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]

BILLING CODE 4160–01–S

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.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 2007, (72 FR 8756), FDA announced the availability of a draft guidance for industry entitled ''Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration.'' The term ''complementary and alternative medicine'' (CAM) encompasses a wide array of health care practices, products, and therapies that are distinct from practices, products, and therapies used in ''conventional'' or ''allopathic'' medicine.

In recent years, the practice of complementary and alternative medicine CAM has increased in the United States, and we have seen increased confusion as to whether certain products used in CAM are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the act) or Public Health Service Act (PHS Act). We have also seen an increase in the number of CAM products imported into the United States. Therefore, the draft guidance discusses when a CAM product is subject to the act or the PHS Act.

The notice announcing the availability of the draft guidance provided a 60-day comment period, so the comment period for the draft guidance was scheduled to end on April 30, 2007. Unfortunately, due to a typographical error in the draft guidance itself (which stated that the comment period would be 90 days from the date of the notice's publication in the **Federal Register**), we became aware that some members of the public believed that the comment period would or should end on May 28 or May 29, 2007. This confusion was compounded by another error that appeared at one section of FDA's Web site; the error, which appeared at the ''Dockets Open for Comment'' portion of the Web site where electronic comments are submitted, stated that the comment period would end on May 29, 2007. (In contrast, other sections of FDA's Web site retained the April 30, 2007, date.)

Given the amount of confusion as to the comment period, we are announcing that we will consider all comments on this draft guidance that are submitted through May 29, 2007. Previously submitted comments do not need to be resubmitted.

Additionally, we are aware of considerable confusion about the content of the draft guidance, which has been widely misinterpreted. Therefore, we want consumers and CAM practitioners to understand that the draft guidance does *not* contain or propose any new regulatory requirements for any complementary and alternative medicine CAM product marketed in the United States and does *not* affect any state licensing requirements for any CAM practitioner or any consumer's ability to buy or receive a CAM product or be treated by any CAM practitioner.

Public concern based on misinterpretations of the draft guidance has generated a large volume of comments to the docket. The large volume of comments has impeded our ability to identify and respond to extension requests. Consequently, we are addressing those unanswered extension requests by considering comments submitted through May 29, 2007.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: May 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–2610 Filed 5–22–07; 3:21 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Application for the Pharmacology Research Associate Program

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of General Medical Sciences (NIGMS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Application for the Pharmacology Research Associate Program. *Type of Information Collection Request:* Extension of a currently approved collection, OMB No. 0925–0378, expiration date August 31, 2007. *Form Numbers:* NIH 2721–1, NIH 2721–2. *Need and Use of Information Collection:* The Pharmacology Research Associate (PRAT) Program will use the applicant and referee information to award opportunities for training and experience in laboratory or clinical investigation to individuals with a Ph.D. degree in pharmacology or a related science, M.D., or other professional degree through appointments as PRAT Fellows at the National Institutes of Health or the Food and Drug Administration. The goal of the program is to develop leaders in pharmacological research for key positions in academic, industrial, and Federal research laboratories. *Frequency of Response:* Once a year. *Affected Public:* Individuals or households; Businesses or other for-profit. *Type of Respondents:* Applicants and Referees.

The annual reporting burden is as follows: