

(6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92-463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of cooperative agreement applications submitted in response to Fiscal Year 2008 Requests for Applications related to the following individual research announcement: CE08-004, Translation Research to Prevent Motor Vehicle-Related Crashes and Injuries to Teen Drivers and Their Passengers (R01).

Agenda items are subject to change as priorities dictate.

National Center for Injury Prevention and Control determines that agency business requires its consideration of this matter on less than 15 days notice to the public and that no earlier notice of this meeting was possible.

Contact Person for More Information: J. Felix Rogers, PhD, M.P.H., Telephone (770) 488-4334, NCIPC/ERPO, CDC, 4770 Buford Highway, NE., M/S F62, Atlanta, Georgia 30341-3724.

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: May 8, 2008.

Elaine L. Baker,

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

[FR Doc. E8-10747 Filed 5-13-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control/ Initial Review Group, (NCIPC/IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned review group:

Time and Date: 1 p.m.-3 p.m., May 19, 2008 (Closed).

Place: Teleconference.

Status: The meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92-463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct research on exposures to volcanic emissions and environmental air pollutants.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of cooperative agreement applications submitted in response to Fiscal Year 2008 Requests for Applications related to the following individual research announcement: E08-001, Program to assess health effects associated with exposures to volcanic emissions and environmental air pollutants.

Agenda items are subject to change as priorities dictate.

NCIPC determines that agency business requires its consideration of this matter on less than 15 days notice to the public and that no earlier notice of this meeting was possible.

Contact Person for More Information: J. Felix Rogers, Ph.D., M.P.H., Telephone (770)488-4334, NCIPC/ERPO, CDC, 4770 Buford Highway, NE., M/S F62, Atlanta, GA 30341-3724.

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: May 8, 2008.

Elaine L. Baker,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Meeting

AGENCY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Public Meeting.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following public meeting: "Partnerships to Advance the National Occupational Research Agenda (NORA)".

Public Meeting Time and Date:

9 a.m.-3 p.m. EDT, June 19, 2008.

Place: Patriots Plaza, 395 E Street, SW., Conference Room 9000, Washington, DC 20201.

Purpose of Meeting: The National Occupational Research Agenda (NORA) has been structured to engage partners with each other and/or with NIOSH to advance NORA priorities. The NORA Liaison Committee continues to be an opportunity for representatives from organizations with national scope to learn about NORA progress and to suggest possible partnerships based on their organization's mission and contacts. This opportunity is now structured as a public meeting via the Internet to attract participation by a larger number of organizations and to further enhance the success of NORA. Some of the types of organizations of national scope that are especially encouraged to participate are employers, unions, trade associations, labor associations, professional associations, and foundations. Others are welcome.

This meeting will include updates from NIOSH leadership on NORA as well as updates from approximately half of the Sector Councils on their progress, priorities, and implementation plans to date, including the Construction Sector, Manufacturing Sector, Services Sector, Public Safety Sub-Sector, and Wholesale and Retail Trade Sector. After each update, there will be time to discuss partnership opportunities.

Status: The meeting is open to the public, limited only by the capacities of the conference call and conference room facilities. There is limited space available in the meeting room (capacity 34). Therefore, information to allow participation in the meeting through the Internet (to see the slides) and a teleconference call (capacity 50) will be provided to registered participants. Participants are encouraged to consider attending by this method. Each participant is requested to register for the free meeting by sending an e-mail to noracoordinator@cdc.gov containing the participant's name, organization name, contact phone number on the day of the meeting, and preference for participation by Web meeting (requirements include: computer, Internet connection, and phone, preferably with "mute" capability) or in person. An e-mail confirming

registration will include the details needed to participate in the web meeting. Non-US citizens are encouraged to participate in the web meeting. Non-US citizens registering to attend in person after June 2 will not have time to comply with security procedures.

Background: NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see <http://www.cdc.gov/niosh/nora/about.html>.

Since 2006, NORA has been structured by industrial sectors. Eight sector groups have been defined using the North American Industrial Classification System (NAICS). After receiving public input through the web and town hall meetings, NORA Sector Councils have been working to define sector-specific strategic plans for conducting research and moving the results into widespread practice. During 2008, most of these Councils will post draft strategic plans for public comment. For more information, see the link above and choose "Sector-based Approach," "NORA Sector Councils" and "Comment on Draft Sector Agendas" from the right-side menu.

Contact Person for Technical Information: Sidney C. Soderholm, PhD, NORA Coordinator, e-mail noracoordinator@cdc.gov, telephone (202) 245-0665.

Dated: May 5, 2008.

James D. Seligman,
Chief Information Officer, Centers for Disease Control and Prevention.
[FR Doc. E8-10753 Filed 5-13-08; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Delegation of Authority

Notice is hereby given that I have redelegated to Charles N.W. Keckler, Esq., Senior Advisor, Immediate Office of the Assistant Secretary, Administration for Children and Families (ACF), the following authority

vested in the Assistant Secretary for Children and Families.

(a) Authority Delegated.

Authority to review and make decisions to approve or disapprove requests for testimony by ACF employees or former ACF employees concerning information acquired in the course of performing official duties or because of such persons' official capacity with the Department of Health and Human Services in proceedings where the United States is not a party.

(b) Limitations and Conditions.

This redelegation may not be further redelegated.

(c) Effect on Existing Delegations.

None.

(d) Effective date.

This redelegation is effective on the date of signature. I hereby affirm and ratify any actions taken by Mr. Charles Keckler which, in effect, involved the exercise of this authority prior to the effective date of this redelegation.

Dated: May 2, 2008.

Daniel C. Schneider,
Acting Assistant Secretary for Children and Families.
[FR Doc. E8-10766 Filed 5-13-08; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-E-0102] (formerly Docket No. 2007E-0184)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AVASTIN 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 biological product.

ADDRESSES: Submit written or electronic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human biologic product AVASTIN (bevacizumab). AVASTIN, used in combination with intravenous 5-fluorouracil-based chemotherapy, is indicated for first-line treatment of patients with metastatic carcinoma of the colon or rectum. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AVASTIN (U.S. Patent No. 6,639,055) from Genentech, 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 July 24, 2007, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of AVASTIN represented the