Dated: March 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–5470 Filed 3–23–07; 8:45 am]

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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Determination That DURICEF (Cefadroxil USP) Tablets, 1 Gram, and Capsules, 500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) has determined that DURICEF (cefadroxil USP) Tablets, 1 gram (g), and Capsules, 500 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product REVLIMID (lenalidomide). REVLIMID is indicated for treatment of patients with transfusion-dependent anemia due to Low- or Intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for REVLIMID (U.S. Patent No. 5,635,517) from Celgene Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 14, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of REVLIMID represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for REVLIMID is 2,069 days. Of this time, 1,804 days occurred during the testing phase of the regulatory review period, while 265 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: April 30, 2000. The applicant claims May 1, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 30, 2000, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 7, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for REVLIMID (NDA 21–880) was initially submitted on April 7, 2005.

3. *The date the application was approved*: December 27, 2005. FDA has verified the applicant's claim that NDA 21–880 was approved on December 27, 2005.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,166 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 25, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 24, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–5439 Filed 3–23–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0034]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PREVICOX 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 animal drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a