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Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.''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 Sponsors are encouraged to use this draft guidance to design cancer clinical trials and to discuss protocols with the agency. This draft guidance provides background information and discusses general regulatory principles.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DATES: Submit written or electronic comments on the draft guidance by June 3, 2005.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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 The draft guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709 or 301–827–1800.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

comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

Proposed Collection: Title: Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will obtain information on policies, programs, and practices for colorectal cancer screening among health plans in the U.S. The purpose of the study is to assess (1) health plan policies, programs, and practices for colorectal cancer screening; (2) health plan activities in response to the National Committee on Quality Assurance's new Health Employer Data Information Set measure for colorectal cancer screening; and (3) characteristics of health plans and plan policies and activities that may be associated with higher rates of colorectal cancer screening. A questionnaire will be administered by mail or Internet using a national sample of health plans. Study participants will be health plan medical directors or administrators, and they will select their preferred response mode. Burden estimates are as follows:

Type of respondents	Estimated number respondents	Estimated number responses per respondent	Average burden hours per response	Estimated total annual burden hours
Health plan medical directors	400	1	0.333	133

Request For Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Carrie N. Klabunde, Ph.D., Epidemiologist, National Cancer Institute, EPN 4005, 6130 Executive Boulevard, Bethesda, Maryland 20892–7344. Telephone: (301) 402–3362; e-mail: *ck97b@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: March 21, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 05–6603 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Outcome Evaluation of the Small Grants Program for Behavioral Research in Cancer Control

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the (National Cancer Institute), the National Institutes of Health 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 August 31, 2004, page 53079 and allowed 60 days for public comment. No public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Outcome Evaluation of the Small Grants Program for Behavioral Research in Cancer Control. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The Small Grants Program support projects that can be completed in a short period of time, such as pilot projects, development and testing of new methodologies, secondary data analyses, or innovative studies that provide a basis for more extended research. This evaluation is being conducted to identify progress of this program in establishing a cohort of scientists with a high level of research expertise in behavioral research cancer control. A primary objective of this study is to determine if the program's small grants R03 funding mechanism is effective in attracting investigators to the field of behavioral research and if so, what impact does the program have on the career of successful applicants. The findings will provide valuable information regarding (1) effectiveness of the program in attracting investigators to the field; (2) the impact of the program on investigators careers; and (3) the overall benefit provided by the program through the R03 funding mechanism and assist the agency in determining whether changes to the program are necessary in future. *Frequency of Response:* On occasion. *Affected Public:* Individuals; teaching institutions or other non-profit. *Type of Respondents:* Grantees funded under PAR 99–006 (n = 80). *Type of Respondents:* Principal Investigator awarded grants funded by PAR 00–006 (Dec. 1999–Nov. 2001); *Estimated Number of Respondents:* 80; *Estimated Number of Response Per Respondent:* 1; *Average Burden Hours Per Response:* 75; and *Estimated Total Annual Burden Hours Requested:* 60.