Contact Person: Suzan Nadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, 301–435–1259, *nadis@csr.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biomaterials and Biointerfaces Study Section.

Date: January 5–6, 2011.

Time: 8 a.m. to 5 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: Steven J Zullo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5146, MSC 7849, Bethesda, MD 20892, 301–435–2810, *zullost@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 16, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–29361 Filed 11–19–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0586]

Hoffmann-La Roche Inc.; Withdrawal of Approval of a New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for ACCUTANE (isotretinoin) Capsules held by Hoffmann-La Roche Inc., 340 Kingsland St., Nutley, NJ 07110–1199. Hoffmann-La Roche Inc. notified the Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.

DATES: *Effective Date:* November 22, 2010.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche Inc. has requested that FDA withdraw approval of NDA 18–662, ACCUTANE (isotretinoin) Capsules, under the process in § 314.150(c) (21 CFR 314.150(c)), stating that the drug product is no longer marketed. Hoffmann-La Roche Inc. has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of NDA 18–662, ACCUTANE (isotretinoin) Capsules, and all amendments and supplements thereto, is hereby withdrawn, effective November 22, 2010. Introduction or delivery for introduction into interstate commerce of a product without an approved application violates sections 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). ACCUTANE (isotretinoin) Capsules that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug product has reached its expiration date or otherwise become violative, whichever occurs first.

In the **Federal Register** of July 7, 2010 (75 FR 39024), FDA issued a notice announcing its determination that ACCUTANE (isotretinoin) Capsules were not withdrawn from sale for reasons of safety or effectiveness, and isotretinoin continues to be marketed under approved abbreviated new drug applications (ANDAs). The holders of ANDAs for isotretinoin are subject to an approved risk evaluation and mitigation strategy (REMS) under section 505–1 of the FD&C Act (21 U.S.C. 355–1), and the REMS, known as the iPLEDGE program, remains in effect.

Dated: November 2, 2010.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2010–29348 Filed 11–19–10; 8:45 am]

BILLING CODE 4160–01–P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of Meeting; Advisory Council on Historic Preservation

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will meet Thursday, December 2, 2010. The meeting will be held in Room MO9 of the Old Post Office Building, 1100 Pennsylvania Ave, NW., Washington, DC at 9 a.m.

The ACHP was established by the National Historic Preservation Act of 1966 (16 U.S.C. 470 *et seq.*) to advise the President and Congress on national historic preservation policy and to comment upon Federal, federally assisted, and federally licensed undertakings having an effect upon properties listed in or eligible for inclusion in the National Register of Historic Places. The ACHP's members are the Architect of the Capitol; the Secretaries of the Interior, Agriculture, Defense, Housing and Urban Development, Commerce, Education, Veterans Affairs, and Transportation; the Administrator of the General Services Administration; the Chairman of the National Trust for Historic Preservation; the President of the National Conference of State Historic Preservation Officers; a Governor; a Mayor; a Native American; and eight non-Federal members appointed by the President.

Call to Order—9 a.m.

I. Chairman's Welcome
II. Chairman's Report
III. Executive Director's Report
IV. Native American Activities
  A. Native American Program Report
  1. HUD Delegation of Tribal Consultation Responsibilities
  2. DOI–DoD–ACHP Memorandum of Understanding on Consultation with Native Hawaiians
  B. Native American Advisory Group
V. Strategic Planning: Next Steps
VI. Sustainability and Historic Preservation Task Force
VII. Preservation Initiatives Committee
  A. America's Great Outdoors Initiative and Historic Preservation
  B. Economic Benefits Study
  C. Legislation
VIII. Federal Agency Programs Committee
  A. Historic Preservation and Energy Development Working Group
  B. National Trust Section 106 Report
  C. Section 106 Update
IX. Communications, Education, and Outreach Committee
  A. Engaging Youth in Historic Preservation
  B. New Directions for ACHP Awards Programs
X. New Business
XI. Adjourn

Note: The meetings of the ACHP are open to the public.