m. to 4 p.m.

**Addresses:** Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select Docket No. 2007N-0195—Science Board and follow prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852, by close of business on June 7, 2007. All comments received will be posted without change, including any personal information provided. Comments received on or before June 7, 2007, will be provided to the committee before or at the meeting.

**Location:** Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD 20879, Grand Ballroom Conference Room.

**Contact Person:** Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF-33), 5600 Fishers Lane, Rockville, Maryland, 20857, 301-827-6687, [carlos.Peña@fda.hhs.gov](mailto:carlos.Peña@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The Science Board will hear about and discuss the agency's bioinformatics initiative and fellowship program. The Science Board will then continue their discussion of the review of both the agency's science programs and the National Antimicrobial Resistance Monitoring System (NARMS) Program, from the March 31, 2006, Science Board meeting. Discussions will first include a subcommittee update to the Science Board on the progress of the review of the agency's science programs.

The Science Board will then hear about and discuss the subcommittee review of the NARMS Program including the public meeting regarding the NARMS Program on April 10, 2007, and subsequent deliberations. The Science Board will also hear about and discuss the agency's updates on drug safety, post approval surveillance, and food safety.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 31, 2007. Two oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. and 3:15 p.m. and 4:15 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 23, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing sessions. The contact person will notify interested persons regarding their request to speak by May 24, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Carlos Peña at least 7 days in advance of the meeting.