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

day before the meeting at: *www.fda.gov/ohrms/dockets/ac/acmenu.htm.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 25, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 4, 2003, and between approximately 8:30 a.m. and 9 a.m. and 11:30 a.m. and 12 noon on March 5, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 25, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact LaNise Giles at 301–827–7001 at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the March 4, 2003, Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Arthritis Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 13, 2003.

Linda Arey Skladany,

Associate Commissioner for External Affairs.

[FR Doc. 03–4350 Filed 2–24–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0061]

Draft Guidance for Industry on Comparability Protocols—Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Comparability Protocols—Chemistry, Manufacturing, and Controls Information.'' This draft document provides recommendations to applicants on preparing and using comparability protocols for postapproval changes in chemistry, manufacturing, and controls (CMC) information.

DATES: Submit written or electronic comments on the draft guidance by June 25, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448 or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Stephen Moore, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 8800 Rockville Pike, Rockville, MD 20892, 301–435–5681, or Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Comparability Protocols—Chemistry, Manufacturing, and Controls Information.'' This draft guidance applies to comparability protocols that would be submitted in new drug applications (NDAs), abbreviated new drug applications (ANDAs), new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), or supplements to these applications, except for applications for protein products. Well-characterized synthetic peptides submitted in these applications are included within the scope of this guidance. This draft guidance also applies to comparability protocols submitted in drug master files (DMFs) and veterinary master files (VMFs) that are referenced in these applications. A separate guidance will address comparability protocols for proteins as well as for peptide products outside the scope of this guidance that are submitted in these applications. This separate guidance will also address comparability protocols for products submitted in biologics license applications (BLAs).

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control numbers 0910–0001 and 0910–0032.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on ''Comparability Protocols; Chemistry, Manufacturing, and Controls Information''. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see