Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 240–402–1200. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette M. McCarthy, Center for Food and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1057, FAX 301–436–2972, email: *Annette.McCarthy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives.'' This draft guidance, when finalized, will represent FDA's current thinking on the factors to be considered when determining whether changes in manufacturing process, including the intentional reduction in particle size to the nanoscale, for a food substance already in the market affects the safety and regulatory status of the food substance, and whether a new regulatory submission is warranted.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 170.101, 170.106, 171.1 (21 CFR 171.1) have been approved under OMB control number 0910–0495; the collections of information in §§ 70.25, 71.1, 170.35, and 171.1 have been approved under OMB control number 0910–0016; the collections of information in § 170.39 have been approved under OMB control number 0910–0298; and the collections of information in proposed § 170.36 [1] have been approved under OMB control number 0910–0342.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.regulations.gov* or *http://www.fda.gov/FoodGuidances.* Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: April 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–9936 Filed 4–24–12; 8:45 am]

BILLING CODE 4160–01–P

[1] In April 1997, FDA proposed a voluntary procedure (proposed § 170.36) whereby manufacturers would notify FDA about a view that a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is generally recognized as safe (GRAS) (62 FR 18938, April 17, 1997). FDA invited interested persons who determine that a use of a substance is GRAS to notify FDA of those determinations, under the framework of the 1997 proposed rule, during the interim between the proposed and final rules (62 FR 18938 at 18954). FDA received OMB approval for submissions received under the framework of the 1997 proposed rule.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0370]

AstraZeneca Pharmaceuticals LP; Withdrawal of Approval of a New Drug Application for IRESSA

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 IRESSA (gefitinib) Tablets held by AstraZeneca Pharmaceuticals LP (AstraZeneca), 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355. AstraZeneca has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

DATES: Effective April 25, 2012.

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 IRESSA (gefitinib) Tablets on May 2, 2003, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. IRESSA is indicated as monotherapy after failure of both platinum-based and docetaxel chemotherapies for the continued treatment of patients with locally advanced or metastatic non-small cell lung cancer who are benefiting or have benefited from IRESSA. On August 26, 2010, FDA requested that AstraZeneca voluntarily withdraw IRESSA (gefitinib) Tablets from the market, because the postmarketing studies required as a condition of approval under subpart H failed to verify and confirm clinical benefit. In a letter dated February 1, 2011, AstraZeneca requested that FDA withdraw approval of NDA 21–399 for IRESSA (gefitinib) Tablets, which AstraZeneca characterized as a business decision, effective September 30, 2011. In that letter, AstraZeneca waived any opportunity for a hearing otherwise provided under §§ 314.150 and 314.530. The letter also stated that approximately 250 patients then receiving IRESSA treatment through the Iressa Access Program would continue treatment under an expanded access program, but no new patients would be added to the protocol. In FDA's letter of February 4, 2011, responding to AstraZeneca's

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]

BILLING CODE 4160–01–P

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]

BILLING CODE 4160–01–P

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.*

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