FDA estimates that approximately 250 respondents will participate in this voluntary survey. These respondents will consist mostly of other Federal agencies, health plan data sources, health information exchanges, large multi-specialty medical groups and academic medical centers, large hospital systems, pharmacies, medical societies, consumer-oriented Web sites, commercial data sets, research networks, lab data, and registries.

Each respondent will extend approximately 24.5 hours to complete 1 survey for a total of 6,125 hours (250 x 1 x 24.5 = 6,125).

Dated: February 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4830 Filed 3–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0164]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALTABAX OINTMENT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ALTABAX OINTMENT 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 human drug product.

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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 ALTABAX OINTMENT (retapamulin). ALTABAX OINTMENT is indicated for the topical treatment of impetigo due to *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes* in patients aged 9 months or older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ALTABAX OINTMENT (U.S. Patent No. RE39,128E) from SmithKline Beecham P.L.C., and SmithKline Beecham 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 April 28, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ALTABAX OINTMENT 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 ALTABAX OINTMENT is 1,602 days. Of this time, 1,297 days occurred during the testing phase of the regulatory review period, while 305 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*: November 24, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 24, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: June 12, 2006. FDA has verified the applicant's claim that the new drug application (NDA) for ALTABAX OINTMENT (NDA 22–055) was initially submitted on June 12, 2006.

3. *The date the application was approved*: April 12, 2007. FDA has verified the applicant's claim that NDA 22–055 was approved on April 12, 2007.

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 833 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 May 8, 2009. 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 September 8, 2009. 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: February 17, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–4914 Filed 3–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill expected vacancies on the Advisory Council on Blood Stem Cell Transplantation.

The Advisory Council on Blood Stem Cell Transplantation was established pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended). In accordance with Public Law 92–463, the Council was chartered on December 19, 2006.

DATES: The agency must receive nominations on or before April 8, 2009.

ADDRESSES: All nominations should be submitted to the Executive Secretary, Advisory Council on Blood Stem Cell Transplantation, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 12–105, 5600 Fishers Lane, Rockville, Maryland 20857. Federal Express, Airborne, or UPS, mail delivery should be addressed to Executive Secretary, Advisory Council on Blood Stem Cell Transplantation, Healthcare Systems Bureau, HRSA, at the above address.

FOR FURTHER INFORMATION CONTACT: Remy Aronoff, Executive Secretary, Advisory Council on Blood Stem Cell Transplantation, at (301) 443–3264 or e-mail *Remy.Aronoff@hrsa.hhs.gov* or Robert Baitty, Director, Blood Stem Cell Transplantation Program, Division of Transplantation, at (301) 443–2612 or e-mail *Robert.Baitty@hrsa.hhs.gov*.

SUPPLEMENTARY INFORMATION: The Council was established to implement a statutory requirement of the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109–129). The Council is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The Advisory Council advises the Secretary and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program.

The Council shall, as requested by the Secretary, discuss and make recommendations regarding the C.W. Bill Young Cell Transplantation Program (Program). It shall provide a consolidated, comprehensive source of expert, unbiased analysis and recommendations to the Secretary on the latest advances in the science of blood stem cell transplantation. The Council shall advise, assist, consult and make recommendations, at the request of the Secretary, on broad Program policy in areas such as the necessary size and composition of the adult donor pool available through the Program and the composition of the National Cord Blood Inventory, requirements regarding informed consent for cord blood donation, accreditation requirements for cord blood banks, the scientific factors that define a cord blood unit as high quality, public and professional education to encourage the ethical recruitment of genetically diverse donors and ethical donation practices, criteria for selecting the appropriate blood stem source for transplantation, Program priorities, research priorities, and the scope and design of the Stem Cell Therapeutic Outcomes Database. It also shall, at the request of the Secretary, review and advise on issues relating more broadly to the field of blood stem cell transplantation, such as regulatory policy including compatibility of international regulations, and actions that may be taken by the State and Federal Governments and public and private insurers to increase donation and access to transplantation. The Advisory Council also shall make recommendations regarding research on emerging therapies using cells from bone marrow and cord blood.

The Council consists of up to 25 members, including the Chair. Members of the Advisory Council shall be chosen to ensure objectivity and balance, and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and to limit the number of members of the Advisory Council with any such affiliation.

The members and Chair shall be selected by the Secretary from outstanding authorities and representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of a bone marrow transplant; recipients of a cord blood transplant; persons who require such transplants; family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood; persons with expertise in bone marrow and cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in the social sciences; basic scientists with expertise in the biology of adult stem cells; ethicists, hematology and transfusion medicine researchers with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public.

In addition, representatives from the Division of Transplantation of the Health Resources and Services Administration, the Department of Defense Marrow Recruitment and Research Program operated by the Department of the Navy, the Food and Drug Administration, the National Institutes of Health, the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention serve as non-voting *ex officio* members.

Specifically, HRSA is requesting nominations for voting members of the Advisory Council on Blood Stem Cell Transplantation in these categories: Marrow donor centers and transplant centers representatives; cord blood banks and participating hospitals representatives; family members of bone marrow transplant and cord blood transplant recipients or family members of a patient who has requested assistance by the Program in searching for an unrelated donor; persons with expertise in bone marrow or cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; basic scientists with expertise in the biology of adult stem cells; researchers in hematology and transfusion medicine with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public. Nominees will be invited to serve a 2- to 6-year term beginning after January 1, 2010.