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Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.''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 Sponsors are encouraged to use this draft guidance to design cancer clinical trials and to discuss protocols with the agency. This draft guidance provides background information and discusses general regulatory principles.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DATES: Submit written or electronic comments on the draft guidance by June 3, 2005.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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 The draft guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research Voice Information System at 1–800–835–4709 or 301–827–1800.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