purpose of cigarette warning labels is to alert consumers about the health hazards of smoking, research suggests that current U.S. warnings fail to get the attention of smokers, an important first step if warnings are to have any deterrent effect. Cigarette warning labels have not changed since 1984 in the United States.

The proposed study will be conducted through implementation of a web-based survey. We propose to administer a 10 minute survey to 2000 persons 18 to 24 years of age. The survey will include images of Canadian cigarette packs with their current warning labels and questions about reactions to these warnings, including acceptability, and perceived usefulness (perceived impact on starting to smoke or deciding to quit). The results of this study will be shared with policy makers and public health officials. The total burden for this data collection is 200 hours.

Respondents	Number of respondents	Responses/respondent	Avg. burden per Response (in hrs)
Persons 18–24 years old	1200	1	10/60

Dated: March 19, 2002.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–7275 Filed 3–26–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Preliminary Investigation of Health Effects of Occupational Exposures in Paducah Gaseous Diffusion Plant Workers, Program Announcement OH–99–143; Correction

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Centers for Disease Control and Prevention, published a document in the **Federal Register**, March 19, 2002, (67 FR 12570), concerning Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Preliminary Investigation of Health Effects of Occupational Exposures in Paducah Gaseous Diffusion Plant Workers, Program Announcement OH–99–143. The meeting time has changed.

CONTACT PERSON FOR MORE INFORMATION: Kathleen Goedel, National Institute for Occupational Safety and Health, CDC, 4676 Columbia Parkway, M/S R–6, Cincinnati, Ohio 45226, telephone 513–841–4560.

Correction: In the **Federal Register** of March 19, 2002, (Volume 67, Number 53) [Notices] Page 12570, correct the ''Times and Dates'' to read:

Times and Dates:

2 p.m.–2:15 p.m., April 2, 2002 (Open)

2:20 p.m.–4 p.m., April 2, 2002 (Closed)

The meeting place, status, and purpose, announced in the original notice remain unchanged.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 21, 2002.

Alvin Hall,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–7317 Filed 3–26–02; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0458]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by April 26, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review (OMB Control No. 0910–0389)—Extension

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506 (21 U.S.C. 356). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrates a potential to address an unmet medical need. Under section 112(b) of FDAMA, FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the act. The guidance discusses collections of information that are specified under section 506 of the act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving collections of information: (1) Fast track designation requests, (2) premeeting packages, and (3) requests to submit portions of an application. Of these, fast track designation requests and

premeeting packages, in support of receiving a fast track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the agency, may, in some cases, be incorporated into the request by referring to the information rather than resubmitting it.

Under section 506(a)(1) of the act, an applicant who seeks fast track designation is required to submit a request to the agency showing that the product meets the statutory standard for designation, i.e., that: (1) The product is intended for a serious or life-threatening condition; and (2) the product has the potential to address an unmet medical need. Mostly, the agency expects that information to support a designation request will have been gathered under existing provisions of the act, the PHS Act, or the implementing regulations. If such information has already been submitted to the agency, the information may be summarized in the fast track designation request. The guidance recommends that a designation request include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the agency makes a fast track designation, a sponsor or applicant may submit a premeeting package which may include additional information supporting a request to participate in certain fast track programs. As with the request for fast track designation, the agency expects that most sponsors or applicants will have gathered such information to meet existing requirements under the act, the PHS Act, or implementing regulations. These may include descriptions of clinical safety and efficacy trials not conducted under an investigational new drug application (IND) (i.e., foreign studies), and information to support a request for accelerated approval. The discussion of such information in a premeeting package may be summarized if it has already been previously submitted to FDA under an OMB approved collection of information. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

Under section 506(c) of the act, a sponsor must submit sufficient clinical data for the agency to determine, after preliminary evaluation, that a fast track product may be effective. Section 506(c) of the act also requires that an applicant provide a schedule for the submission of information necessary to make the application complete before FDA can commence its review. The guidance does not provide for any new collection of information regarding the submission of portions of an application that is not required under section 506(c) of the act or any other provision of the act. All forms referred to in the guidance have a current OMB approval: FDA Forms 1571 (OMB Control No. 0910–0014, expires September 30, 2002); 356h (OMB Control No. 0910–0338, expires March 31, 2003); and 3397 (OMB Control No. 0910–0297, expires February 29, 2004).

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the act. The agency estimates the total annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) will be approximately 45. To obtain this estimate, FDA averaged the number of requests for fast track designation received by CBER and CDER in the 3-year period of 1998 to 2000. For these 3 years, CBER and CDER together received a yearly average of 53 requests from 45 respondents. The rate of submissions is not expected to change significantly in the next few years. FDA estimates that the number of hours needed to prepare a request for fast track designation may range between 40 and 80 hours per request, depending on the complexity of each request, with an average of 60 hours per request, as indicated in table 1 of this document. Not all requests for fast track designation may meet the statutory standard. Of the average 53 requests made per year, the agency granted 33 requests for fast track designation. For each of the 33 granted requests, FDA estimates that a premeeting package was submitted to the agency. FDA estimates that a premeeting package needs more preparation time than needed for a designation request because the issues may be more complex and the data may need to be more developed. FDA estimates that the preparation hours may generally range between 80 and 120 hours, with an average of 100 hours per package, as indicated in table 1 of this document. The hour burden estimates contained in table 1 of this document are for information collections requests in the guidance only and do not include burden estimates for statutory requirements specifically mandated by the act, the PHS Act, or implementing regulations. FDA estimates the burden of this collection of information as follows:

In the **Federal Register** of October 23, 2001 (66 FR 53612), FDA published a 60-day notice requesting public comment on the information collection provisions (the October 2001 notice). One letter of comment was received in response to the 60-day notice on the information collection.

The comment declared, without any explanation or supporting information, that the proposed collection of information was unnecessary. The comment also attempted to reserve judgment as to whether our estimated information collection burden was accurate. The comment seemed to object to fast track drug development programs and stated in part that ''for our Congress to even think about letting it happen is playing games with the existing laws.''

FDA disagrees with the comment. Section 506 of the act requires sponsors to submit sufficient clinical data for FDA to determine, after preliminary evaluation, whether a fast track product may be effective. To obtain that clinical data as described in the guidance document, FDA must have an approved collection of information. Failure to obtain OMB approval for the proposed collection of information would undermine the guidance document's value (because FDA might not receive information that would help the review or receive unnecessary or confusing information) and ultimately undermine the efficiency of the review under a fast track drug development program.

Additionally, the October 2001 notice provided sufficient information and opportunity for public comment on the information collection burden estimates given in the notice. The comment received did not provide any figures or explanations that would cause us to change our burden estimates, so FDA has no reason to revise the collection burden estimates.

As for the comment's remarks regarding fast track drug development programs and Congress, such matters are outside the scope of this notice. We do, however, regard the statute as providing sufficient safeguards to

prevent unsafe or ineffective drugs from reaching the public.

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation request	45	1.18	53	60	3,180
Premeeting packages	33	1.00	33	100	3,300
Total					6,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 19, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–7375 Filed 3–26–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(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: National Cancer Institute Initial Review Group, Subcommittee C—Basic & Preclinical.

Date: April 24–26, 2002.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Holiday Inn, 2101 Wisconsin Ave., NW., Washington, DC 20007.

Contact Person: Michael B. Small, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8040, Bethesda, MD 20892, 301/402–0996.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 20, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–7266 Filed 3–26–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: May 9, 2002.

Open: 8:30 a.m. to 2 p.m.

Agenda: For discussion of program policies and issues.

Place: National Institutes of Health, Building 31, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Closed: 2 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Deborah P. Beebe, Director, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Two Rockledge Center, Room 7100, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435–0260, *beebed@nhlbi.nih.gov*.

Information is also available on the Institute's/Center's home page: www.nhlbi.nih.gov/meetings/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 20, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–7269 Filed 3–26–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 552b(c)(60), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with