DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–822, CMS–209 and CMS–R–305]

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

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Federal Health Care Programs Provider/Supplier Enrollment Application; *Form No.:* CMS–855 (OMB# 0938–0685); *Use:* This information is needed to enroll providers and suppliers into the Medicare program by identifying them, pricing and paying their claims, and verifying their qualifications and eligibility to participate in Medicare; *Frequency:* Initial enrollment/recertification and Every three years; *Affected Public:* Business or other for-profit, individuals or households, and not-for-profit institutions; *Number of Respondents:* 274,000; *Total Annual Responses:* 274,000; *Total Annual Hours:* 642,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Laboratory Personnel Report Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1—493.2001; *Form No.:* HCFA–0209 (OMB# 0938–0151); *Use:* CLIA requires the Department of Health and Human Services (DHHS) to establish certification requirements for any laboratory that performs tests on human specimens, and to certify through the issuance of a certificate that those laboratories meet the requirements established by DHHS. The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA. Information on personnel qualifications of all technical personnel is needed to ensure the sample is representative of all laboratories; *Frequency:* Biennially; *Affected Public:* Business or other for profit, not for profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 22,500; *Total Annual Responses:* 11,250; *Total Annual Hours:* 5,625.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* External Quality Review of Medicaid MCOs and Supporting Regulations in 42 CFR 438.352,438.360, 438.362, and 438.36; *Form No.:* CMS–R–305 (OMB# 0938–0786); *Use:* The results of Medicare reviews, Medicare accreditation surveys, and Medicaid external quality reviews will be used by States in assessing the quality of care provided to Medicaid beneficiaries provided by managed care organizations or to provide information on the quality of the care provided to the general public upon request. Three of the protocol activities are mandatory and six are optional; *Frequency:* Annually; *Affected Public:* Business or other for-profit, State, local or tribal govt.; *Number of Respondents:* 500; *Total Annual Responses:* 14,226; *Total Annual Hours:* 648,877.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://cms.hhs.gov/regulations/pra/default.asp*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, 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: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 13, 2003.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 4, 2003, from 9 a.m. to 4 p.m. and on March 5, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, fax: 301–827-6776, e-mail: *reedyk@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 4, 2003, the committee will hear a safety update on tnf alpha inhibitors; Humira (adalimumab), Abbott Laboratories; REMICADE (infliximad), Centocor; and ENBREL (etanercept), Immunex. On March 5, 2003, the committee will discuss the approved product new drug application (NDA) 20–905, ARAVA, (leflunomide), Aventis Pharmaceuticals, Inc., clinical data regarding efficacy for improvement in physical function in rheumatoid arthritis, as well as a safety update. The background material for this meeting will be posted on the Internet when available or 1-working