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 DUREZOL (difluprednate ophthalmic emulsion). DUREZOL is indicated for the treatment of inflammation and pain associated with ocular surgery. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DUREZOL (U.S. Patent No. 6,114,319) from Senju Pharmaceutical Co. Ltd., 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 18, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DUREZOL 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 DUREZOL is 560 days. Of this time, 369 days occurred during the testing phase of the regulatory review period, while 181 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:* December 13, 2006. FDA has verified the applicant's claim that the investigational new drug application became effective on December 13, 2006.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* December 26, 2007. FDA has verified the applicant's claim that the new drug application (NDA) for DUREZOL (NDA 22–212) was initially submitted on December 26, 2007.

3. *The date the application was approved:* June 23, 2008. FDA has verified the applicant's claim that NDA 22–212 was approved on June 23, 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 369 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 September 28, 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 January 25, 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. E9–18034 Filed 7–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 27, 2009, 9 a.m. to July 28, 2009, 6 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on July 1, 2009, 74 FR 31453–31454.

The meeting will be held August 3, 2009 to August 4, 2009. The meeting time and location remain the same. The meeting is closed to the public.

Dated: July 23, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–18023 Filed 7–28–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Go Applications.

Date: August 5, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call)

Contact Person: Raul A Saavedra, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC; 6001 Executive Blvd., Ste. 3208, Bethesda, MD 20892–9529, 301–496–9223, *saavedrr@ninds.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Go Applications.

Date: August 6, 2009.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call)

Contact Person: Ernest W Lyons, Ph.D. Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 952, Bethesda, MD 20892–9529, 301–496–4056, *lyonse@ninds.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: July 23, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–18025 Filed 7–28–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 28, 2009, 9 a.m. to July 28, 2009, 8 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on July 17, 2009, 74 FR 34762–34764.

The meeting will be held August 3, 2009 to August 4, 2009. The meeting time and location remain the same. The meeting is closed to the public.

Dated: July 23, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–18022 Filed 7–28–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 73 FR 30406–30408 dated May 27, 2008).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice renames the Office of Financial Management (RB) to the Office of Operations (RB); moves the Office of Management (RAM) under the Office of Operations (RB) and moves the Office of Information Technology (RAG) under the Office of Operations (RB).

Chapter RA—Office of the Administrator

Section RA–10, Organization

Delete in its entirety and replace with the following:

The Office of the Administrator (RA) is headed by the Administrator, Health Resources and Services Administration, who reports directly to the Secretary. The OA includes the following components:

(1) Immediate Office of the Administrator (RA);
(2) Office of Equal Opportunity and Civil Rights (RA2);
(3) Office of Planning and Evaluation (RA5);
(4) Office of Communications (RA6);
(5) Office of Minority Health and Health Disparities (RA9);
(6) Office of Legislation (RAE);
(7) Office of International Health Affairs (RAH).

Chapter RB—Office of Operations

Section RB–10, Organization

Delete in its entirety and replace with the following:

The Office of Operations (RB) is headed by the Chief Operating Officer who reports directly to the Administrator, Health Resources and Services Administration. The Office of Operations includes the following components:

(1) Office of the Chief Operating Officer (RB);
(2) Office of Budget (RB1);
(3) Office of Financial Policy and Controls (RB2);
(4) Office of Acquisitions Management and Policy (RB3);
(5) Office of Management (RB4); and
(6) Office of Information Technology (RB5).

Section RB–20, Functions

(1) Rename the Office of Financial Management (RB) to the Office of Operations (RB); (2) delete the functional statement for the Office of Management (RAM) and transfer the function to the Office of Operations (RB); and (3) delete the functional statement for the Office of Information Technology (RAG) and transfer the function to the Office of Operations (RB).

Office of the Chief Operating Officer (RB)

(1) Provides leadership for operational activities, interaction and execution of Agency initiatives across the Health Resources and Services Administration; (2) plans, organizes and manages annual and multi-year budgets and resources and assures that the conduct of Agency administrative and financial management activities effectively support program operations; (3) provides an array of Agency-wide services including information technology, procurement management, facilities, workforce management, and budget execution and formulation; (4) maintains overall responsibility for policies, procedures, monitoring of internal controls and systems related to payment and disbursement activities; (5) provides management expertise, staff advice, and support to the Administrator in program and policy formulation and execution; (6) provides leadership in the development, review and implementation of policies and procedures to promote improved information technology management capabilities and best practices throughout HRSA; (7) coordinates IT workforce issues and works closely with the Department on IT recruitment and training issues; and (8) administers functions of the Chief Financial Office.

Office of Budget (RB1)

(1) Reviews funds control measures to assure that no program, project or activity of HRSA obligates or disburses funds in excess of appropriations or obligates funds in violation of authorized purposes; (2) provides advice and assistance to senior HRSA management to verify the accuracy, validity, and technical treatment of budgetary data in forms, schedules, and reports, or the legality and propriety of using funds for specific purposes; (3) maintains primary liaison to expedite the flow of financial management work and materials within the Agency and/or between Agency components and HHS, Office of Management and Budget (OMB), and congressional staff; (4) provides overall financial-based analyses and fiduciary review for senior HRSA management in order to assure appropriate workforce planning, funds control guidance, and analytical technical assistance in all phases of the budgetary process; and (5) develops the long-range program and financial plan for the Agency in collaboration with the Office of Planning and Evaluation, and other administrative Agency components.