ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product.'' The guidance document provides guidance to applicants on the content and format of the chemistry, manufacturing and controls (CMC) and establishment description sections of the ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' (revised Form FDA 356h) for vaccines or related products. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 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 guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product.'' This guidance document is intended to provide guidance to applicants in completing the CMC section and the establishment description information of revised Form FDA 356h. The guidance announced in this notice supersedes the draft guidance entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product'' announced in the **Federal Register** of June 19, 1998 (63 FR 33686). In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of Form FDA 356h that will be used as a single harmonized application form for all drug and licensed biological products. Manufacturers may voluntarily begin using this form for vaccines or related products. FDA will announce in the future when manufacturers are required to use this form for all products. Use of the new harmonized Form FDA 356h will allow a biologic product manufacturer to submit one biologics license application instead of two separate applications (product license application and establishment license application).

This guidance document represents FDA's current thinking on the content and format of the CMC and establishment description sections of a license application for a vaccine or related product. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons, may at any time, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: December 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–30 Filed 1–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Physician Survey on Cancer Susceptibility Testing

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Physicians Survey on Inherited Cancer Susceptibility Testing. Type of Information Collection Request: New. Need and Use of Information Collection: The Physicians Survey on Inherited Cancer Susceptibility Testing will be used by the National Cancer Institute to establish baseline information on the prevalence of genetic testing for cancer susceptibility among primary care physicians in the United States. The survey will assess whether there are statistically significant differences in (1) self-reported knowledge, current use of, and future intentions to use genetic testing for cancer susceptibility, and (2) perceptions of barriers to testing, among primary care physicians by their type and location of practice, and recency of training. Primary care physicians (internists, pediatricians, family and general practitioners) will also be compared with specialty groups (gastroenterologists, surgeons, urologists and oncologists) with respect to their

use, attitudes toward, and knowledge of, genetic testing for cancer susceptibility. A questionnaire will be administered by mail, telephone, facsimile and Internet, using a nationally representative sample of physicians. The study physicians will select their preferred response mode. Frequency of Response: One-time study. Affected Public: Medical community. Type of Respondents: Primary care and specialty physicians with active licenses to practice medicine in the U.S. The annualized cost to respondents is estimated at $33,750. Burden estimates are presented here:

Questionnaire	Estimated # respondents	Estimated # responses/respondent	Average burden hours per response	Estimated total annual burden hours
Primary care physicians	1,096	1	0.250	274
Specialty physicians	254	1	0.250	64
Total	.....	.....	.....	338

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 proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Louise Wideroff or Andrew Freedman, Epidemiologists, National Cancer Institute, EPN 313, Executive Boulevard MSC 7334, Bethesda, Maryland 20892–7344, Telephone (301) 435–6823 or (301) 435–6819, FAX (301) 435–3710, or E-mail your request, including your address, to *wideroff@nih.gov* or Andrew__Freedman@nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before March 8, 1999.

Dated: December 29, 1998.

Reesa Nichols,

OMB Project Clearance Liaison.

[FR Doc. 99–108 Filed 1–4–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 662b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: January 4, 1999.
Time: 1:00 PM to 2:00 PM.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: David Monsees, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3199, MSC 7816, Bethesda, MD 20892, (301) 435–0684.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel ZRG1 HPD(4).
Date: January 5, 1999.
Time: 2:00 PM to 3:00 PM.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: David Monsees, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3199, MSC 7816, Bethesda, MD 20892, (301) 435–0684.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel ZRG1 HPD(4).
Date: January 5, 1999.
Time: 2:00 PM to 3:00 PM.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Richard Panniers, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, 7842, Bethesda, MD 20892, (301) 435–1741.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.
Date: January 6, 1999.
Time: 1:30 PM to 2:30 PM.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: David Monsees, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3199, MSC 7816, Bethesda, MD 20892, (301) 435–0684.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel ZRG1–MEP–04S.
Date: January 6, 1999.
Time: 2:00 PM to 4:00 PM.
Agenda: To review and evaluate grant applications.
Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).
Contact: Person Marcelina B. Powers, DVM, MS, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7804, Bethesda, MD 20892, (301) 435–1720.