4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0828]

Wyeth Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application for MYLOTARG

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 MYLOTARG (gemtuzumab ozogamicin) for Injection, held by Wyeth Pharmaceuticals, Inc. (Wyeth), 500 Arcola Rd., Collegeville, PA 19426. Wyeth, now a part of Pfizer, Inc., has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.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 MYLOTARG (gemtuzumab ozogamicin) for Injection on May 17, 2000, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. MYLOTARG was indicated for the treatment of patients with CD33-positive acute myeloid leukemia in first relapse who were 60 years of age or older and who were not considered candidates for other cytotoxic chemotherapy. On May 21, 2010, FDA requested that Wyeth voluntarily withdraw MYLOTARG from the market, after results of a required postapproval clinical trial failed to verify clinical benefit to patients and raised new concerns about the drug's safety. In a letter dated October 25, 2010, Wyeth requested that FDA withdraw approval of NDA 21-174, MYLOTARG (gemtuzumab ozogamicin) for Injection, under §314.150(d) (21 CFR 314.150(d)). In that letter, Wyeth also waived its opportunity for a hearing, provided under 21 CFR 314.150 and 314.530. In FDA's acknowledgment letter of November 2, 2010, the Agency stated that a large prospective trial that tested the addition of MYLOTARG to first-line chemotherapy for patients with newly diagnosed acute myelogenous leukemia failed to verify clinical benefit of MYLOTARG and raised safety concerns. FDA also acknowledged that Wyeth waived its opportunity for a hearing.

Therefore, under sections 505(e) and 506(b)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e) and 356(b)(3)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 21-174, and all amendments and supplements thereto, is withdrawn (see DATES).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: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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