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.

360j(g)) for human tests to begin became effective February 1, 2001.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: June 28, 2002. FDA has verified the applicant's claim that the premarket approval application (PMA) for CYPHER (PMA P020023) was initially submitted June 28, 2002.

3. *The date the application was approved*: April 24, 2003. FDA has verified the applicant's claim that PMA P020023 was approved on April 24, 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 557 days of patent term extension.

Anyone with knowledge that any of the dates as published is 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 6, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–1436 Filed 1–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0017]

Human Subject Protection—Information for Institutional Review Boards, Clinical Investigators, and Sponsors; Rescission, Reissuance, and Development of Food and Drug Administration Guidance Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an initiative, the Information Sheet Guidance Initiative, to update its process for developing, issuing, and making available guidances intended for institutional review boards (IRBs), clinical investigators, and sponsors. Known as ''Information Sheets,'' these guidances have provided recommendations for IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by FDA since the early 1980s. The Information Sheet Guidance Initiative is intended to provide updated information and to issue the Information Sheets in accordance with FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue Information Sheet Guidances that address current issues, and develop new Information Sheet Guidances as needed. The agency is also announcing the availability of five revised Information Sheet Guidances.

DATES: Submit written or electronic comments on the Information Sheet Guidance Initiative or the Information Sheet Guidances by April 4, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the Information Sheets are available on the Internet at *http://www.fda.gov/oc/gcp/guidance.html*. Submit written requests for single copies of the Information Sheet Guidances to the Office of Training and Communications (HFD–240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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*. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: Bonnie M. Lee, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the Information Sheet Guidance Initiative, which will update the current process for developing, issuing, and making available Information Sheets intended for IRBs, clinical investigators, and sponsors.

Following issuance of human subject protection regulations by the Department of Health, Education, and Welfare and FDA in the late 1970s, IRBs frequently contacted FDA for advice on the best ways to achieve compliance with the new rules. In response, FDA issued informal guidance to answer the IRBs' specific questions. In 1984, FDA consolidated the informal guidance into a series of documents known as FDA's ''Information Sheets for Institutional Review Boards and Clinical Investigators.'' These Information Sheets were revised in 1995 and updated in 1998 to reflect new contact information. They were also edited to make them user friendly.

The Information Sheets have provided answers to frequently asked questions about human subject protection, informed consent, review of research, and related topics. The Information Sheets are intended to help IRBs, clinical investigators, and sponsors ensure that the rights and welfare of human research subjects are protected.

In 1997, the Food and Drug Administration Modernization Act required the agency to codify its GGPs policy. The GGP final rule, issued in 2000 (§ 10.115 (21 CFR 10.115)), requires that the agency make its guidance development and issuance procedures consistent and transparent. According to § 10.115, among other things, all FDA policy documents must be called guidance, and all agency guidance must be developed and issued according to the requirements in § 10.115. The Information Sheets are being converted to ''Information Sheet Guidance'' and are being issued in accordance with GGPs.