

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:* June 7, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 7, 1994.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* April 29, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for Arranon (NDA 21-877) was initially submitted on April 29, 2005.

3. *The date the application was approved:* October 28, 2005. FDA has verified the applicant's claim that NDA 21-877 was approved on October 28, 2005.

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 5 years 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 5, 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 2, 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. E9-4770 Filed 3-5-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, FIRCA and GRIP in Behavioral and Social Sciences.

Date: March 24, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle Conference Room, Washington, DC 20037.

Contact Person: Manana Sukhareva, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892. 301-435-1116, sukharem@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR-08-160: Metabolic Effects Psychotropic Medications.

Date: March 25-26, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Reed A. Graves, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, MSC 7892, Bethesda, MD 20892. (301) 402-6297, gravesr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Millennium Promise Awards: Non-communicable Disease.

Date: March 25, 2009.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Admiral Fell Inn, 888 South Broadway, Baltimore, MD 21231.

Contact Person: Cathy Wedeen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3213,

MSC 7808, Bethesda, MD 20892. 301-435-1191, wedeenc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ICBG Review.

Date: March 25-26, 2009.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Dan D. Gerendasy, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5132, MSC 7843, Bethesda, MD 20892. 301-594-6830, gerendad@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Tools for Zebrafish Research.

Date: March 27, 2009.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications, *Place:* The River Inn, 924 Twenty-Fifth Street, NW. Conference, Washington, DC 20037.

Contact Person: Neelakanta Ravindranath, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5140, MSC 7843, Bethesda, MD 20892. 301-435-1034, ravindrn@csr.nih.gov.

Name of Committee: Center for Scientific Review, Special Emphasis Panel, Zebrafish Genetic Screens.

Date: March 27, 2009.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 Twenty-Fifth Street, NW. Conference, Washington, DC 20037.

Contact Person: Neelakanta Ravindranath, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5140, MSC 7843, Bethesda, MD 20892. 301-435-1034, ravindrn@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Enzyme Specificity Program Project.

Date: April 1-2, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David R. Jollie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892. (301) 435-1722, jollieda@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Epigenomics of Human Health and Disease.

Date: April 2-3, 2009.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael K. Schmidt, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2214, MSC 7890, Bethesda, MD 20892. (301) 435-1147, mschmidt@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Assays, Detectors, and Devices.

Date: April 2-3, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 5144, MSC 7812, Bethesda, MD 20892. 301-435-2902, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflicts in Biological Chemistry and Macromolecular Biophysics.

Date: April 2-3, 2009.

Time: 11 a.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Donald L. Schneider, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5160, MSC 7842, Bethesda, MD 20892. (301) 435-1727, schneidd@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 26, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-4622 Filed 3-5-09; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2009-0114]

National Boating Safety Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Committee Management; notice of meeting.

SUMMARY: The National Boating Safety Advisory Council (NBSAC) and its subcommittees will meet on April 4, 5, and 6, 2009, in Orlando, FL. The meetings will be open to the public.

DATES: NBSAC will meet April 4, 2009, from 8:30 a.m. to 12 noon, and on April 6, 2009, from 8:30 a.m. to 5 p.m. The Boats and Associated Equipment

Subcommittee will meet on April 4, and the Prevention through People Subcommittee and the Recreational Boating Safety Strategic Planning Subcommittee will meet on April 5, 2009. Please note that the meetings may conclude early if the council has completed it business.

All written materials, comments, and requests to make oral presentations at the meetings should reach Mr. Jeff Ludwig by March 13, 2009, via one of the methods described in **ADDRESSES**. Requests to have a copy of your material distributed to each member of the committee prior to the meeting should reach Mr. Ludwig by March 13, 2009.

ADDRESSES: The meeting will be held at the Grand Bohemian Hotel, 325 S. Orange Ave, Orlando, FL 32801.

Please send written material, comments, and requests to make oral presentations to Mr. Jeff Ludwig by one of the submission methods described below. All materials, comments, and requests must be identified by docket number USCG-2009-0114.

Submission Methods: Please use only one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* jeffrey.a.ludwig@uscg.mil.

Include the docket number in the subject line of the message.

- *Fax:* (202) 372-1932.

- *Mail:* Mr. Jeff Ludwig, COMDT (CG-54221), 2100 2nd Street, SW., Washington, DC 20593.

Instructions: All submissions received must include the words "U.S. Coast Guard" and docket number USCG-2009-0114. All submissions received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided. Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

Docket: For access to the docket to read background documents or submissions received by the NBSAC, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Ludwig, COMDT (CG-54221), 2100 2nd Street, SW., Washington, DC 20593; (202) 372-1061; Jeffrey.a.ludwig@uscg.mil.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App.

(Pub. L. 92-463). NBSAC was established by the Federal Boat Safety Act of 1971. That law requires the Secretary of Homeland Security, and the Commandant of the Coast Guard by delegation, to consult with NBSAC in prescribing Federal regulations, and on other major matters regarding boating safety. See 46 U.S.C. 4302(c) and 13110(c).

NBSAC will meet for the purpose of discussing issues related to recreational boating safety.

A. Tentative Agendas of Meetings

National Boating Safety Advisory Council (NBSAC):

Saturday, April 4, 2009:

(1) Remarks—Mr. James P. Muldoon, NBSAC Chairman;

(2) Chief, Office of Auxiliary and Boating Safety Update on NBSAC Resolutions and Recreational Boating Safety Program report.

(3) Executive Secretary's report.

(4) Chairman's session.

(5) TSAC Liaison's report.

(6) NAVSAC Liaison's report.

(7) National Association of State Boating Law Administrators report.

(8) Boats and Associated Equipment Subcommittee meeting.

Sunday, April 5, 2009:

(9) Prevention through People Subcommittee meeting.

(10) Recreational Boating Safety Strategic Planning Subcommittee meeting.

Monday, April 6, 2009:

(11) Prevention through People Subcommittee report.

(12) Boats and Associated Equipment Subcommittee report.

(13) Recreational Boating Safety Strategic Planning Subcommittee report.

A more detailed agenda can be found at: <http://www.uscgboating.org/nbsac/nbsac.htm>, after March 27, 2009.

B. NBSAC Subcommittees

Prevention Through People Subcommittee: Discuss current regulatory projects, grants, contracts, and new issues affecting the prevention of boating accidents through outreach and education of boaters.

Boats and Associated Equipment Subcommittee: Discuss current regulatory projects, grants, contracts, and new issues affecting boats and associated equipment.

Recreational Boating Safety Strategic Planning Subcommittee: Discuss current status of the strategic planning process and any new issues or factors that could impact, or contribute to, the development of the strategic plan for the recreational boating safety program.