copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: February 23, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5030 Filed 3–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0839]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Atacand 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 Atacand (candesartan cilexetil). Atacand is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Atacand (U.S. Patent No. 5,196,444) from Takeda Chemical Industries Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Atacand 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 Atacand is 1,087 days. Of this time, 686 days occurred during the testing phase of the regulatory review period, while 401 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:* June 15, 1995. The applicant claims May 16, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 15, 1995, 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:* April 30, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Atacand (NDA 20,838) was initially submitted on April 30, 1997.

3. *The date the application was approved:* June 4, 1998. FDA has verified the applicant's claim that NDA 20,838 was approved on June 4, 1998.

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 413 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 3, 1999, 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 August 30, 1999, 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: February 16, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–5032 Filed 3–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–228]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the

Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Managed Care Adjusted Community Rate (ACR) Proposal and Supporting Regulations in 42 CFR 422.300–422.312;

Form No.: HCFA–R–228 (OMB# 0938–0742);

Use: This collection effort will be used to price the M+C plan offered to Medicare beneficiaries by an M+C organization. Organizations submitting the Adjusted Community Rate form would include all M+C organizations plus any organization intending to contract with HCFA as a M+C organization. These current M+C organization contractors will be required to submit this form no later than May 1, 1999 for the calendar year 2000.;

Frequency: Annually;

Affected Public: Businesses or other for profit, Not-for-profit institutions.;

Number of Respondents: 500;

Total Annual Responses: 500;

Total Annual Hours Requested: 50,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE **ADDRESS** at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 9, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–5121 Filed 3–1–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel I in March 1999.

A summary of the meeting and a roster of the members may be obtained from: Ms. Coral Sweeney, SAMHSA, Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: 301–443–2998.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The 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 Dates: March 23, 1999.

Place: Parklawn Building, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20852.

Closed: March 23, 1999, 2:00 p.m.—adjournment.

Panel: Substance Abuse and Mental Health Services Administration HIV/AIDS High Risk Behavior Supplement.

Contact: Raquel Crider, Room 17–89, Parklawn Building, Telephone: 301–443–5063 and FAX: 301–443–3437.

Dated: February 16, 1999.

Sandi Stephens,

Team Leader, Extramural Activities Team, Substance Abuse and Mental Health Services Administration.

[FR Doc. 99–5091 Filed 3–1–99; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–960–1410–00 24 1A]

Agency Information Collection Activities; Comment Request

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) announces its intention to request approval to collect certain information from Alaskan Native Vietnam Era Veterans interested in applying for up to 160 acres of Federal land in Alaska. This information will allow BLM to adjudicate the applications submitted by Alaskan Native Vietnam Era Veterans according to Public Law 105–276.

DATES: BLM must receive comments on the proposed information collection by May 3, 1999, to assure consideration of them.

ADDRESSES: Mail comments to: Director (630), Bureau of Land Management, 1849 C Street NW, Room 401 L Street, Washington, D.C. 20240.

Send comments via Internet to: WoComment@wo.blm.gov. Please include ''ATTN: 1004–NEW.''

You may hand deliver comments to the Bureau of Land Management, Administrative Record, Room 401, 1620 L Street, NW, Washington, D.C. 20240.

BLM will make comments available for public review at the L Street address during regular business hours (7:45 A.M. to 4:15 P.M.), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dennis Benson, Bureau of Land Management, Alaska State Office, (907) 271–3248.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 1320.12(a), BLM is required to provide 60-day notice in the **Federal Register** concerning a collection of information contained in BLM Form 2561–10 (March 1999) and 43 CFR Part 2561, to solicit comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the