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Display Date 7-10-07

Publication Date 7-11-07

Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0218]

Determination That ARISTOCORT FORTE Injectable Suspension (Triamcinolone Diacetate), 40 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 milligrams (mg) per milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for triamcinolone diacetate suspension, 40 mg/mL.

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 typically a version of the drug that was

previously 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, is the subject of approved NDA 12–802 currently held by Sandoz Canada Inc., a Novartis AG company (Sandoz). Triamcinolone diacetate suspension (40 mg/mL) is a synthetic glucocorticoid for use as an anti-inflammatory or immunosuppressant agent. Sandoz ceased manufacturing ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, in March 2004. West-ward Pharmaceutical Corp. submitted a citizen petition dated May 22, 2006 (Docket No. 2006P–0218/CP1), under 21 CFR 10.30, requesting that the agency determine whether triamcinolone diacetate

suspension, 40 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that triamcinolone diacetate suspension, 40 mg/mL, was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined previously in this document, ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, 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 ARISTOCORT FORTE Injectable Suspension (triamcinolone diacetate), 40 mg/mL, 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 labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: 6/28/07
June 28, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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

BILLING CODE 4160–01–S