

**Register** of August 11, 2009 (74 FR 40207). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:**

Kalyani Bhatt, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail:

[Kalyani.Bhatt@fda.hhs.gov](mailto:Kalyani.Bhatt@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), codes 3014512529 or 3014512535. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 11, 2009, FDA announced that a meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee would be held on September 23, 2009, from 8 a.m. to 4:30 p.m. On page 40207, in the second column, the *Agenda* portion of the document is changed to read as follows:

*Agenda:* The committees will discuss new drug application (NDA) 21-217, EXALGO (hydromorphone HC1), Neuromed Pharmaceuticals, Inc., a modified-release hydromorphone drug product indicated for the treatment of moderate-to-severe pain in opioid-tolerant patients.

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

Dated: August 19, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-20377 Filed 8-24-09; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-N-0664]

**Oncologic Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Oncologic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 6, 2009, from 8 a.m. to 4 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel phone number is 301-977-8900.

*Contact Person:* Nicole Vesely, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-6793, FAX: 301-827-6776, e-mail: [nicole.vesely@fda.hhs.gov](mailto:nicole.vesely@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/ phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss new drug application (NDA) 021-825, proposed trade name FERRIPROX (deferiprone) film-coated tablets and oral solution, manufactured by ApoPharma Inc. The proposed indications (uses) for this product is as an iron chelating agent, which is a drug that binds with iron in the body and helps to make elimination of iron easier, reducing iron build-up. There are two specific proposed indications (uses) of FERRIPROX: (1) the treatment of iron overload, or build-up in patients with transfusion-dependent thalassemia, an inherited blood disorder that necessitates frequent transfusion of normal blood which can lead to iron build-up due to the iron content in the blood a patient receives; and (2) for the treatment of iron overload in patients with other transfusion-dependent anemias (other blood disorders that require frequent transfusions) for which the use of other iron chelating agents has been considered inappropriate.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 21, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those

desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 11, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 14, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 19, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-20378 Filed 8-24-09; 8:45 am]

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**DEPARTMENT OF HOMELAND SECURITY**

**U.S. Customs and Border Protection**

**Agency Information Collection Activities: Crew Member's Declaration**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 30-Day notice and request for comments; Revision of an existing information collection: 1651-0021.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Crew Member's Declaration. This is a proposed extension and revision of an information collection that was

previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (74 FR 30103) on June 24, 2009, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

**DATES:** Written comments should be received on or before September 24, 2009.

**ADDRESSES:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-5806.

**SUPPLEMENTARY INFORMATION:** U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104-13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

*Title:* Crew Member's Declaration.

*OMB Number:* 1651-0021.

*Form Number:* Form 5129.

*Abstract:* The Form 5129 is used to accept and record importations of merchandise by crewmembers, and to enforce agricultural quarantines, currency reporting laws, and revenue

collection laws. CBP is proposing to increase the burden hours for this collection of information as a result of increasing the estimated time to fill out Form 5129 from 3 minutes to 10 minutes.

*Current Actions:* This submission is being made to extend the expiration date with a change to the burden hours.

*Type of Review:* Revision and Extension.

*Affected Public:* Businesses.

*Estimated Number of Respondents:* 6,000,000.

*Estimated Time per Respondent:* 10 minutes.

*Estimated Total Annual Burden Hours:* 996,000.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., 7th Floor, Washington, DC 20229-1177, at 202-325-0265.

Dated: August 12, 2009.

**Tracey Denning,**

*Agency Clearance Officer, Customs and Border Protection.*

[FR Doc. E9-20425 Filed 8-24-09; 8:45 am]

**BILLING CODE 9111-14-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-1854-DR; Docket ID FEMA-2008-0018]

### Iowa; Major Disaster and Related Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of Iowa (FEMA-1854-DR), dated August 13, 2009, and related determinations.

**DATES:** *Effective Date:* August 13, 2009.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated August 13, 2009, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Iowa resulting

from a severe storm on July 10, 2009, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Iowa.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas, Hazard Mitigation throughout the State, and any other forms of assistance under the Stafford Act that you deem appropriate. Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs. If Other Needs Assistance under Section 408 of the Stafford Act is later requested and warranted, Federal funding under that program will also be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael L. Parker of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following area of the State of Iowa has been designated as adversely affected by this major disaster:

Black Hawk County for Public Assistance.

All counties within the State of Iowa are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. E9-20420 Filed 8-24-09; 8:45 am]

**BILLING CODE 9111-23-P**