4160-01-P

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 AstraZeneca has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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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 04/24/2012 at 8:45 am; Publication Date: 04/25/2012]