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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product 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 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 PREZISTA (darunavir ethanolate). PREZISTA, co-administered with 100 milligrams ritonavir and with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus (HIV) infection in antiretroviral treatment-experienced adult patients, such as those with HIV–1 strains resistant to more than one protease inhibitor. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PREZISTA (U.S. Patent No. 6,248,775) from G.D. Searle & Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 6, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PREZISTA represented the first permitted 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 PREZISTA is 1,253 days. Of this time, 1,070 days occurred during the testing phase of the regulatory review period, while 183 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 act) (21 U.S.C. 355(i)) became effective*: January 19, 2003. The applicant claims January 20, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 19, 2003, which was 30 days after FDA 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 act*: December 23, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for PREZISTA (NDA 21–976) was initially submitted on December 23, 2005.

3. *The date the application was approved*: June 23, 2006. FDA has verified the applicant's claim that NDA 21–976 was approved on June 23, 2006.

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 717 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 24, 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 21, 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. E7–10147 Filed 5–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0495]

Determination of Regulatory Review Period for Purposes of Patent Extension; KDR 401 and 403 PACEMAKERS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for KDR 401 and 403 PACEMAKERS 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 those medical devices.

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 approved for marketing the medical devices, KDR 401 and 403 PACEMAKERS. KDR 401 and 403 PACEMAKERS are indicated for the following: Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity and/or minute ventilation; accepted patient conditions warranting chronic cardiac pacing which include: symptomatic paroxysmal or permanent second or third-degree atrioventricular (AV) block; Symptomatic bilateral bundle branch block; symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders; bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; and vasovagal syndromes or hypersensitive carotid sinus syndromes. KDR 401 and 403 PACEMAKERS are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include: Various degrees of AV block to maintain the atrial contribution to cardiac output and vasovagal intolerance in the presence of persistent sinus rhythm. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for KDR 401 and 403 PACEMAKERS (U.S. Patent No. 4,958,632) from Medtronic, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 22, 2007, FDA advised the Patent and Trademark Office that these medical devices had undergone a regulatory review period and that the approval of KDR 401 and 403 PACEMAKERS represented the first permitted commercial marketing or use of the products. Thereafter, the Patent and Trademark Office requested that FDA determine the products' regulatory review period.

FDA has determined that the applicable regulatory review period for KDR 401 and 403 PACEMAKERS is 716 days. Of this time, 358 days occurred during the testing phase of the regulatory review period, while 358 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*: February 16, 1996. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on May 21, 1997. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on February 16, 1996, 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)*: February 7, 1997. The applicant claims February 6, 1997, as the date the premarket approval application (PMA) for KDR 401 and 403 PACEMAKERS (PMA 970012) was initially submitted. However, FDA records indicate that PMA 970012 was submitted on February 7, 1997.

3. *The date the application was approved*: January 30, 1998. FDA has verified the applicant's claim that PMA 970012 was approved on January 30, 1998.

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 358 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 24, 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 21, 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. E7–10127 Filed 5–24–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0480]

Draft Guidance for Industry on Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we) is announcing that it will consider comments submitted through May 29, 2007, for a draft guidance for industry entitled ''Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.'' Although the comment period for the draft guidance ended on April 30, 2007, we will consider comments submitted through May 29, 2007, due to confusion as to the closing date for comments on the draft guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance, submit written or electronic comments on the draft guidance by May 29, 2007.