Avandia 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 Avandia (rosiglitazone maleate). Avandia is indicated for use in combination with a sulfonylurea in patients with type 2 diabetes mellitus when diet and exercise with either single agent does not achieve adequate glycemic control. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Avandia (U.S. Patent No. 5,002,953) from Smithkline Beecham 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 April 26, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Avandia 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 Avandia is 2,042 days. Of this time, 1,859 days occurred during the testing phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: October 23, 1993. The applicant claims October 22, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 23, 1993, 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 of the act*: November 24, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Avandia (NDA 21–071) was initially submitted on November 24, 1998.

3. *The date the application was approved*: May 25, 1999. FDA has verified the applicant's claim that NDA 21–071 was approved on May 25, 1999.

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 1,021 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination by April 14, 2003. 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 12, 2003. 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 Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit a single copy. Copies 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–3555 Filed 2–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1239]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Rapamune 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 Rapamune (sirolimus (also rapamycin)). Rapamune is indicated for prophylaxis of organ rejection in patients receiving renal transplants. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Rapamune (U.S. Patent No. 5,100,899) from Sir Roy Caine, 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 13, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Rapamune 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 Rapamune is 2,709 days. Of this time, 2,434 days occurred during the testing phase of the regulatory review period, while 275 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective: April 17, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 17, 1992.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the act: December 15, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Rapamune (NDA 21–083) was initially submitted on December 15, 1998.

3. The date the application was approved: September 15, 1999. FDA has verified the applicant's claim that NDA 21–083 was approved on September 15, 1999.

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 1,492 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination by April 14, 2003. 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 12, 2003. 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 Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit a single copy. Copies 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–3556 Filed 2–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Grant Awards

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of grant awards.

SUMMARY: The Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA), has awarded the following grants. Funds for these grants were appropriated under Public Law 107–116, the ''Departments of Labor, HHS, Education, and Related Agencies Appropriations Act for FY 2002.'' The awards are Special Projects of Regional and National Significance (SPRANS), authorized by Section 501(a)(2) of the Social Security Act, the MCH Federal Set-Aside Program (42 U.S.C. 701(a)(2)).

• *Replicating ''Lessons Learned'' in Alcohol Screening During Pregnancy Demonstration Program.* (CFDA #93.110) This grant promotes replication of strategies found to motivate providers to systematically screen for alcohol use during pregnancy, provide information on associated risks, and refer clients for interventions. Competition for this award was open to only two existing grantees of a preceding three-year initiative entitled: ''Improving Screening for Alcohol Use During Pregnancy Among Providers Demonstration Program.'' Each of the following two grantees was awarded $150,000 for the first year of the three-year grant period with second and third year grant awards subject to acceptable performance and the availability of funds:

- Illinois Department of Human Services, Office of Family Health; and
- Massachusetts Department of Public Health, Bureau of Family.

FOR FURTHER INFORMATION: Contact Ellen Hutchins, ScD, Division of Perinatal Systems and Women's Health, Maternal and Child Health Bureau, 5600 Fishers Lane, Room 11A–55, Rockville, MD 20857, (301) 443–9534.

• *New Investigators in MCH Research: Dissertation Awards.* (CFDA #93.110RD) This grant program supports doctoral candidates' research-based