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.gov/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 ZETIA (ezetimibe). ZETIA, administered alone, is indicated as adjunctive therapy to diet for the reduction of elevated total-chlorestorol (total-C), low density lipoprotein (LDL–C), and Apo B in patients with primary hypercholesterolemia. ZETIA, administered in combination with an HMG–CoA reductase inhibitor, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL–C, and Apo B in patients with primary hypercholesterolemia. The combination of ZETIA atorvastatin or simvastatin is indicated for the reduction of elevated total-C and LDL–C levels in patients with HoFH, as an adjunct to other lipid-lowering treatments or if such treatments are unavailable. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZETIA (U.S. Patent No. 37,721) from Schering 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 February 3, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZETIA 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 ZETIA is 1,983 days. Of this time, 1,680 days occurred during the testing phase of the regulatory review period, while 303 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 23, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 23, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: December 27, 2001*. FDA has verified the applicant's claim that the new drug application (NDA) for ZETIA (NDA 21–445) was initially submitted on December 27, 2001.

3. *The date the application was approved*: October 25, 2002. FDA has verified the applicant's claim that NDA 21–445 was approved on October 25, 2002.

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 497 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 16, 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 October 14, 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 (see **ADDRESSES**). 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 31, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–9534 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2003 Funding Opportunity

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

ACTION: Notice of funding availability for SAMHSA State Incentive Grants (COSIG) for Treatment of Persons with Co-Occurring Substance Related and Mental Disorders.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) and Center for Mental Health Services (CMHS) announces the availability of FY 2003 funds for the grant program described below. A synopsis of this funding opportunity, as well as many other Federal Government funding opportunities, is also available at the Internet site: *http://www.fedgrants.gov*.

This notice is not a complete description of the program; potential applicants must obtain a copy of the

Request for Applications (RFA), including Part I, State Incentive Grants (COSIG) for Treatment of Persons with Co-Occurring Substance Related and Mental Disorders, Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application.

Funding Opportunity Title: State Incentive Grants (COSIG) for Treatment of Persons with Co-Occurring Substance Related and Mental Disorders—Short Title: COSIG.

Funding Opportunity Number: TI 03–003.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section: 509 of the Public Health Service Act, as amended and subject to the availability of funds.

Funding Opportunity Description: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), and Center for Mental Health Services (CMHS), are accepting applications for Fiscal Year 2003 grants to develop and enhance the infrastructure of States and their treatment service systems to increase the capacity to provide accessible, effective, comprehensive, coordinated/integrated, and evidence-based treatment services to persons with co-occurring substance abuse and mental health disorders, and their families.

Eligible Applicants: Only the immediate Office of the Governor of States may apply. State-level agencies are not considered to be part of the immediate Office of the Governor. This means, for example, that the State Mental Health or Substance Abuse Authorities or other State-level agencies within the Office of the Governor cannot apply independently. SAMHSA has limited the eligibility to Governors of States because the immediate Office of the Governor has the greatest potential to provide the multi-agency leadership needed to develop the State's infrastructure/treatment service systems to increase the State's capacity to provide accessible, effective, comprehensive, coordinated/integrated, and evidence-based services to persons with co-occurring substance abuse and mental health disorders, and their families.

As defined in the Public Health Service (PHS) Act, the term ''State'' includes all 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands. Applications from State agencies other than the Office of the Governor, or from government entities that do not meet the definition of ''State,'' are not eligible for funding and will not be reviewed.

Due Date for Applications: June 13, 2003.

Estimated Funding Available/Number of Awards: It is expected that $6.5 million will be available for 6 to 10 awards in FY 2003. The average annual award will range from $500,000 to $1.1 million in total costs (direct and indirect). Grantees in years 1–3 will receive up to $1.1 million per year. Grantees with service pilots will receive up to half of the third year award in the 4th year to phase down the services pilot and up to $100,000 for evaluation in year 5. Grantees without service pilots will receive up to $100,000 for evaluation in both years 4 and 5. Applications with proposed budgets that exceed these amounts in any year will be returned without review.

Is Cost Sharing Required: No.

Period of Support: Up to 5 years, with annual continuations depending on availability of funds and progress achieved.

How to Get Full Announcement and Application Materials: Complete application kits may be obtained from: the National Clearinghouse for Alcohol and Drug Information (NCADI) at 1–800–729–6686. The PHS 5161–1 application form and the full text of the funding announcement are also available electronically via SAMHSA's World Wide Web Home Page: *http://www.samhsa.gov* (Click on ''Grant Opportunities'').

When requesting an application kit, the applicant must specify the funding opportunity title and number for which detailed information is desired. All information necessary to apply, including where to submit applications and application deadline instructions, are included in the application kit.

Contact for Additional Information: Richard E. Lopez, J.D., Ph.D., Substance Abuse and Mental Health Agency, Center for Substance Abuse Treatment, Division of State and Community Assistance, 5600 Fishers Lane/Rockwall II, Room 8–147, Rockville, MD 20857, (301) 443–7615, E-Mail: *rlopez@samsha.gov*.

Dated: April 10, 2003.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–9387 Filed 4–16–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Suspension of Application Receipt Dates for a Fiscal Year (FY) 2003 Funding Opportunity

AGENCY: Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Suspension of future application receipt dates until further notice for SAMHSA/CSAT Grants to Expand Substance Abuse Treatment Capacity in Targeted Areas of Need Program (PA 03–001).

SUMMARY: This notice is to inform the public that future application receipt dates under the SAMHSA/CSAT program announcement, Grants to Expand Substance Abuse Treatment Capacity in Targeted Areas of Need—PA 03–001, are being cancelled until further notice. Effective immediately, no applications will be received for the future September 10 and January 10 receipt dates under this announcement.

The notice of funding opportunity for PA 03–001 was published in the **Federal Register** on June 24, 2002, (Vol. 67, Number 121, pages 42573–42574).

SAMHSA is currently re-engineering its discretionary grants process and it is possible that PA 03–001 may ultimately be withdrawn.

Information related to this notice may be obtained from: Tom Edwards, Division of Services Improvement, CSAT/SAMHSA, Tele: (301) 443–8453, e-mail: *tedwards@samhsa.gov*.

Dated: April 10, 2003.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–9388 Filed 4–16–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Paperless Drawback Prototype: Delay of Commencement of Test and Reopening of Application Period

AGENCY: Customs and Border Protection, Homeland Security; Treasury.

ACTION: General notice.

SUMMARY: In a document published in the **Federal Register** on September 27,