

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]

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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Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.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.

If you need special accommodations due to a disability, please contact the Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., Room 803, Washington, DC, 202-606-8503, at least seven (7) days prior to the meeting. For further information: Additional information concerning the meeting is available from the Executive Director, Advisory Council on Historic Preservation, 1100 Pennsylvania Avenue, NW., #803, Washington, DC 20004.

Dated: November 16, 2010.

John M. Fowler,

Executive Director.

[FR Doc. 2010-29355 Filed 11-19-10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2010-0065]

Public Meetings of National Flood Insurance Program (NFIP) Reform Effort; Correction

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Announcement of Public Meetings; correction.

SUMMARY: The Federal Emergency Management Agency (FEMA) published a document in the **Federal Register** on November 10, 2010 (75 FR 69096), announcing two public meetings. The document contained an incorrect e-mail address. Due to the incorrect e-mail address, FEMA is lengthening the amount of time that the public has to contact FEMA to request special accommodations. FEMA has chosen to republish the corrected notice in its entirety. This notice announces two public meetings of the National Flood Insurance Program (NFIP) Reform Effort. In performing its mission, FEMA believes it is important to continually update stakeholders on its programs and answer any questions and listen to comments from them on how its programs can be more efficient and effective at meeting the needs of the public. To this end, FEMA has engaged in a comprehensive reform effort to address the concerns of the wide array of stakeholders involved in the ongoing debate about the NFIP. FEMA chose a participatory policy analysis framework to guide the NFIP Reform effort. Policy analysis employs systematic inquiry and evaluation to assess policy alternatives. The participatory policy analysis

process allows public decisions to be made in a structured, defensible, and collaborative manner.

The effort is comprised of three phases designed to engage the greatest number of stakeholders and consider the largest breadth of public policy options. Phase I focused on the capture and analysis of stakeholder concerns and recommendations. During Phase II, FEMA performed additional analysis of existing data and identified a set of evaluation criteria. In Phase III, a portfolio of public policy alternatives is being developed and will be analyzed using the evaluation criteria. The resulting recommendations will be reported to FEMA leadership. The purpose of the public meetings is to describe, update, and explain straw man policy alternatives and to answer questions and listen to comments from interested stakeholders. Additional information on the straw man policy alternatives has been made available prior to the meeting via the NFIP Reform website and has been posted to Docket ID: FEMA-2010-0065.

In addition, through these public meetings, FEMA will accept stakeholder input of the policy evaluation process through the use of a pair-wise comparison method. The pair-wise tool is also available via the NFIP Reform Web site at http://www.fema.gov/business/nfip/nfip_reform.shtm.

DATES: *Meeting Date:* The first public meeting will be held on December 2, 2010, from 10 a.m. to 5 p.m. EST. This meeting will be held in Washington, DC. The second public meeting will be held on December 9, 2010, from 10 a.m. to 5 p.m. MST. This meeting will be held in Denver, CO.

Comment Date: Written comments must be received by December 31, 2010.

ADDRESSES: All written comments must be received by Friday, December 31, 2010. All submissions received must include the Docket ID: FEMA-2010-0065 and may be submitted by any one of the following methods:

Federal Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments on the Web site.

E-mail: FEMA-RULES@dhs.gov. Include Docket ID: FEMA-2010-0065 in the subject line of the message.

Facsimile: (703) 483-2999.

Mail: FEMA, Office of Chief Counsel, 500 C Street, SW., Room 840, Washington, DC 20472-3100.

Hand Delivery/Courier: FEMA, Office of Chief Counsel, 500 C Street, SW., Room 840, Washington, DC 20472-3100.

Instructions: All submissions received must include the Docket ID: FEMA-

2010-0065. Comments received will also be posted without alteration at <http://www.regulations.gov>, including any personal information provided. You may want to read the Privacy Act Notice located on the Privacy and Use Notice link on the Administration Navigation Bar of the Web site <http://www.regulations.gov>.

Docket: For access to the docket to read documents or comments received by FEMA, go to <http://www.regulations.gov>. The straw man policy alternatives have been posted to Docket ID: FEMA-2010-0065.

Special Accommodations: For anyone attending the meeting who is hearing or visually impaired, or who requires special assistance or accommodations, please contact Jason "Tommy" Kennedy by November 29, 2010. For further information, please contact Mr. Kennedy by telephone at 202-646-3779.

Meeting Locations: The first public meeting will be held in Washington, DC, at the Washington Marriott at Metro Center, 775 12th Street NW., Washington, DC. The second public meeting will be held in Denver, Colorado at the Denver Federal Center, Building 810—Entrance W-5, Denver, CO.

Meeting Accessibility: Due to space constraints of the facilities, seating will be limited to 200 participants. To reserve a seat in advance, please provide a request via email or mail with the contact information of the participant (including name, mailing address, and e-mail address), the meeting(s) to be attended, and include the subject/attention line (or on the envelope if by mail): Reservation Request for NFIP Reform Meeting. Advance reservations must be received 3 business days prior to the meeting to ensure processing. Unregistered participants will be accepted after all participants with reservations have been accommodated and will be admitted on a first-come, first-serve basis, provided the 200 person capacity is not exceeded. To submit reservations, please email: FEMA-NFIP-REFORM@dhs.gov or send by mail to the address listed in the **FOR FURTHER INFORMATION CONTACT** caption.

Web site: http://www.fema.gov/business/nfip/nfip_reform.shtm.

FOR FURTHER INFORMATION CONTACT: Michael Grimm, by telephone at 202-646-2878 or by e-mail at FEMA-NFIP-REFORM@dhs.gov. *Mailing Address:* NFIP Reform, 1800 South Bell Street, Room 970, Arlington, VA 20598-3030.

Meeting Topics: Background information about these topics is available on the NFIP Reform website. The straw man policy alternatives have