and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as the Global Harmonization Task Force (GHTF) to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using their own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of a document that has been developed by one of the Study Groups (4).

Study Group 4 was initially tasked with the responsibility of developing guidance documents on quality systems auditing practices. As a result of its efforts, this group has developed document SG4/N33R16:2007. The final document (SG4/N33R16:2007) entitled ''Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 3: Regulatory Audit Reports'' provides a structure for audit reports used in multiple jurisdictions, promoting consistency and uniformity and should assist the auditor in preparing a report for use by multiple regulators and/or auditing organizations. Having reports that are consistent in content should facilitate the review and exchange of audit reports. Acceptance of audit reports by multiple regulators should eventually reduce the number of audits for manufacturers. This document was announced as available for comment on February 6, 2007 (72 FR 5443). GHTF received several comments on the document proposed on February 6, 2007. In response to the comments, GHTF made changes to clarify the document.

II. Significance of Guidance

This document represents recommendations from the GHTF study groups and does not describe regulatory requirements. FDA is making this document available so that industry and other members of the public may express their views and opinions.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Paperwork Reduction Act of 1995

For this final document, FDA concludes that there are no collection of information requirements under the Paperwork Reduction Act of 1995.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: March 14, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–5927 Filed 3–24–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

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 meeting.

The meeting 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 Child Health and Human Development Special Emphasis Panel; Down Syndrome.

Date: April 18, 2008.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Norman Chang, Ph.D., Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01 Bethesda, MD 20892, (301) 496–1485, *changnmaiI.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 17, 2008.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–5818 Filed 3–24–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

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 meeting.

The meeting 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 Child Health and Human Development Special Emphasis Panel; Growth and Development of the Nervous System: Molecular Mechanisms.

Date: April 10, 2008.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Boulevard, Bldg. Rm. 5B01, Rockville, MD 20852, (301) 435–6889, *bhatnagg@mail.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. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 17, 2008.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–5822 Filed 3–24–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

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 meeting.

The meeting 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 Child Health and Human Development Special Emphasis Panel; Chronic Aberrant Behavior.

Date: April 14, 2008.

Time: 12:30 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health And Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892, (301) 435–6911, *hopmannmmail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 17, 2008.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–5823 Filed 3–24–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Proposed Collection; Comment Request; Alien Crewman Landing Permit

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; Extension of existing collection of information: 1651–0114.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, U.S. Customs and Border Protection (CBP) invites the general public and other Federal agencies to comment on an information collection requirement concerning the Alien Crewman Landing Permit. This request for comment is being made pursuant to the Paperwork Reduction Act (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before May 27, 2008, to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Information Services Group, Room 3.2.C, 1300 Pennsylvania Avenue, NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Customs and Border Protection, Attn.: Tracey Denning, Room 3.2.C, 1300 Pennsylvania Avenue, NW., Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Alien Crewman Landing Permit.

OMB Number: 1651–0114.

Form Number: Form I–95.