to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 24, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 (address above) in three copies (except that individuals may submit single copies) and 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: August 16, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–21849 Filed 8–26–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0100]

Determination of Regulatory Review Period for Purposed of Patent Extension; CEDAX® Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CEDAX® Capsules 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brain J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

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 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 Commissioner 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 CEDAX® Capsules (ceftibuten dihydrate). CEDAX® Capsules is indicated for the treatment of individuals with mild-to-moderate infections cause by susceptible strains of the designated microorganisms in the specific conditions: Acute Bacterial Exacerbations of Chronic Bronchitis due to *Heamophilus influenzae* (including B-lactamase-producing strains), *Moraxella catarrhalis* (including B-lactamase producing strains) or *Streptoccocus pneumoniae* (penicillin-susceptible strains only), Acute Bacterial Otitis Media due to *H. influenzae* (including B-lactamase producing strains), *M. catarrhalis* (including B-lactamase producing strains) or *S. pyogenes*, or Pharyngitis and Tonsillitis due to *S. pyogenes*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CEDAX® Capsules (U.S. Patent No. 4,812,561) from Schering-Plough Corp. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a latter dated April 10, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CEDAX® Capsules 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 CEDAX® Capsules is 3,065 days. Of this time, 1,603 days occurred during the testing phase of the regulatory review period, while 1,462 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 (21 U.S.C. 355(i)) became effective: August 1, 1987. The applicant claims August 2, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 1987, which was 30 days after FDA receipt on the IND.

2. The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357): December 20, 1991. FDA has verified the applicant's claim that the new drug application (NDA) for CEDAX® Capsules (NDA 50–685) was initially submitted on December 20, 1991.

3. The date the application was approved: December 20, 1995. FDA has verified the applicant's claim that NDA 50–685 was approved on December 20, 1995.

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 902 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 28, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 24, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 (address above) in three copies (except that individuals may submit single copies) and 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: August 15, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–21851 Filed 8–26–96; 8:45 am]

BILLING CODE 4160–01–M

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the following teleconference meetings of SAMHSA's Special Emphasis Panel II and Special Emphasis Panel I in August, 1996.

A summary of the meetings may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: (301)443–4783.

Substantive program information may be obtained from the individuals named as Contacts for the meetings listed below.

The Special Emphasis Panel II meeting will include the review, discussion and evaluation of individual contract proposals. These discussions could reveal personal information concerning individuals associated with the proposals and confidential and financial information about an individual's proposal. The discussion may also reveal information about procurement activities exempt from disclosure by statute and trade secrets and commercial or financial information obtained from a person and privileged and confidential. Accordingly, the meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c) (3), (4), and (6) and 5 U.S.C. App. 2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel II.

Panel: Research Utilization & Integration into Substance Abuse Treatment.

Meeting Date: August 27, 1996.

Place: Parklawn Building, Room 17–74, 5600 Fishers Lane, Rockville, MD 20852.

Closed: August 27, 1996, 2:00 p.m.–5:00 p.m.

Contact: Katie Baas, Room 17–89, Parklawn Building, Telephone: (301)443–0411 and FAX: (301)443–3437.

The Special Emphasis Panel I meeting will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, this meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, § 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Date: August 28, 1996—1:30 p.m.–3:00 p.m.

Place: Parklawn Building, Room 17–90, 5600 Fishers Lane, Rockville, MD 20852.

Closed: August 28, 1996—1:30 p.m.–3:00 p.m.

Contact: Sandra E. Stephens, Room 17–89, Parklawn Building, Telephone: (301) 443–9915 and FAX: (301) 443–3437.

This notice is being published less than 15 days prior to the meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: Augut 21, 1996.

Jeri Lipov,

Committee Management Officer, SAMHSA.

[FR Doc. 96–21792 Filed 8–26–96; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4070–N–02 and FR–4105–N–027]

Office of Administration; Notice of Submission of Proposed Information Collection to OMB

AGENCY: Office of the Assistant Secretary for Policy Development and Research—HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: The due date for comments is: September 3, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships—telephone (202) 708–1537. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Karadbil.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, an information collection package with respect to a proposed Notice of Funding Availability for the Hispanic-Serving Institutions Work Study Program (HSI–WSP). HUD seeks to implement this initiative as soon as possible.

The Hispanic-Serving Institutions Work Study Program provides grants to certain institutions of higher education (i.e., Hispanic-serving community colleges) to assist economically disadvantaged and minority students who participate as full-time students participating in associate degree programs in a community building academic discipline. Approximately 30 grants will be awarded with Fiscal Year 1996 funds.

Submission of the information required under this information collection is mandatory in order to compete for and receive the benefits of the program. All materials submitted are subject to the Freedom of Information Act and can be disclosed upon request. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number. The OMB control number, when assigned, will be announced by a separate notice in the Federal Register.

The Department has submitted the proposal for the collection of information to OMB for review as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The department has requested emergency clearance of the collection of information, as described below, with approval being sought by August 28, 1996:

(1) *Title of the information collection proposal:* Application Kit—Hispanic-Serving Institutions Work Study Program.

(2) *Summary of the collection of information:* Each application for HSI–WSP would be required to submit current information, as listed below as:

1. Transmittal letter signed by the Chief Executive Officer of the institution.

2. OMB Standard Forms 424 (Application for Federal Assistance),