

guidance, the draft guidance provides the Agency's current thinking on the appropriate classification of co-crystal solid-state forms.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on regulatory classification of pharmaceutical co-crystals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

III. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. This draft guidance refers to information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.50(d)(1) and 314.94(a)(5) and 314.94(a)(9) have been approved under OMB control number 0910–0001.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 29, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31022 Filed 12–1–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

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 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: Center for Scientific Review Special Emphasis Panel, Member Conflicts in Child and Adolescent Psychopathology.

Date: December 20, 2011.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Dana Jeffrey Plude, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, (301) 435–2309, pluded@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: November 28, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–31048 Filed 12–1–11; 8:45 am]

BILLING CODE 4140–01–P

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. 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: Center for Scientific Review Special Emphasis Panel, PAR10–238 ACCORD Ancillary Studies.

Date: December 14–15, 2011.

Time: 9 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: Russell T. Dowell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, MSC 7814, Bethesda, MD 20892, (301) 435–1850, dowellr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Inflammation, Osteoarthritis and Rheumatoid Arthritis.

Date: December 19, 2011.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Priscilla B. Chen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435–1787, chenp@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: November 25, 2011

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–31049 Filed 12–1–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel, NIAID Investigator Initiated Program Project Application.

Date: December 20, 2011.

Time: 10 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Quirijn Vos, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 451-2666, qvoss@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Investigator Initiated Program Project Application.

Date: December 21, 2011.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Quirijn Vos, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 451-2666, qvoss@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 28, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-31055 Filed 12-1-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Diabetes, Endocrinology, and Metabolism Career Awards.

Date: December 20, 2011.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7791, goterrobinsonc@extra.niddk.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. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 25, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-31050 Filed 12-1-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Completion of the Broker Self-Assessment Outreach Pilot

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

ACTION: General notice.

SUMMARY: This document announces the completion of the Broker Self-Assessment (BSA) Outreach Pilot (BSA Pilot), a voluntary partnership with the customs brokerage community, which began in July 2009. CBP has decided to

end the BSA pilot without a plan to proceed with another Importer Self-Assessment type model. CBP and the National Customs Brokers and Forwarders Association of America (NCBFAA) have agreed to pursue other avenues to collaborate pertaining to trade modernization efforts.

DATES: *Effective Date:* December 2, 2011.

FOR FURTHER INFORMATION CONTACT:

Florence Constant, Partnership Programs Branch, Trade Policy and Programs, Office of International Trade, Tel.: (202) 863-6537.

SUPPLEMENTARY INFORMATION:

Background

This document announces the completion of the Broker Self-Assessment Outreach Pilot (BSA Pilot), which began July 2009 after its announcement in the **Federal Register** (74 FR 19103) on April 27, 2009. The pilot was a collaborative effort by U.S. Customs and Border Protection (CBP) and the National Customs Brokers and Forwarders Association of America (NCBFAA) to develop a voluntary partnership between CBP and the customs brokerage community.

Purpose

The purpose of the partnership was to facilitate a higher level of broker compliance with CBP laws and regulations, specifically those in part 111 of title 19 of the Code of Federal Regulations (19 CFR part 111), so that the agency could focus on higher-risk trade enforcement issues. All brokers who were current members of the Customs-Trade Partnership Against Terrorism (C-TPAT) were permitted to apply for the BSA pilot by signing a BSA Memorandum of Understanding (MOU) and completing a BSA questionnaire.

A total of twenty-seven (27) brokers applied and four (4) were selected to participate in the pilot based on the criteria discussed above and CBP and NCBFAA's desire to have brokerages that represented small, medium, and large volumes of activities.

Pilot Design

CBP and NCBFAA modeled the pilot after the existing Importer Self-Assessment (ISA) program, which is based on the premise that importers with internal controls in place achieve the highest level of compliance with CBP laws and regulations. Similarly, the premise with the BSA pilot was that brokers with strong internal controls would achieve the highest level of compliance with customs laws and regulations.