The Family and Youth Services Bureau (FYSB) of the Administration for Children and Families (ACF), United States Department of Health and Human Services, administers the MCP program.

The MCP program provides children of prisoners with caring adult mentors, supporting one-to-one mentoring relationships. Research in other populations has shown that such relationships can lead to reductions in risk behaviors and improvements in academic, behavioral, and psychological outcomes in children and youth. Although the MCP program was developed based on research documenting the efficacy of mentoring as a general intervention strategy, it is not yet known if this particular intervention yields positive outcomes for the children of prisoners population. Little is known about how mentoring relationships work for these youth and how effective mentoring relationships for children of prisoners differ from effective mentoring relationships for other youth. In addition, little is known about children of prisoners in general and thus a survey of MCP program youth has the potential to provide important data about this relatively unstudied population.

The evaluation and data collection proposed in this notice are to fulfill the statutory requirement under Section 8, subsection h(l) of the Child and Family Services Improvement Act of 2006, as amended, that the Secretary of the Department of Health and Human Services evaluate outcomes of the MCP service delivery demonstration project and report to Congress on the findings. The information collected will also be used for accountability monitoring, management improvement, and research.

Data collection will ensure that grantees know that mentoring relationships are meeting the established milestones and that mentoring activities are faithful to characteristics established by research as essential to success. Data collected will allow ACF to compare the MCP service delivery demonstration project with the MCP grant program. Data collected will also support grantees as they carry out ongoing responsibilities and manage information for internal use.

Respondents: Public, faith-based and community organizations applying to and implementing the MCP service delivery demonstration project.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Child Application	4,200	1	.5	2,100
Program Application	325	1	2	650
MentorPRO Basic:				
Mentoring Practices and Relationship Data	250	120	.5	15,000
Baseline Youth Survey	3,000	1	.5	1,500
Follow-up Youth Survey	2,000	1	.5	1,000
Relationship Quality Survey	2,250	1	.5	1,125
Program Survey	250	1	.5	125
Mentor Survey	2,000	1	.5	1,000
Payment Information	1	52	2	104

Estimated Total Annual Burden Hours: 22,604.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 23, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–9292 Filed 4–30–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0457] (formerly Docket No. 2007E–0138)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ARTEFILL 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 medical device.

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 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 recently approved for marketing the medical device, ARTEFILL. ARTEFILL is indicated for correction of nasolabial folds. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ARTEFILL (U.S. Patent No. 5,344,452) from Artes Medical USA, 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 May 16, 2007, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of ARTEFILL 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 ARTEFILL is 3,530 days. Of this time, 1,859 days occurred during the testing phase of the regulatory review period, while 1671 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 28, 1997. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective February 28, 1997.

2. *The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: April 1, 2002. FDA has verified the applicant's claim that the premarket approval application (PMA) for ARTEFILL (PMA P020012) was initially submitted April 1, 2002.

3. *The date the application was approved*: October 27, 2006. FDA has verified the applicant's claim that PMA P020012 was approved on October 27, 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 1,827 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 June 30, 2008. 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 28, 2008. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: April 21, 2008.

Jane A. Axelrad,

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

[FR Doc. E8–9592 Filed 4–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–E–0196] (formerly Docket No. 2006E–0500)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AZILECT 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