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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0281]

Determination That ORUDIS KT (Ketoprofen) Tablets, 12.5 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Food and Drug Administration (FDA) has determined that ORUDIS KT (ketoprofen) tablets, 12.5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ketoprofen tablets, 12.5 mg.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, 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 approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

In a citizen petition dated July 11, 2006 (Docket No. 2006P–0281/CP1), submitted under 21 CFR 10.30, Camargo Pharmaceutical Services, LLC, requested that the agency determine whether ORUDIS KT (ketoprofen) tablets, 12.5 mg, were withdrawn from sale for reasons of safety or effectiveness. ORUDIS KT (ketoprofen) tablets, 12.5 mg, are the subject of approved NDA 20–429 held by Wyeth Consumer Healthcare (Wyeth). ORUDIS KT, an over-the-counter nonsteroidal anti-inflammatory (NSAID) drug indicated for the temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, minor pain of arthritis and menstrual cramps. ORUDIS KT (ketoprofen) is also indicated to temporarily reduce fever. In a letter dated August 24, 2005, Wyeth informed FDA of the

firm's decision to discontinue manufacture of ORUDIS KT (ketoprofen) tablets, 12.5 mg, and the product was moved to the "Discontinued Drug Product List" section of the Orange Book.

The agency has determined that ORUDIS KT (ketoprofen) tablets, 12.5 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner referenced, among other information, certain labeling changes intended to assist consumers in the safe use of the drug, and some adverse event reports. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has determined that this product was not withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons outlined in this notice, ORUDIS KT (ketoprofen) tablets, 12.5 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ORUDIS KT (ketoprofen) tablets, 12.5 mg, 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 ORUDIS KT (ketoprofen) tablets, 12.5 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: 8·7·07

August 7, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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