I. Background

In the **Federal Register** of November 3, 2009 (74 FR 56842), FDA announced the availability of a draft guidance document entitled ''Listing of Ingredients in Tobacco Products.'' The agency considered received comments as it finalized this guidance. This guidance document is designed to assist tobacco product manufacturers and importers with making tobacco product ingredient submissions to FDA. Under section 904(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387d(a)(1)), as amended by the Tobacco Control Act, each tobacco product manufacturer or importer, or agent thereof, is required to submit ''a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.'' For tobacco products on the market as of June 22, 2009, information must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. FDA does not, however, intend to enforce the statutory deadline of this subsection provided the ingredient list is submitted on or before June 22, 2010. For tobacco products not on the market as of June 22, 2009, section 904(c)(1) requires that the list of ingredients be submitted at least 90 days prior to delivery for introduction into interstate commerce. Section 904(c) of the act also requires submission of information whenever additives, or the quantities of additives, are changed. FDA does not, however, intend to enforce the statutory deadlines for ingredient reporting under section 904(c) of the act for additive changes or the initial introduction of products into interstate commerce occurring between June 22, 2009, and 90 days after the section 904(a)(1) ingredient list is submitted, provided that these report(s) are submitted at the time of the section 904(a)(1) submission and the report(s) include the date, or planned date, of making the change to the additive or introducing the product into interstate commerce.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Listing of Ingredients in Tobacco Products.'' 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 statute and regulations.

III. 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.

IV. Paperwork Reduction Act of 1995

This guidance contains 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 collection of information in this guidance was approved under OMB control number 0910–0650.

V. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: November 25, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28747 Filed 11–27–09; 11:15 am]

BILLING CODE 4160–01–S

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, Drug Targeting.

Date: December 15, 2009.

Time: 1 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: Hungyi Shau, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, 301–435–1720, *shauhung@csr.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: Center for Scientific Review Special Emphasis Panel, OBT Review Panel Member Applications.

Date: January 7–8, 2010.

Time: 9 a.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Nywana Sizemore, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, 301–435–1718, *sizemoren@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 24, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–28732 Filed 11–30–09; 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, November 24, 2009, 3 p.m. to November 24, 2009, 5 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on November 18, 2009, 74 FR 59569.

The meeting will be held December 9, 2009, from 12 p.m. to 2 p.m. The meeting location remains the same. The meeting is closed to the public.