Display Date 11-23-07
Publication Date 11-26-07
Certifier C. CLAWSON
ADM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2006P–0291, 2006P–0299, 2006P–0298, 2006P–0309, and 2007P–0062]

Determination That ELOXATIN (Oxaliplatin for Injection), 50 and 100 Milligrams Per Vial, Sterile Lyophilized Powder for Injection, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ELOXATIN (oxaliplatin for injection), 50 and 100 milligrams (mg) per vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously

cd06123

2006P-0298

N 1

approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, is the subject of approved NDA 21–492 held by Sanofi-Aventis. Oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, is a chemotherapeutic agent indicated for adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor. Sanofi-Aventis ceased manufacturing ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, in June 2006.

FDA received five citizen petitions, submitted under 21 CFR 10.30, requesting that the agency determine whether oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, was withdrawn from sale for reasons of safety or effectiveness. The petitions were submitted as follows:

- Sicor Pharmaceuticals, Inc., submitted a citizen petition dated July 24, 2006 (Docket No. 2006P–0291/CP1).
- Rothwell, Figg, Ernst & Manbeck, P.C., submitted a citizen petition dated July 24, 2006 (Docket No. 2006P–0299/CP1).
- AAC Consulting Group submitted a citizen petition dated July 25, 2006 (Docket No. 2006P–0298/CP1).
- Frommer Lawrence & Haug LLP submitted a citizen petition dated August 4, 2006 (Docket No. 2006P–0309/CP1).
- Regulus Pharmaceutical Consulting, Inc., submitted a citizen petition dated February 20, 2007 (Docket No. 2007P–0062/CP1).

The agency has determined that ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that oxaliplatin sterile lyophilized powder for injection, 50 and 100 mg/vial, was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant information has uncovered no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing agency records, FDA determines that for the reasons outlined previously, ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly,

the agency will continue to list ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ELOXATIN (oxaliplatin for injection), 50 and 100 mg/vial, sterile lyophilized powder for injection, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. If FDA determines that the labeling of this drug product

should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: NOV 15 2007

November 15, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

BILLING CODE 4160–01–S