2722, under the index ''AERS Public Meeting,'' document No. 0510. Information about the meeting will be available via Internet using the World Wide Web (WWW). To connect to the CDER home page, type http://www.fda.gov/cder and go to the ''What's Happening'' section. Also available on the CDER home page is a link to the new AERS home page, which contains a brief summary of the materials that will be discussed at the meeting. Information distributed at the public meeting will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 10 business days after the meeting at a cost of 10 cents per page.

The agenda will be placed on display, under the docket number found in brackets in the heading of this document, at the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert C. Nelson, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–700), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3206.

SUPPLEMENTARY INFORMATION: The primary purpose of FDA's postmarketing surveillance program is to identify potentially serious drug safety problems, focusing especially on newly marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provides, for the first time, the opportunity to collect information on rare, latent, and long-term effects. Reports are obtained from a variety of sources, including patients, treating physicians, foreign regulatory agencies, and clinical investigators. Over 75 percent of the ADR reports that FDA receives are routed from health care practitioners through pharmaceutical companies. The remainder of the reports come directly to FDA through the agency's MedWatch program.

FDA's computerized spontaneous reporting system (SRS) contains 1.4 million ADR reports for human drugs and therapeutic biologics. FDA plans to replace SRS with AERS by September 1997. All SRS historical data will be migrated to AERS. AERS will enable FDA to receive reports from pharmaceutical companies by electronic submission, transmitted data base to data base through standardized pathways. The technical specifications of the AERS computerized system will be described at the public meeting and made available to participants, especially as they relate to the electronic submission of expedited and periodic ADR reports.

FDA has participated in the development of several guidelines by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that relate to the submission of ADR reports under the AERS system: ''Clinical Safety Data Management: Definitions and Standards for Expedited Reporting'' (E2A); ''Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports'' (E2B); and ''Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' (E2C). In addition, two other guidelines are currently under development by ICH: ''Medical Terminology (MEDDRA)'' (M1) and ''Electronic Standards for the Transfer of Regulatory Information (ESTRI)'' (M2).

At the public meeting, FDA will explain how it intends to incorporate these recommended standards into the requirements for the electronic submission of ADR reports under AERS. The meeting will include a general discussion of CDER's plans to propose revisions to its postmarketing ADR reporting regulations. The goals of this rulemaking are to implement the recommendations in the ICH guidelines and to enhance the quality of ADR reports received by the agency. The agency hopes to familiarize the pharmaceutical industry with the procedures for the electronic submission of ADR reports under AERS so that they are prepared to comply with any revised regulations that may issue as a result of the rulemaking initiative.

Additional information on the technical specifications of the AERS system will be placed on display, as they are available in final form, at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4161 Filed 2–19–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Form # HCFA–P–15A]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHSS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, thus causing the disruption of this collection of information, which is essential to the agency's mission of ensuring that beneficiary needs are evaluated and implemented, to the extent possible, in a cost-effective manner. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result if normal clearance procedures are followed. Without this information, HCFA would not be able to properly determine the services needed by beneficiaries or the most cost efficient manner to meet beneficiary needs, possibly resulting in the denial of beneficiary warranted services and a loss of program dollars.

HCFA is requesting that OMB provide a 24-hour review and a 180-day approval. During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.5.

1. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Medicare Current Beneficiary Survey (MCBS) Round 18; *Form No.:* HCFA–P–15A; *Use:* The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons for Medicare. The survey provides a comprehensive source of information on beneficiary characteristics, needs, and satisfaction with Medicare-related activities. The proposed MCBS revisions will focus on the evaluation of beneficiary informational needs. This information will enable HCFA to better coordinate and integrate its current communication objectives effectively and efficiently; *Frequency:* On occasion; *Affected Public:* Individuals and households; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 16,000.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1325. Written comments and recommendations for the proposed information collections should be faxed to OMB at (202) 395–6974, or sent within 48 hours 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: February 18, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97–4337 Filed 2–19–97; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: Alendronate.
Date: February 18, 1997.
Time: 3:00 p.m. - adjournment.
Place: NIAMS Review Branch, 45 Natcher Building, Bethesda, Maryland 20892.
Contact Person: Melvin H. Gottlieb, Ph.D., Natcher Building, 45 Center Drive, Rm 5AS–25U, Bethesda, Maryland 20892–6500, Telephone: 301–594–4952.
Purpose/Agenda: To evaluate and review an individual contract proposal. The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. The discussion of this proposal could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the proposal, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

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

(Catalog of Federal Domestic Assistance Program Nos. [93.846, Project Grants in Arthritis, Musculoskeletal and Skin Diseases Research], National Institutes of Health, HHS)

Dated: February 13, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–4260 Filed 2–14–97; 4:34 pm]

BILLING CODE 4140–01–M

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.
Committee Name: National Institute of Mental Health Special Emphasis Panel.
Date: February 20, 1997.
Time: 8 a.m.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.
Contact Person: Rehana A. Chowdhury, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301–443–6470.

Committee Name: National Institute of Mental Health Special Emphasis Panel.
Date: March 6, 1997.
Time: 2 p.m.
Place: Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857.
Contact Person: Lawrence E. Chaitkin, Parklawn, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301–443–4843.

The meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

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

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: February 13, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–4261 Filed 2–14–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4200–N–25]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Community Planning and Development, 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: April 21, 1997.

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: Reports Liaison Officer, Shelia E. Jones, Department of Housing & Urban Development, 451—7th Street, SW, Room 7230, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Donner Buchet (202) 708–2290 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35 as amended).

The Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate 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; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Designation of 20 Community Development Corporations for authority to offer tax credits for contributions.

OMB Control Number, if applicable:

Description of the need for the information and proposed use: To assess progress of designated CDCs in accomplishing the program and activities for which they received designation.

Agency form numbers, if applicable:

Members of affected public: Staff of the 20 community development corporations (CDCs).