DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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 Institutional National Research Service Awards.

Date: December 15, 2010.

Time: 1 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817. [Virtual Meeting]

Contact Person: Roy L White, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924. 301–435–0725. johnsonw@nhlbi.nih.gov.

(Directorate of Federal Advisory Committee Policy.

[FR Doc. 2010–29525 Filed 11–22–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Amendment of Notice

[FR Doc. 2010–29524 Filed 11–22–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Oncologic Drugs 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 meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the Federal Register of October 19, 2010 (75 FR 64314). The amendment is being made to reflect changes in the Date and Time, Agenda, and Procedure portions of the document. We also are postponing a session regarding biologics license application (BLA) 125377, with the proposed trade name Yervoy (ipilimumab), manufactured by Bristol-Myers Squibb Co. The proposed indication (use) for this product is for the treatment of advanced melanoma in patients who have received prior therapy. This portion of the meeting has been postponed due to the need to complete the review of additional data submitted by the applicant. Future meeting dates may be announced in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, e-mail: Nicole.Vesely@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–828–0510, 301–443–0572 in the Washington, DC area, code 301–451–2542. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 19, 2010 (75 FR 64314), FDA announced that a meeting of the Oncologic Drugs Advisory Committee would be held on December 2, 2010. On page 64314, in the first column, the Date and Time portion of the document is changed to read as follows:

Date and Time: The meeting will be held on December 2, 2010, from 8 a.m. to 12:30 p.m.

On page 64314, in the second column, the Agenda portion of the document is changed to read as follows:

Agenda: On December 2, 2010, the committee will discuss new drug application (NDA) 022–405, with the proposed trade name Zictifa (vandetanib) Tablets, manufactured by iPR Pharmaceuticals, Inc., represented by AstraZeneca Pharmaceuticals LP (authorized U.S. agent). The proposed indication (use) for this product is for the treatment of patients with unresectable (non-operable) locally advanced or metastatic medullary thyroid cancer.

On page 64314, in the second column, the third sentence in the Procedure portion of the document is changed to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. 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: November 17, 2010.

Joanne Less, Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–29522 Filed 11–22–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health