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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the human biological 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 biological product and continues until FDA grants permission to market the biological 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 biological 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 biological product ELAPRASE (idursulfase). ELAPRASE is indicated for patients with Hunter Syndrome (Mucopolysaccharidosis II). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ELAPRASE (U.S. Patent No. 5,932,211) from Women's and Children's Hospital, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 6, 2007, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ELAPRASE 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 ELAPRASE is 2,008 days. Of this time, 1,764 days occurred during the testing phase of the regulatory review period, while 244 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*: January 25, 2001. The applicant claims March 12, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 25, 2001, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: November 23, 2005. FDA has verified the applicant's claim that the biologics license application (BLA) for ELAPRASE (BLA 125151) was initially submitted on November 23, 2005.

3. *The date the application was approved*: July 24, 2006. FDA has verified the applicant's claim that BLA 125151 was approved on July 24, 2006.

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 1,103 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 July 23, 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 November 19, 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: May 7, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–9951 Filed 5–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002P–0399]

Determination That ESTROSTEP 21 (Ethinyl Estradiol and Norethindrone Acetate) Tablets 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 ESTROSTEP 21 (ethinyl estradiol and norethindrone acetate) tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for the combination drug ethinyl estradiol and norethindrone acetate tablets, 0.02 milligram (mg)/1 mg, 0.03 mg/1 mg, and 0.035 mg/1 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 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 removed 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 (§ 314.162)(21 CFR 314.162)).

Under § 314.161(a)(1)(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.

ESTROSTEP 21 (ethinyl estradiol and norethindrone acetate) tablets, 0.02 mg/1 mg, 0.03 mg/1 mg, and 0.035 mg/1 mg, are the subject of approved NDA 20–130 held by Warner Chilcott. ESTROSTEP 21 tablets, 0.02 mg/1 mg, 0.03 mg/1 mg, and 0.035 mg/1 mg, were approved on October 9, 1996, as oral contraceptives indicated for the prevention of pregnancy in women who elect to use these products as a method of contraception. FDA also approved ESTROSTEP FE under NDA 20–130 on October 9, 1996, for the same indication. On July 1, 2001, FDA approved ESTROSTEP 21 and ESTROSTEP FE for the treatment of moderate acne vulgaris under NDA 21–276. Both ESTROSTEP 21 and ESTROSTEP FE provide a gradually increasing estrogen dose with a constant dose of progestin. Both drugs provide the same dosage regimen of oral contraceptive tablets for the first 21 days of a 28–day cycle. ESTROSTEP FE provides an additional seven ferrous fumarate tablets. The ferrous fumarate tablets, which are nonhormonal and serve no therapeutic purpose, are added to facilitate patient compliance by the use of a 28-day regimen where the patient takes a pill every day. Except for the nontherapeutic ferrous fumarate tablets, ESTROSTEP 21 and ESTROSTEP FE have the same therapeutic regimen.

ESTROSTEP 21 is listed in the Orange Book as a discontinued product. ESTROSTEP FE, currently named ESTROSTEP, remains on the list of currently marketed drug products.

Barr Laboratories, Inc., submitted a citizen petition dated September 4, 2002 (Docket No. 2002P–0399/CP1), under 21 CFR 10.30 and § 314.161, requesting that FDA determine whether ESTROSTEP 21 tablets had been discontinued from sale for reasons of safety or effectiveness. In a letter dated December 1, 2004, Warner Chilcott confirmed to the agency that the firm never commercially marketed ESTROSTEP 21 in the United States. In previous instances (see the **Federal Register** of December 30, 2002 (67 FR 79640 at 79641) (addressing a relisting request for Diazepam Autoinjector)), FDA has concluded that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

The agency has determined that ESTROSTEP 21 tablets, 0.02 mg/1 mg, 0.03 mg/1 mg, and 0.035 mg/1 mg, were not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that Warner Chilcott continues to market ESTROSTEP FE, which contains the same therapeutic dosage regimen as ESTROSTEP 21. The petitioner identified no data or other information suggesting that ESTROSTEP 21 was withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports associated with this combination drug product and has found no information that would indicate this product was 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, ESTROSTEP 21 tablets, 0.02 mg/1 mg, 0.03 mg/1 mg, and 0.035 mg/1 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ESTROSTEP 21 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 ESTROSTEP 21 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 these drugs products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: May 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9949 Filed 5–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0191]

Determination That Protamine Sulfate Injection and 26 Other Drug Products 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 the 27 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) for the drug products, and it will allow FDA to continue to approve ANDAs for the products.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 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). 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 (the 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