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

dissertation in maternal and child health (MCH) or an MCH-related discipline. Competition for this award was limited to existing grantees of ''Long-Term Leadership Training Grants.'' The following grantees received awards for a single project:

- The University of Maryland, School of Social Work; $29,411;
- The Johns Hopkins University, School of Public Health; $30,000;
- The Boston University, School of Public Health; $19,972;
- The University of Illinois at Chicago, School of Public Health; $20,560;
- The University of California, Los Angeles, School of Public Health; $22,482;
- The University of Minnesota, School of Public Health; $22,525; and
- The University of North Carolina at Chapel Hill, School of Social Work; $6,052.

FOR FURTHER INFORMATION: Contact Hae Young Park, M.P.H., Division of Research, Training and Education, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18A–55, Rockville, MD 20857, (301) 443–2127.

- *New Investigators in MCH Research: Training Program Enhancement Awards.* (CFDA #93.110TU) This grant program supports the development, demonstration and dissemination of program models in five institutions of higher education to enhance the research training of their MCH trainees. Competition for this award was limited to existing grantees of ''Long-Term Leadership Training Grants.'' Each of the following two grantees received a maximum grant award of $20,000 for the first year of a 3-year project period:
- The University of Minnesota Center for Adolescent Health and Research—Leadership Education in Adolescent Health Training Program; $20,000;
- The Children's Hospital Los Angeles—Leadership Education in Neurodevelopmental Disabilities Training Program; $20,000;
- The Boston University School of Public Health—MCH Training Program; $20,000;
- The Virginia Commonwealth University—Leadership Education in Neurodevelopmental Disabilities Training Program; $20,000; and
- The University of Rochester—Leadership Education in Adolescent Health and Leadership Education in Neurodevelopmental Disabilities Training Programs; $20,000.

FOR FURTHER INFORMATION: Contact Hae Young Park, M.P.H., Division of Research, Training and Education, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18A–55, Rockville, MD 20857, (301) 443–2127.

Dated: February 6, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–3594 Filed 2–12–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Substance Abuse Prevention and Treatment Block Grant: Waiver for U.S. Territories (Other Than Puerto Rico) of Synar Program Requirements

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

SUMMARY: In keeping with the Substance Abuse and Mental Health Services Administration's (SAMHSA) delegation of authority from the Secretary and in compliance with title XIX, subpart II, section 1932(c) and with section 1926 of the Public Health Service Act, SAMHSA is issuing the following guidance to be used in determining whether to approve a U.S. Territory's request for a waiver from the requirements of section 1926 of the Public Health Service (PHS) Act (the Synar Amendment), and its implementing regulations, 45 CFR 96.130.

This guidance will become effective only at such time that an appropriation act for the Department of Health and Human Services (HHS) does not contain a prohibition on penalizing the territories under section 1926 of the PHS Act that receive less than $1,000,000. (*See, e.g.*, section 214 of Departments of Labor Health and Human Services, and Education, and Related Agencies Appropriation Act, Pub. L. 107–116 (Jan. 10, 2002).) SAMHSA, however, is seeking comment from the public on this guidance.

Section 1926 of the Public Health Service (PHS) Act and its implementing regulation, require each State, the District of Columbia and each U.S. Territory, as a condition for receiving a Substance Abuse Prevention and Treatment (SAPT) Block Grant award, to enact and enforce laws making illegal the sale or distribution of tobacco products to individuals under the age of 18 years. States, the District of Columbia and the Territories are also required to annually conduct unannounced inspections of tobacco retail outlets to ensure compliance with the law. These inspections must be based on a statistically valid random sample of retail outlets across the State, the District of Columbia or the Territory. Additionally, States, the District of Columbia and Territories are required, unless extraordinary circumstances exist, to meet negotiated annual retailer violation target rates, and to annually submit a report to the Secretary describing their activities to enforce the laws and reduce the availability of tobacco products to minors. Section 1926 also stipulates that any State, the District of Columbia or Territory failing to meet the requirements stated above may receive a 40 percent penalty against their SAPT Block Grant.

Section 1932(c) of the PHS Act authorizes the Secretary, in the case of any territory of the United States except Puerto Rico, to waive such provisions of this subpart II and subpart III as the Secretary determines to be appropriate, * * *'' The reference is to subpart II and III of title XIX of the PHS Act which authorize the SAPT Block Grant. This discretionary authority extends to section 1926. This authority has been delegated by the Secretary to the Administrator of SAMHSA. This guidance explains the conditions under which the Administrator of SAMHSA, in his discretion, will grant a waiver for any Territory other than Puerto Rico from the requirements of section 1926.

DATES: Comments on the guidance must be in writing and should be sent to Mr. David Robbins, Acting Director, Division of State and Community Systems Development, Center for Substance Abuse Prevention (CSAP), Rockwall II Building, Room 930, 5600 Fishers Lane, Rockville, MD 20857, by April 14, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. David Robbins, Acting Director, Division of State and Community Systems Development, Center for Substance Abuse Prevention (CSAP), Rockwall II Building, Room 930, 5600 Fishers Lane, Rockville, MD 20857. Mr. Robbins may be reached on (301) 443–2068.

SUPPLEMENTARY INFORMATION: U.S. Territories have faced many challenges in meeting the Synar legislative and regulatory requirements. Specifically, cultural issues have created significant challenges for the conduct of tobacco outlet inspections to assess the youth tobacco access rates within each of the U.S. Territories, as required by the Synar legislation. For example, in some Territories it is customary for individuals under the age of 18 to buy provisions, including tobacco, for their elders. In others, it is considered inappropriate to ask a person's age for