randomly sampled as part of the CERT process; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 1600; *Total Annual Responses:* 1600; *Total Annual Hours:* 454.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement; *Form No.:* CMS–460 (OMB# 0938–0373); *Use:* Form number CMS–460 is completed by nonparticipating physicians and suppliers if they choose to participate in Medicare Part B. By signing the agreement, the physician or supplier agrees to take assignment on all Medicare claims. To take assignment means to accept the Medicare allowed amount as payment in full for the services they furnish and to charge the beneficiary no more than the deductible and coinsurance for the covered service. In exchange for signing the agreement, the physician or supplier receives a significant number of program benefits not available to nonparticipating suppliers. The information associated with this collection is needed to identify the recipients of the program benefits; *Frequency:* Other—when starting a new business; *Affected Public:* Business or other for-profit; *Number of Respondents:* 6000; *Total Annual Responses:* 6000; *Total Annual Hours:* 1500.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in Final Peer Review Organization Regulations, 42 CFR Sections 1004.40, 1004.50, 1004.60, 1004.70; *Form No.:* CMS–R–65 (OMB# 0938–0444); *Use:* This final rule updates the procedures governing the imposition and adjudication of program sanctions predicated on the recommendations of Peer Review Organizations (PROs). These changes are being made as a result of statutory revisions designed to address health care fraud and abuse issues in the OIG sanction process. The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act, creating the Utilization and Quality Control Peer Review Organization program. Section 1156 of the Social Security Act imposes obligations on health care practitioners and other persons who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met. Quality Improvement Organizations (QIOs) are responsible for identifying violations. QIOs may allow practitioners or other persons, opportunities to submit relevant information before determining that a violation has occurred. These requirements are used by the QIOs to collect the information necessary to make their determinations; *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 53; *Total Annual Responses:* 1060; *Total Annual Hours:* 22,684.

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://www.cms.hhs.gov/regulations/pra/*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.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 CMS Paperwork Reduction Act Reports Clearance Officer designated at the address below:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: William N. Parham, III, Room C5–13–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 24, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–6533 Filed 4–1–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10008]

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

AGENCY: Centers for Medicare & 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 & Medicaid Services (CMS), 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 function; (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:* Revision of a currently approved collection; *Title of Information Collection:* Process and Information Required to Determine Eligibility of Drugs, Biologicals, and Radio-pharmaceutical Agents for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS) and Supporting Regulations in 42 CFR, Section 419.43; *Use:* Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biological agents. Interested parties such as hospitals, pharmaceutical companies, and physicians can apply for transitional pass-through payment for drugs and biologicals used with services covered under the OPPS. CMS uses this information to determine if the criteria for making a transitional pass-through payment are met and if an interim HCPCS code for a new drug or biological is necessary. The revisions made to this collection include the addition of Section 303 of the MMA. This new section establishes the use of the average sales price (ASP) methodology for payment; *Form Number:* CMS–10008 (OMB# 0938–0802); *Frequency:* On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 203.

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://www.cms.hhs.gov/regulations/pra/*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.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: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 24, 2005.

John P. Burke, III,

CMS Paperwork Reduction Act Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group.

[FR Doc. 05–6534 Filed 4–1–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0112]

Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; 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 ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.''

This is the first of a series of guidances that will provide recommendations to sponsors on endpoints for cancer clinical trials submitted to FDA to support effectiveness claims in new drug applications (NDAs), biologics license applications (BLAs), or supplemental applications. Sponsors are encouraged to use this draft guidance to design cancer clinical trials and to discuss protocols with the agency. This draft guidance provides background information and discusses general regulatory principles. Each subsequent guidance will focus on endpoints for specific cancer types (e.g., lung cancer, colon cancer) to support drug approval or labeling claims. These guidances are expected to speed the development and improve the quality of protocols submitted to the agency to support anticancer effectiveness claims.

DATES: Submit written or electronic comments on the draft guidance by June 3, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or 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. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (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:

Grant Williams, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–5758;

Patricia Keegan, Center for Drug Evaluation and Research (HFD–107), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–827–5097; or

Steven Hirschfeld, Center for Biologics Evaluation and Research (HFM–755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6536.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.'' FDA is developing guidance on oncology endpoints through a process that includes public workshops of oncology experts and discussions before FDA's Oncologic Drugs Advisory Committee. This draft guidance is the first in a planned series of cancer endpoint guidances. It provides background information and general principles. The endpoints discussed in this draft guidance are for drugs to treat patients with an existing cancer. This draft guidance does not address endpoints for drugs to prevent or decrease the incidence of cancer.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on clinical trial endpoints for the approval of cancer drugs and biologics. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit one copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6647 Filed 4–1–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans

SUMMARY: In compliance with the provisions of section 3507(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 29, 2004 (Volume 69, No. 209, pages 63159–63160) and allowed 60 days for public