

February 1, 2011, letter, the Agency acknowledged AstraZeneca's agreement to permit FDA to withdraw approval of IRESSA under § 314.150(d) and waive its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 21-399, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 5, 2012.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 2012-9944 Filed 4-24-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0376]

#### **Sanofi-aventis, U.S., LLC; Withdrawal of Approval of a New Drug Application for OFORTA**

**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 OFORTA (fludarabine phosphate) Tablets held by sanofi-aventis, U.S., LLC (sanofi-aventis), 55 Corporate Dr., Bridgewater, NJ 08807-0977. Sanofi-aventis has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

**DATES:** Effective December 31, 2011.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6250, Silver Spring, MD 20993-0002, 301-796-3601.

**SUPPLEMENTARY INFORMATION:** FDA approved OFORTA (fludarabine phosphate) Tablets on December 18, 2008, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. OFORTA is approved for use as a single agent for the treatment of

adult patients with B-cell chronic lymphocytic leukemia whose disease has not responded to or has progressed during or after treatment with at least one standard alkylating agent-containing regimen. On February 10, 2011, FDA requested that sanofi-aventis voluntarily withdraw OFORTA (fludarabine phosphate) Tablets from the market, because the postmarketing study required as a condition of approval under subpart H had not been completed and clinical benefit had not been verified. In a letter dated June 24, 2011, sanofi-aventis requested that FDA withdraw approval of NDA 22-273 for OFORTA (fludarabine phosphate) Tablets under § 314.150(d), noting the lack of commercial demand for OFORTA and significant challenges to completing the postmarketing study. In that letter, sanofi-aventis also waived its opportunity for a hearing, otherwise provided under §§ 314.150 and 314.530. In a letter dated July 8, 2011, the Agency acknowledged sanofi-aventis' agreement to permit FDA to withdraw approval of OFORTA under § 314.150(d) and waive its opportunity for a hearing. The Agency noted that the required postmarketing study had not been completed and clinical benefit had not been verified.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 22-273, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 5, 2012.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 2012-9943 Filed 4-24-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Institute of General Medical Sciences; Notice of Meeting**

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

National Advisory General Medical Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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 Advisory General Medical Sciences Council.

*Date:* May 24-25, 2012.

*Closed:* May 24, 2012, 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

*Open:* May 25, 2012, 8:30 a.m. to Adjournment.

*Agenda:* For the discussion of program policies and issues, opening remarks, report of the Director, NIGMS, and other business of the Council.

*Place:* National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

*Contact Person:* Ann A. Hagan, Ph.D., Associate Director for Extramural Activities, NIGMS, NIH, DHHS, 45 Center Drive, Room 2AN24H, MSC 6200, Bethesda, MD 20892, (301) 594-4499, [hagana@nigms.nih.gov](mailto:hagana@nigms.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's/Center's home page: <http://www.nigms.nih.gov/About/Council/> where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry