

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]
BILLING CODE 4163-19-P

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]
BILLING CODE 4184-01-P

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