Because there is not a public comment period, written comments may be submitted. Any written comments received will be included in the official record of the meeting and should be submitted to the contact person below in advance of the meeting.

*Contact Person for more Information:* Theodore M. Katz, M.P.A., Executive Secretary, NIOSH, CDC, 1600 Clifton Road, NE., Mailstop: E–20, Atlanta, GA 30333, Telephone (513) 533–6800, Toll Free 1–800–CDC–INFO, E-mail *ocas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: June 16, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011–15681 Filed 6–22–11; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### National Institute for Occupational Safety and Health (NIOSH); Request for Nominations To Serve on the World Trade Center Health Program Science/Technical Advisory Committee (WTCHP–STAC)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the WTCHP–STAC. This committee was established by Public Law 111–347 (The James Zadroga 9/11 Health and Compensation Act of 2010), enacted on January 2, 2011, Section 3302(a). The Advisory Committee is governed by the provisions of Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees in the Executive Branch.

Section 3302(a)(1) of the James Zadroga 9/11 Health and Compensation Act of 2010 (the Act) establishes that the WTCHP–STAC will review scientific and medical evidence and make recommendations to the WTC Program Administrator on additional program eligibility criteria and additional health conditions for program inclusion. The committee will be consulted on other matters as related to and outlined in the Act at the discretion of the WTC Program Administrator. In accordance with Public Law 111–347, Section 3302(a)(2), the WTC Program Administrator will appoint the members of the committee and include at least:

- 4 occupational physicians, at least two of whom have experience treating WTC rescue and recovery workers;
- 1 physician with expertise in pulmonary medicine;
- 2 environmental medicine or environmental health specialists;
- 2 representatives of WTC responders;
- 2 representatives of certified-eligible WTC survivors;
- 1 industrial hygienist;
- 1 toxicologist;
- 1 epidemiologist; and, at least
- 1 mental health professional.

For the mental health professional category, specific expertise is sought in trauma-related psychiatry or psychology and psychiatric epidemiology. Other members may be appointed at the discretion of the WTC Program Administrator.

A WTCHP–STAC member's term appointment may last four years. If a vacancy occurs, the WTC Program Administrator may appoint a new member who represents the same interest as the predecessor. WTCHP–STAC members may be appointed to successive terms. The frequency of committee meetings shall be determined by the WTC Program Administrator based on program needs. Meetings may occur up to four times a year. Members are paid the Special Government Employee rate of $250 per day, and travel costs and per diem are included and based on the Federal Travel Regulations.

Any interested person or organization may self-nominate or nominate one or more qualified persons for membership. Nominations must include the following information:

- The nominee's contact information and current occupation or position;
- The nominee's resume or curriculum vitae, including prior or current membership on other NIOSH, CDC, HHS advisory committees or other relevant organizations, associations, and committees;
- The category of membership (occupational, pulmonary or environmental medicine physician, environmental health specialist, representative of responder or survivor beneficiary group, industrial hygienist, toxicologist, epidemiologist, or mental health) that the candidate is qualified to represent;
- A summary of the background, experience, and qualifications that demonstrates the nominee's suitability for each of the nominated membership categories;
- Articles or other documents the nominee has authored that indicate the nominee's knowledge, and experience in relevant subject categories; and
- A statement that the nominee is aware of the nomination, is willing to regularly attend and participate in WTCHP–STAC meetings, and has no known conflicts of interest that would preclude membership on WTCHP–STAC.

WTCHP–STAC members will be selected upon the basis of their relevant experience and competence in their respective categorical fields. The information received through this nomination process, in addition to other relevant sources of information, will assist the WTC Program Administrator in appointing members to serve on WTCHP–STAC. In selecting members, the WTC Program Administrator will consider individuals nominated in response to this **Federal Register** notice, as well as other qualified individuals.

NIOSH is committed to bringing greater diversity of thought, perspective and experience to its advisory committees. Nominees from all races, gender, age and persons living with disabilities are encouraged to apply. Nominees must be U.S. citizens.

Candidates invited to serve will be asked to submit the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the Centers for Disease Control and Prevention." This form allows CDC to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded at *http://www.usoge.gov/forms/oge450_pdf/oge450_accessible.pdf.* This form should not be submitted as part of a nomination.

Nominations should be submitted (postmarked or received) by July 7, 2011.

You may submit nominations for WTCHP–STAC, identified by NIOSH Docket No. NIOSH–229, by any of the following methods:

- *Electronic submissions:* You may submit nominations, including attachments, electronically to the NIOSH Docket No. NIOSH–229 located at *http://www.cdc.gov/niosh/docket/.* Follow the instructions for submitting

electronic comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, Microsoft Word is preferred.

• *Regular, Express, or Overnight Mail:* Written nominations may be submitted (one original and two copies) to the following address only: NIOSH Docket 229 or Zaida Burgos, Committee Management Specialist, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., M/S E–20, Atlanta, Georgia 30333. Telephone and facsimile submissions cannot be accepted.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 16, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011–15684 Filed 6–22–11; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–E–0315]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; Fusilev, Levoleucovorin

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Fusilev (Levoleucovorin) 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 electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 Fusilev (levoleucovorin calcium), a folate analog. Levoleucovorin rescue is indicated after high-dose methotrexate therapy in osteosarcoma and is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and/or inadvertent overdosage of folic acid antagonists. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Fusilev (U.S. Patent No. 6,500,829) from the University of Strathclyde, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration and that FDA determine the product's regulatory review period. In a letter dated June 1, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Fusilev represented the first permitted commercial marketing or use of the product.

FDA has determined that the applicable regulatory review period for Fusilev is 6,993 days. Of this time, 703 days occurred during the testing phase of the regulatory review period, while 6,290 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* January 15, 1989. The applicant claims December 15, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 15, 1989, 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 FD&C Act:* December 18, 1990. The applicant claims December 14, 1990, as the date the new drug application (NDA) for FUSILEV (NDA 20–140) was initially submitted. However, FDA records indicate that NDA 20–140 was submitted on December 18, 1990.

3. *The date the application was approved:* March 7, 2008. FDA has verified the applicant's claim that NDA 20–140 was approved on March 7, 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 797 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**) either electronic or written comments and ask for a redetermination by August 22, 2011. 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 December 20, 2011. 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.

Interested persons may submit to the Division of Dockets Management (see