unapproved hydrocodone products based on FDA's exercise of enforcement discretion as set forth in this notice. FDA also will not exercise its enforcement discretion with respect to continued manufacturing or shipping of any combination drug product that contains a drug subject to an earlier deadline for the exercise of agency enforcement discretion.[7]

Drug manufacturers and distributors should be aware that the agency is exercising its enforcement discretion as described previously only in regard to unapproved drug products containing hydrocodone that are marketed under an NDC number listed with the agency on the effective date of this notice. Unapproved drug products containing hydrocodone that are not currently marketed, or that are currently marketed but are not listed with the agency on the effective date of this notice, must, as of the effective date of this notice, have approved applications prior to their introduction or delivery for introduction into interstate commerce. Moreover, submission of an application does not excuse timely compliance with this notice.

C. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the act. Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including the product NDC number(s), and stating that the product(s) has (have) been discontinued. The letter should be sent to Jennifer Devine (see **ADDRESSES**) with a copy to the district director of the firm's FDA district office. Firms should also update the listing of their product(s) under section 510(j) of the act to reflect discontinuation of unapproved hydrocodone products. FDA plans to rely on its existing records, the results of a subsequent inspection, or other available information when we evaluate whether to initiate enforcement action.

[7]For example, if a person is marketing an unapproved product containing both hydrocodone bitartrate and timed-release guaifenesin on or after August 27, 2007, then under the notice FDA issued May 29, 2007 (72 FR 29517), that person is subject to immediate enforcement; FDA will not extend the exercise of its enforcement discretion to the later dates set out in this notice.

D. Reformulated Products

In addition, FDA cautions firms against reformulating their products into unapproved new drugs without hydrocodone that are marketed under the same name or substantially the same name (including a new name that contains the old name) in anticipation of an enforcement action based on this notice. In the Marketed Unapproved Drugs CPG, FDA stated that it intends to give higher priority to enforcement actions involving unapproved drugs that are reformulated to evade an anticipated FDA enforcement action. In addition, reformulated products marketed under a name previously identified with a different active ingredient, or combination of active ingredients, have the potential to confuse healthcare practitioners and harm patients.

This notice is issued under sections 502 and 505 of the act (21 U.S.C. 352) and under authority delegated to the Deputy Commissioner for Policy under section 1410.10 of the FDA Staff Manual Guide.

Dated: September 25, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–19340 Filed 9–28–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P–0074]

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee. This meeting was announced in the **Federal Register** of August 16, 2007 (72 FR 46091). The amendment is being made to reflect a change in the *Procedure* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Darrell Lyons, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *darrell.lyons@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512541 and 8732310001. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 16, 2007, FDA announced that a joint meeting of Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee would be held on October 18 and 19, 2007. On page 46091, in the third column, the third sentence of the *Procedure* portion of the document is changed to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 10:30 a.m. on October 19, 2007.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 23, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–19332 Filed 9–28–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 a meeting of the Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

Date: November 5, 2007.

Time: 9 a.m. to 2 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31/Conference Room 10, Rockville, MD 20852.

Time: 6 p.m. to 10 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Double Tree Hotel, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Brian E. Wojcik, PhD, Senior Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, 6116 Executive Boulevard, Room 2114, Bethesda, MD 20892, (301) 496–7628, *wojcikb@mail.nih.gov.*

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/bsc.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 21, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4819 Filed 9–28–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 a meeting of the Board of Scientific Counselors for Basic Sciences National Cancer Institute. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intrumural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Basic Sciences National Cancer Institute.

Date: November 5–6, 2007.

Time: November 5, 2007, 6 p.m. to 10 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Double Tree Hotel, 8120 Wisconsin AVenue, Bethesda, MD 20814.

Time: November 6, 2007, 9 a.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20892.

Contact Person: Florence E. Farber, PhD, Executive Secretary, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2115, Bethesda, MD 20892, 301–496–7628, *ff6p@nih.gov.*

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 21, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4820 Filed 9–28–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Center for Complementary and Alternative Medicine Special Emphasis Panel, October 25, 2007, 9 a.m. to October 26, 2007, 5 p.m. Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD, 20814 which was published in the **Federal Register** on August 16, 2007, 7246093.

The meeting notice is being amended due to the meeting dates changing from October 25–26, 2007 to October 25, 2007. The meeting is closed to the public.

Dated: September 19, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4811 Filed 9–28–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Short Term Research Education Program (R25's).

Date: October 22, 2007.

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

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda North Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Rina Das, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892–7294, (301) 435–0297, *dasr2@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 98.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 19, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4810 Filed 09–28–07; 8:45 am]

BILLING CODE 4140–01–M