D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For technical questions about this program, contact: Leo F. Weakland, Project Officer, Global Immunization Division, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E–05, Atlanta, Georgia 30333, telephone: 404–639–8252, E-mail Address: *lfwo@cdc.gov.*

Dated: March 9, 2004.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–5740 Filed 3–12–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0393]

Determination That DIAZEPAM Injection United States Pharmacopeia (5 Milligrams/Milliliter in a 1-Milliliter Container) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that DIAZEPAM Injection United States Pharmacopeia (USP) (5 milligrams/milliliter (mg/mL) in a 1-mL container) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for DIAZEPAM Injection USP (5 mg/mL in a 1-mL container).

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 §314.162 (21 CFR 314.162).

Under § 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.

DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) is the subject of approved ANDA 72–079 held by Abbott Laboratories, Inc. (Abbott). DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety. PharmaForce, Inc., submitted a citizen petition dated August 25, 2003 (Docket No. 2003P–0393/CP1), under 21 CFR 10.30, requesting that the agency determine whether DIAZEPAM Injection USP (5 mg/mL, 1 mL) was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that DIAZEPAM Injection USP in a 5-mg strength (5 mg/mL in a 1–mL container) was not withdrawn from sale for reasons of safety or effectiveness. Two grounds support the agency's finding. First, DIAZEPAM Injection USP currently is being marketed in a 10-mg strength (5 mg/mL in a 2-mL container). Adverse drug events would be less likely with the discontinued lower dose than the currently marketed higher dose. In addition, by using only a portion of the amount currently marketed, the 5-mg strength in question still can be obtained. Second, the lower 5-mg strength of DIAZEPAM Injection USP would be considered an effective dosage form because it is still within the dosing range. The usual recommended dose for older children and adults ranges from 2 to 20 mg intramuscularly or intraveneously, depending on the indication and its severity.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, DIAZEPAM Injection, USP (5 mg/mL in a 1-mL container) was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DIAZEPAM Injection USP (5 mg/mL in a 1-mL container) 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 DIAZEPAM Injection USP (5 mg/mL, 1 mL) may be approved by the agency.

Dated: March 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5756 Filed 3–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0419]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IPRIVASK 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 that 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: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,240–453–6699.

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 drug 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 IPRIVASK (desirudin). IPRIVASK is indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism, in patients undergoing voluntary hip replacement surgery. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IPRIVASK (U.S. Patent No. 4,745,177) from Novartis Corp. and UCP Gen-Pharma AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 18, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of IPRIVASK 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 IPRIVASK is 4,707 days. Of this time, 3,696 days occurred during the testing phase of the regulatory review period, while 1,011 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*: May 17, 1990. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 17, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: June 28, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for IPRIVASK (NDA 21ndash;271) was initially submitted on June 28, 2000.

3. *The date the application was approved*: April 4, 2003. FDA has verified the applicant's claim that NDA 21ndash;271 was approved on April 4, 2003.

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 5 years 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 14, 2004. 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 13, 2004. 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: February 17, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–5703 Filed 3–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0406]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FABRAZYME 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 biological product.

ADDRESSES: Submit written or electronic comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

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