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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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

TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), is the subject of approved NDA 21–062 held by Bristol-Myers Squibb. TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), is an antibiotic used to treat adults with lung, sinus, or urinary tract infections.

FDA approved the NDA for TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg) and 10 mg/mL (400 mg), on December 17, 1999. On January 27, 2003, FDA received revised product labeling relating to several approved supplements for TEQUIN (gatifloxacin). This revised labeling deleted references to TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), indicating that this product was no longer being marketed. Therefore, it was moved from the prescription drug product list to 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.

Apotex Corp., submitted a citizen petition dated January 13, 2005 (Docket No. 2005P–0023/CP1), under 21 CFR 10.30, requesting that the agency determine whether TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records, FDA has determined that TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), approved under NDA 21–062, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant literature and data has not uncovered anything that would indicate that this product was withdrawn for reasons of safety or effectiveness. Accordingly, the agency will continue to list TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), in the ''Discontinued Drug Product List'' section of the Orange Book. ANDAs that refer to TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), may be approved by the agency.

Dated: January 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1475 Filed 2–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0389]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SURPASS 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: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product SURPASS (diclofenac sodium). SURPASS is indicated for the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock, and pastern) joints in horses. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SURPASS (U.S. Patent No. 4,937,078) from Mezei Associates, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 8, 2005, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of SURPASS represented the first permitted commercial marketing or use of the product. 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 SURPASS is 2,262 days. Of this time, 1,028 days occurred during the testing phase of the regulatory review period, while 1,234 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under subsection 512(j) of the act became effective*: March 6, 1998. The applicant claims January 11, 1999, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was March 6, 1998, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act*: December 27, 2000. The applicant claims January 2, 2001, as the date the new animal drug application (NADA) for SURPASS (NADA 141–186) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141–186 was December 27, 2000, which is considered to be the initially submitted date for NADA 141–186.

3. *The date the application was approved*: May 13, 2004. FDA has verified the applicant's claim that NADA 141–186 was approved on May 13, 2004.

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 1,590 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 April 4, 2006. 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 August 2, 2006. 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: January 5, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–1434 Filed 2–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0407]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CYPHER 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 medical device.

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, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device CYPHER. CYPHER is indicated for improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete de novo lesions of the length ≤ 30 mm in native coronary arteries with a reference vessel diameter of ≥ 2.5 to ≤ 3.5 mm. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CYPHER (U.S. Patent No. 5,563,146) from Wyeth, 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 24, 2004, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of CYPHER represented the first permitted commercial marketing or use of the product. 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 CYPHER is 814 days. Of this time, 513 days occurred during the testing phase of the regulatory review period, while 301 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) involving this device became effective*: February 1, 2001. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act (21 U.S.C.