D adul:

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–447) 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 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 USPTO 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 has approved for marketing the medical device MICRA TRANSCATHETER PACING SYSTEM. MICRA TRANSCATHETER PACING SYSTEM is indicated for use in patients who have experienced one or more of the following conditions: (1) Symptomatic paroxysmal or permanent high-grade atrioventricular (AV) block in the presence of atrial fibrillation (AF); (2) symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy; (3) symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy. Subsequent to this approval, the USPTO received patent term restoration applications for MICRA TRANSCATHETER PACING SYSTEM (U.S. Patent Nos. 7,824,805 and 8,129,622) from Medtronic, Inc., and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated March 13, 2017, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of MICRA TRANSCATHETER PACING SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MICRA TRANSCATHETER PACING SYSTEM is 788 days. Of this time, 585 days occurred during the testing phase of the regulatory review period, while 203 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 (FD&C Act) (21 U.S.C. 360(j)(g)) involving this device became effective: February 10, 2014. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on April 3, 2014. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on February 10, 2014, which represents the IDE effective date.

2. The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e): September 17, 2015. FDA has verified the applicant’s claim that the premarket approval application (PMA) for MICRA TRANSCATHETER PACING SYSTEM (PMA P150033) was initially submitted September 7, 2015.

3. The date the application was approved: April 6, 2016. FDA has verified the applicant’s claim that PMA P150033 was approved on April 6, 2016. This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several potential limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 457 days and 494 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see DATES). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA 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 comply with all the requirements of § 60.30, including but not limited to: Must be timely (see DATES), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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.

Submit petitions electronically to https://www.regulations.gov at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 8, 2018.

Leslie Kux,
Associate Commissioner for Policy.

Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Anesthetic and Analgesic Drug Products Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on February 14, 2018, from 1:30 p.m. to 5 p.m., and February 15, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommissions/AboutAdvisoryCommittees/ucm408555.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–6826. The docket will close on February 13, 2018. Submit either electronic or written comments on this public meeting by February 13, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 13, 2018. The https://www.regulations.gov electronic filing