GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or *http://www.regulations.gov.*

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–09303 Filed 4–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–M–1452, FDA–2014–M–1596, FDA–2014–M–1597, FDA–2014–M–1599, FDA–2014–M–1735, FDA–2014–M–1736, FDA–2014–M–2042, FDA–2014–M–2246, FDA–2014–M–2248, and FDA–2014–M–2376]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2014, through December 31, 2014. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2014, THROUGH DECEMBER 31, 2014

PMA No., Docket No.	Applicant	Trade name	Approval date
P040037/S060, FDA–2014–M–1452	W.L. Gore & Associates, Inc.	GORE VIABAHN Endoprosthesis, GORE VIABAHN Endoprosthesis with Heparin.	September 19, 2014.
P070015/S122, FDA–2014–M–1596	Abbott Vascular, Inc	XIENCE V® and XIENCE nano® Everolimus Eluting Coronary Stent System.	October 3, 2014.
P110019/S066, FDA–2014–M–1596	Abbott Vascular, Inc	XIENCE PRIME® and XIENCE PRIME LL Everlimus Eluting Coronary Stent System.	October 3, 2014.
P130024, FDA–2014–M–1597	Lutonix, Inc	Lutonix 035 Drug Coated Balloon PTA Catheter.	October 9, 2014.
P110023/S007, FDA–2014–M–1599	ev3, Inc	EverFlex™ Self-Expanding Peripheral Stent System.	October 10, 2014.
P120005/S018, FDA–2014–M–1735	Dexcom, Inc	Dexcom G4™ PLATINUM Continuous Glucose Monitoring System.	October 21, 2014.
P130026, FDA–2014–M–1736	St. Jude Medical	TactiCath Quartz® Catheter and TactiSysQuartz® Equipment.	October 24, 2014.
P120011, FDA–2014–M–2042	Ideal Implant, Inc	IDEAL IMPLANT® Saline-filled Breast Implant	November 14, 2014.
P130007, FDA–2014–M–2246	Animas Corp	Animas Vibe System	November 25, 2014.
P140020, FDA–2014–M–2248	Myriad Genetic Laboratories, Inc.	BRACAnalysis CDx™	December 19, 2014.
P020012/S009, FDA–2014–M–2376	Suneva Medical, Inc	Bellafill	December 23, 2014.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–0131]

Determination of Regulatory Review Period for Purposes of Patent Extension; COMETRIQ

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for COMETRIQ 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

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

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

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 Director of USPTO 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 has approved for marketing the human drug product COMETRIQ (cabozanitinib (S)-maleate). COMETRIQ is indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer. Subsequent to this approval, the USPTO received a patent term restoration application for COMETRIQ (U.S. Patent No. 7,579,473) from Exelixis, Incorporated, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 27, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of COMETRIQ represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for COMETRIQ is 2,698 days. Of this time, 2,513 days occurred during the testing phase of the regulatory review period, while 185 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* July 13, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 13, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* May 29, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for COMETRIQ (NDA 203756) was submitted on May 29, 2012.

3. *The date the application was approved:* November 29, 2012. FDA has verified the applicant's claim that NDA 203756 was approved on November 29, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 688 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**) either electronic or written comments and ask for a redetermination by June 22, 2015. 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 19, 2015. 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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