| Technical assistance provider organizations | Amount of award | Location |
|---|---|---|
| Family Violence Prevention Fund | $175,000 | San Francisco, CA. |
| Domestic Abuse Intervention Programs | 50,000 | Minneapolis, MN. |
| Hektoen Institute, LLC | 50,000 | Chicago, IL. |
| National Network to End Domestic Violence | 100,000 | Washington, DC. |

A $25,000 expansion supplement grant is awarded to the Institute on Domestic Violence in the African American Community (IDVAAC), Minneapolis, MN, for the period of July 1, 2009 through September 30, 2009, to support development of conference materials, a scholarly publication on healing after domestic violence, and conference scholarships.

*Contact for Further Information:* Marylouise Kelley, Ph.D., Director, Family Violence Prevention and Services Program, 1250 Maryland Avenue, SW., Suite 8216, Washington, DC, 20024. Telephone: 202–104–5756 E-mail: *Marylouise.kelley@acf.hhs.gov.*

Dated: September 28, 2009.

**Maiso L. Bryant,**

*Acting Commissioner, Administration on Children, Youth and Families.*

[FR Doc. E9–23922 Filed 10–2–09; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–E–0057]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; EMEND FOR INJECTION

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for EMEND FOR INJECTION 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 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 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 EMEND FOR INJECTION (fosaprepitant meglumine). EMEND FOR INJECTION, in combination with other antiemetic agents, is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, and for prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EMEND FOR INJECTION (U.S. Patent No. 5,691,336) from Merck & Co., 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 26, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EMEND FOR INJECTION 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 EMEND FOR INJECTION is 4,473 days. Of this time, 3,810 days occurred during the testing phase of the regulatory review period, while 663 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*: October 29, 1995. The applicant claims October 28, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 29, 1995, 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*: April 3, 2006. The applicant claims March 31, 2006, as the date the new drug application (NDA) for Emend for Injection (NDA 22–023) was initially submitted. However, FDA records indicate that NDA 22–023 was submitted on April 3, 2006.

3. *The date the application was approved*: January 25, 2008. FDA has verified the applicant's claim that NDA 22–023 was approved on January 25, 2008.

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 1,826 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 December 4, 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 April 5, 2010. 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: June 23, 2009.

**Jane A. Axelrad,**

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

[FR Doc. E9–23900 Filed 10–2–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0470]**

### Draft Guidance for Industry and FDA Staff; the Scope of the Prohibition Against Marketing a Tobacco Product in Combination With Another Article or Product Regulated Under the Federal Food, Drug, and Cosmetic Act; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act.'' This guidance is intended for manufacturers, retailers, importers, and FDA staff. The Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), states ''A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).'' The guidance discusses certain activities that FDA believes do or do not fall within the scope of the prohibition. The guidance is not intended to be an exhaustive analysis of all activities that may or may not fall within the scope of the prohibition.

**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 before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 4, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled ''The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–595–7946. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 0850–3229, 301–796–4800, *Michele.Mital@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

On June 22, 2009, the President signed the FSPTCA (Public Law 111–31) into law. The FSPTCA amended the FDCA (21 U.S.C. 301 *et seq.*) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 201(rr)(4) of the FDCA, as amended by the FSPTCA, states ''A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).''

This guidance discusses certain activities that FDA believes do or do not fall within the scope of the prohibition. The guidance is not intended to be an exhaustive analysis of all activities that may or may not fall within the scope of the prohibition.

#### II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on ''The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

#### III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. The guidance document may be accessed at the Center for Tobacco Products' Web site at *http://www.fda.gov/tobaccoproducts*. This guidance document is also available at *http://www.regulations.gov*. To receive ''The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act,'' you may either send an e-mail request to *michele.mital@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–595–7946 to receive a hard copy.

#### IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. 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