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 OXILAN™ (loxilan). OXILAN™ is indicated for cerebral arteriography, coronary arteriography and left ventriculography, visceral angiography, aortography, and peripheral arteriography. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for OXILAN™ (U.S. Patent No. 4,954,348) from Cook Imaging 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 May 28, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of OXILAN™ 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 OXILAN™ is 2,757 days. Of this time, 1,644 days occurred during the testing phase of the regulatory review period, while 1,113 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*: June 5, 1988. The applicant claims April 29, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 5, 1988, 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(b) of the Federal Food, Drug, and Cosmetic Act*: December 4, 1992. FDA has verified the applicant's claim that the new drug application (NDA) for OXILAN™ (NDA 20–316) was initially submitted on December 4, 1992.

3. *The date the application was approved*: December 21, 1995. FDA has verified the applicant's claim that NDA 20–316 was approved on December 21, 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 737 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 16, 1997, 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 October 14, 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: April 4, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–9917 Filed 4–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[ORD–098–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: February 1997

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: No new proposals for Medicaid demonstration projects were submitted to the Department of Health and Human Services during the month of February 1997 under the authority of section 1115 of the Social Security Act. There were no proposals approved, disapproved, or withdrawn during that time period. (This notice can be accessed on the Internet at HTTP://WWW.HCFA.GOV/ORD/ORDHP1.HTML.)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Susan Anderson, office of Research and Demonstrations, ealth Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the *Federal Register* (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the

authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the **Federal Register** with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, Disapproved, and Withdrawn Proposals for the Month of February 1997

A. Comprehensive Health Reform Programs

1. New, Pending, Approved, Disapproved, and Withdrawn Proposals

We did not receive any new proposals or approve or disapprove any proposals during the month of February nor were any proposals withdrawn during that month. Therefore, pending proposals for the month of January 1997 published in the **Federal Register** of March 31, 1997, 62 FR 15187, remain unchanged.

B. Other Section 1115 Demonstration Proposals

1. New, Pending, Approved, Disapproved, and Withdrawn Proposals

We did not receive any new proposals or approve or disapprove any Other Section 1115 Demonstration Proposals during the month of February nor were any proposals withdrawn during that month.

Pending proposals for the month of January 1997 found in the **Federal Register** of March 31, 1997, 62 FR 15187 remain unchanged, except for the addition of the Minnesota Long Term Care Facility Waiver (a new proposal that was received in January).

III. Requests for Copies of a Proposal

Requests for copies of a specific Medicaid proposal should be made to the State contact listed for the specific proposal. If further help or information is needed, inquiries should be directed to HCFA at the address above.

(Catalog of Federal Domestic Assistance Program, No. 93.779; Health Financing Research, Demonstrations, and Experiments.)

Dated: March 21, 1997.

Barbara Cooper,

Acting Director, Office of Research and Demonstrations.

[FR Doc. 97–9918 Filed 4–16–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 1997:

Name: Maternal and Child Health Research Grants Review Committee

Date and Time: June 18–20, 1997, 9:00 a.m.

Place: Conference Room ''J'', Parklawn Building, 5600 Fishers Lane, 3rd Floor, Rockville, Maryland 20857. Open on Wednesday, June 18, 1997, 9:00 a.m.–10:00 a.m. Closed for remainder of meeting.

Agenda: The open portion of the meeting will cover opening remarks by the Director, Division of Science, Education and Analysis, Maternal and Child Health Bureau, who will report on program issues, congressional activities and other topics of interest to the field of maternal and child health. The meeting will be closed to the public on June 18 at 10:00 a.m. for the remainder of the meeting for the review of grant applications. The closing is in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., and the Determination by the Director, Office of Policy and Information Coordination, Health Resources and Services Administration, pursuant to Public Law 92–463.

Anyone requiring information regarding the subject Council should contact Gontran Lamberty, Dr.P.H., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Room 18A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301)443–2190.

Agenda Items are subject to change as priorities dictate.

Dated: April 11, 1997.

J. Henry Montes,

Director, Office of Policy and Information Coordination.

[FR Doc. 97–9875 Filed 4–16–97; 8:45 am]

BILLING CODE 4160–15 P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4207–C–02]

NOFA for Rental Assistance for Persons With Disabilities in Support of Designated Housing Allocation Plans and Establishment of Preferences for Certain Section 8 Developments; Correction

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

ACTION: Notice of funding availability (NOFA); correction.

SUMMARY: On April 10, 1997, at 62 FR 17672, the Department published a Notice of Funding Availability (NOFA) part of which concerned Rental Assistance for Persons With Disabilities in Support of Preferences for Certain Section 8 Developments. The limit on rental assistance requested, as contained in that NOFA, inadvertently omitted the maximum number of units for which an HA could apply. The following correction adds a 200 unit limitation.

In the notice document 97–9334, beginning on page 17672 in the issue of Thursday, April 10, 1997, make the following correction:

On page 17674 in the second and third columns the paragraph headed ''(3) Limit on Rental Assistance Requested'' should be changed to read:

(3) Limit on Rental Assistance Requested. An HA may apply only for the number of units needed to house those non-elderly disabled families who are on the waiting list of an owner of a Section 8 project-based development, identified in paragraph B.(1) above where the owner elected to provide preferences to elderly families and to house other non-elderly disabled families residing in the community who would qualify for one- or zero-bedroom units, but for not more than 200 units.

Dated: April 11, 1997.

Camille E. Acevedo,

Assistant General Counsel for Regulations.

[FR Doc. 97–9873 Filed 4–16–97; 8:45 am]

BILLING CODE 4210–33–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora—Tenth Regular Meeting; Public Meeting

AGENCY: Fish and Wildlife Service, Interior.