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 PRECOSE™ (acarbose). PRECOSE™ is indicated as an adjunct to diet to lower blood glucose in patients with noninsulin-dependent diabetes mellitus who hyperglycemia cannot be managed by diet alone. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PRECOSE™ (U.S. Patent No. 4,904,769) from Bayer AG, 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 27, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period that the approval of PRECOSE™ 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 PRECOSE™ is 5,647 days. Of this time, 3,789 days occurred during the testing phase of the regulatory review period, while 1,858 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*: March 23, 1980. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on March 23, 1980.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: August 6, 1990. The applicant claims August 9, 1990, as the date the new drug application (NDA) for PRECOSE™ (NDA 20–086) was initially submitted. However, FDA records indicate that NDA 20–086 for the active ingredient in PRECOSE™ (acarbose) was received by the agency on August 6, 1990. This NDA was withdrawn on August 28, 1991. A subsequent NDA for PRECOSE™ (NDA 20–482) was received on September 6, 1994. Therefore, NDA 20–086 signifies the end of the testing phase and the beginning of the approval phase for PRECOSE™, while NDA 20–482 signifies the end of the approval phase. The NDA initially submitted date is August 6, 1990.

3. *The date the application was approved*: September 6, 1995. FDA verified the applicant's claim that NDA 20–482 was approved on September 6, 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 922 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 29, 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 November 26, 1996, 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: May 16, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–13535 Filed 5–29–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–2552–96]

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:* Hospital and Hospital Health Care Complex Cost Report; *Form No.:* HCFA–2552–96; *Use:* This form is required by statute and regulation for participation in the Medicare program. The information is used to determine final payment for Medicare. Hospitals and related complexes are the main users. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 4,599,000.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent 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, D.C. 20503.

Dated: May 22, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–13520 Filed 5–29–96; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Maternal and Child Health Services; Federal Set-Aside Program; Continuing Education and Development Cooperative Agreements

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Extension of application deadline date.

The Maternal and Child Health Services; Federal Set-Aside Program; Continuing Education and Development Cooperative Agreements notice deadline date published on April 26, 1996, beginning on page 18613, is hereby extended to July 8, 1996.

The rest of the notice remains as published.

Dated: May 24, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–13578 Filed 5–29–96; 8:45 am]

BILLING CODE 4160–15–P

Public Health Service

Health Resources and Services Administration;

Statement of Organization, Functions and Delegations of Authority

Part H, Chapter HB (Health Resources and Services Administration) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (47 FR 38409–24, August 31, 1982, as amended most recently at 61 FR 24939–40, May 17, 1996). The changes are as follows:

1. Under Part HB, Health Resources and Services Administration Section HB–20–Functions, ''Bureau of Health Resources Development (HBB)'' delete the statement in its entirety and replace by the following

Bureau of Health Resources Development (HBB).

Administers Federal policy and programs pertaining to health care facilities, activities associated with organ donations, procurements, transplantation, and a variety of program activities related to HIV infection and acquired immune deficiency syndrome (AIDS). This includes financial, capital, organizational, and physical matters. Specifically: (1) Provides national leadership in supporting, identifying, and interpreting national trends and issues of significance relative to the health status of persons with AIDS, and with HIV infections, including the provision of facilities and services for AIDS and AIDS-related patients, persons in need and provision of services to persons and families of low income; and administers block and discretionary grants, contracts, and funding arrangements designed to address those issues; (2) administers and coordinates AIDS-related grants programs of national significance; (3) administers grant, loan, loan guarantees and interest subsidy programs relating to the construction, modernization, conversion, and closure of health and health care organizations; (4) develops long and short range program goals and objectives for health facilities, and for specific health promotional, organ transplantation, and AIDS activities; (5) manages contracts to provide Federal oversight for the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients and the National Marrow Donor Programs and works to increase the availability of donor organs and unrelated bone narrow donors by working with the Organ Procurement Organizations (OPOS) and Donor Centers; (6) serves as advisor to and coordinates activities with other Agency organizational elements, other Federal organizations within and outside the Department, State, and local bodies, professional and scientific organizations; (7) develops, promotes, and directs efforts to improve the management, operational effectiveness, and efficiency of health care systems, organizations, and facilities; (8) provides technical assistance to OPOs and health care delivery systems and facilities in a wide variety of specific technical and technological systems; (9) administers HRSA's regional facility engineering and construction activities; (10) designs and implements special epidemiological and evaluation studies of the impact of the Bureau health care programs and of the characteristics of the population serviced; (11) evaluates models of health care delivery systems through grants, contracts, direct activities designs, and tests; (12) plans and develops collaborative efforts in the scientific aspects of Bureau programs with other PHS agencies, Federal departments, universities, and other scientific organizations; and (13) maintains liaison and coordinates with non-Federal public and private entities as necessary for the accomplishment of Bureau missions and objectives; and

2. Delete the Division of Trauma and Emergency Medical System (HBB8) in its entirety.

Delegations of Authority

All delegations and redelegations of authorities to officers and employees of the Bureau of Health Resources Development which were in effect immediately prior to the effective date of this reorganization will be continued in effect in them or their successors, pending further redelegations, provided they are consistent with this reorganization.

These changes are effective upon date of signature.

Dated: May 15, 1996.

Ciro V. Sumaya,

Administrator, Health Resources and Services Administration.

[Fr. Doc. 96–13539 Filed 5–29–96; 8:45 am]

BILLING CODE 4160–15–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–3917–N–84]

Office of the Assistant Secretary for Public and Indian Housing; Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

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

DATES: Comments due: July 29, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451—7th Street, SW, Room 4255, Washington, D.C. 20410–5000.