Dated: March 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0255]

Determination That DURICEF (Cefadroxil USP) Tablets, 1 Gram, and Capsules, 500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) has determined that DURICEF (cefadroxil USP) Tablets, 1 gram (g), and Capsules, 500 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to continue to approve abbreviated new drug applications (ANDAs) for cefadroxil USP tablets, 1 g, and cefadroxil USP capsules, 500 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 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 Cosmetics 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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), the circumstances under which the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness include: (1) Before an ANDA that refers to that listed drug may be approved and (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug. FDA may not approve an ANDA that does not refer to a listed drug.

DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, are the subjects of approved NDA 50–528 and NDA 50–512, respectively, held by Warner Chilcott, Inc. (Warner Chilcott). DURICEF is an antibiotic indicated to treat infections of the urinary tract, skin, throat, and tonsils, caused by specific bacteria, including streptococci, staphylococci, and *Escherichia coli*. Warner Chilcott has informed FDA that DURICEF (cefadroxil USP) Tablets 1 g, and Capsules, 500 mg, have been withdrawn from sale.

In a citizen petition dated June 13, 2006 (Docket No. 2006P–0255/CP1), submitted under 21 CFR 10.30, Orchid Healthcare (a division of Orchid Chemicals & Pharmaceuticals Ltd.) requested that the agency determine whether DURICEF (cefadroxil USP) Tablets, 1 g, were withdrawn from sale for reasons of safety or effectiveness. In addition, there are approved ANDAs that refer to DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg.

The agency has determined that Warner Chilcott's DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DURICEF Tablets, 1 g, and Capsules, 500 mg, were withdrawn from sale 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 that either DURICEF Tablets, 1 g, or Capsules, 500 mg, were 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 document, DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DURICEF (cefadroxil USP) Tablets, 1 g, and Capsules, 500 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. Approved ANDAs that refer to DURICEF cefadroxil USP) Tablets, 1 g, and Capsules, 500 mg, are unaffected by the withdrawal of these products from sale. ANDAs that refer to cefadroxil USP (tablets, 1 g, and cefadroxil USP capsules, 500 mg, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs.

Dated: March 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–5415 Filed 3–23–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0240]

Determination of Regulatory Review Period for Purposes of Patent Extension; REVLIMID

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for REVLIMID and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug