effective treatments. The design of clinical programs for developing drugs, devices, or biological products intended for the treatment of OA was the subject of a previous draft guidance issued in February 1998 (63 FR 8208, February 18, 1998). The February 1998 draft guidance generated several comments and was the subject of discussion at the Arthritis Advisory Committee meeting held on February 20, 1998.

The agency found the comments and the discussion at the advisory committee meeting very helpful in developing the recommendations to industry, contained in the guidance, on the design of clinical programs for developing drugs, devices, or biological products intended for the treatment of OA. However, the agency believes that more public input would be beneficial in preparing a final version of the guidance. Accordingly, the agency has decided to issue this revised version of the guidance as a draft.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on developing drugs, devices, or biological products intended for the treatment of OA. 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 statute, regulations, or both.

Interested persons may, on or before September 13, 1999, submit to the Dockets Management Branch (address above) written comments on the draft document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft document, appended questions, and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–18031 Filed 7–14–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–9042]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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, 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.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Request for Accelerated Payments and Supporting Regulations in 42 CFR 412.116 and 413.64;

Form No.: HCFA–9042;

Use: Medicare reimbursements are usually arranged through a fiscal intermediary who serves as the Secretary's agent for reviewing claims and making payments equal to the provider's reasonable costs. When a delay in Medicare payment by a fiscal intermediary, for covered services, causes financial difficulties for a provider, the provider may request an accelerated payment. An accelerated payment may also be made in highly exceptional situations where a provider has incurred a temporary delay in its bill processing beyond the provider's normal billing cycle. An accelerated payment can be requested by a provider that is not receiving periodic interim payments. These forms are used by fiscal intermediaries to access a provider's eligibility for accelerated payments.

Frequency: On occasion;

Affected Public: Business or other for-profit, and Not for-profit institutions;

Number of Respondents: 890;

Total Annual Responses: 890;

Total Annual Hours Requested: 445.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 16, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–18007 Filed 7–14–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–0209 and HCFA–1557]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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, 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