DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 5 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, 301–827–7001, FAX: 301–827–6776, e-mail: Nicole.Vesely@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–1890 (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.

SUPPLEMENTAL 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.


David Horowitz,
Assistant Commissioner for Policy.

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Agency Information Collection Activities: Crew Member’s Declaration


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...
DEPARTMENT OF HOMELAND SECURITY
Federal Emergency Management Agency

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.


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, Coralville Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.047, 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; 97.056, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,
Administrator, Federal Emergency Management Agency.