Supplements—Small Entity Compliance Guide." The small entity compliance guide (SECG) is being issued for a final rule and an interim final rule published in the **Federal Register** of June 25, 2007, and is intended to set forth in plain language the requirements of that final rule and interim final rule and to help small businesses understand the regulations. In addition, the SECG includes several recommendations made by FDA in that final rule so that the guidance in those recommendations will be readily accessible to small businesses.

DATES: Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the SECG to the Division of Dietary Supplement Programs (HFS–810), Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Bradford Williams, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1440.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 25, 2007 (72 FR 34752), FDA issued a final rule establishing current good manufacturing practice (CGMP) regulations for dietary supplements (21 CFR part 111) (the DS CGMP final rule). The DS CGMP final rule requires persons who manufacture, package, label, or hold a dietary supplement to establish and follow current good manufacturing practice to ensure the quality of the dietary supplement and to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record. In that same issue of the **Federal Register** (72 FR 34959), FDA also issued an interim final rule (the identity testing interim final rule) that sets forth a procedure for requesting an exemption from a requirement for the manufacturer to conduct at least one appropriate test or examination to verify the identity of any dietary ingredient that is a component of a dietary supplement. The final rule and the identity testing interim final rule became effective August 24, 2007. The compliance date of the DS CGMP final rule and the identity testing interim final rule is June 25, 2008; except that for businesses employing fewer than 500, but 20 or more full-time equivalent employees, the compliance date is June 25, 2009; and except that for businesses that employ fewer than 20 full-time equivalent employees, the compliance date is June 25, 2010.

FDA examined the economic implications of the DS CGMP final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the DS CGMP final rule would have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), FDA is making available this SECG stating in plain language the requirements of the regulations. We also examined the economic implications of the identity testing interim final rule as required by the Regulatory Flexibility Act and determined that the identity testing interim final rule would not have a significant economic impact on a substantial number of small entities. However, because the identity testing interim final rule revises the DS CGMP final rule, the SECG includes the provisions of the identity testing interim final rule.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)).[1] The SECG restates, in simplified format and language, FDA's requirements for Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, including the requirements for a Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients. In addition, the SECG includes several recommendations made by FDA in the DS CGMP rule so that the guidance in those recommendations will be readily accessible to small businesses.

The SECG represents FDA's current thinking on current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements. 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. We note, however, that the regulations that serve as the basis for this guidance document establish requirements for all covered activities. For this reason, we recommend that affected parties consult the regulations at 21 CFR part 111 in addition to reading the SECG.

[1] We note that the American Herbal Products Association submitted a petition for reconsideration on July 25, 2007, under 21 CFR 10.33, requesting reconsideration of certain provisions of the DS CGMP final rule. FDA is currently considering this petition and the SECG does not represent a response to such petition.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 111 have been approved under 0910–0606.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments on the SECG. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the SECG at *http://www.fda.gov/FoodGuidances.html* or *http://www.regulations.gov.*

Dated: December 13, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31613 Filed 12–15–10; 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 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. Member Conflict: Renal Disease.

Date: January 7, 2011.

Time: 2 p.m. to 5 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: Ryan G. Morris, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892. 301–435–1501. *morrisr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Member Conflict: BGES Member.

Date: January 14, 2011.

Time: 1:30 p.m. to 2:30 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: J Scott Osborne, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892. (301) 435–1782. *osbornes@csr.nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group. Cancer Etiology Study Section.

Date: January 18, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Wardman Park, 2660 Woodley Road, NW., Washington, DC 20008.

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779. *riverase@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group. Biochemistry and Biophysics of Membranes Study Section.

Date: January 26–27, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.

Contact Person: Nuria E. Assa-Munt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892. (301) 451–1323. *assamunu@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group. Hepatobiliary Pathophysiology Study Section.

Date: January 31–February 1, 2011.

Time: 8 a.m.to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rass M. Shayiq, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892. (301) 435–2359. *shayiqr@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group. Basic Mechanisms of Cancer Therapeutics Study Section.

Date: January 31–February 1, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Lambratu Rahman, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892. 301–451–3493. *rahmanl@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: December 10, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–31594 Filed 12–15–10; 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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Central Repositories Non-Renewable Sample Access (PAR–10–90)–Type 1 Diabetes.

Date: January 24, 2011.

Time: 2 p.m. to 4 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: Najma Begum, PhD, Scientific Review Officer, Review Branch, Dea, Niddk, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, Md 20892–5452. (301) 594–8894. *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PO1 Vascular Complications in Diabetes.

Date: January 25, 2011.

Time: 2 p.m. to 5 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: D.G. Patel, PhD, Scientific Review Officer, Review Branch, Dea, Niddk, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, Md 20892–5452. (301) 594–7682. *pateldg@niddk.nih.gov.*

(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: December 10, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–31607 Filed 12–15–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver 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. 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