

comments should be received within 60 days of this notice.

Proposed Project

Survey of Consumer Reaction to Canadian-style Warning Labels of Tobacco Products—NEW—The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC), proposes to conduct a national survey of young persons to assess their attitudes towards larger and

more graphic cigarette warning labels, such as those currently used in Canada. Although the 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. There are no costs to respondents.

Respondents	Number of respondents	Responses/respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
Persons 18–24 years old	2000	1	10/60	333
Total	333

Dated: October 12, 2001.

John Moore,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–02–03]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) 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. Send comments to Anne O’Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Perceptions of Tuberculosis Among Foreign Born Persons: Ethnographic Studies—New—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

The National Center for HIV, STD, and TB Prevention, CDC proposes to conduct an ethnographic study to assess the attitudes, beliefs, and practices of selected foreign born persons regarding tuberculosis (TB). The purpose of this two-year effort is to provide formative research findings to use when designing future surveys, planning interventions, and evaluating programs to improve TB screening and adherence to therapy among foreign born persons. This research will also identify program gaps in addressing the special needs of these populations. A review of published data and consensus among TB researchers suggest that elimination of TB in the United States will depend largely upon reducing the impact of the disease among the foreign born. Currently, almost half of all domestic TB cases occur among foreign-born persons, and this proportion is growing. Providing culturally appropriate and responsive services to people from a variety of ethnic and cultural backgrounds is a challenge for local TB control programs and has been identified as a priority area in TB elimination activities.

Recognizing this challenge, the CDC Working Group on Tuberculosis Among Foreign Born Persons in 1998 developed recommendations for increasing emphasis on prevention and control of TB in foreign-born populations. The recommendations highlighted the need to utilize operational and behavioral research to gain a better understanding of relevant barriers to diagnosis and care. While few studies have examined these issues with the goal of developing practical tools to enhance TB services, one research project, conducted in New York State among Vietnamese refugees, created a valid research method for assessing TB issues among this population. The project resulted in policy change that increased this group’s adherence to therapy.

The proposed study will build upon this research with Vietnamese refugees but will incorporate several cultural groups in four U.S. cities with a high burden of foreign-born TB patients. In depth ethnographic interviews will be conducted with 200 adults from the four ethnic/cultural groups, 50 per site. The information will be gathered by trained professional, multilingual/multi-cultural interviewers who will be rendered by the contracting agent. The data collection instrument will be comprised of semi-structured and open-ended questions intended to elicit a full range of responses concerning the participants’ cultural beliefs and attitudes toward TB. Interviews will last no longer than one hour. Analysis of data will be performed with Atlas.ti, a qualitative analysis computer program.

The ultimate project outcomes will include a cultural competency resource manual with profiles of TB beliefs and behaviors from the studied cultural groups. The manual will assist local and

state health departments in developing customized interventions tailored to the local context. Culturally appropriate interventions will increase tuberculin skin testing and patient adherence to treatment for active TB disease and

latent TB infection. In addition, the results can be used to develop targeted outreach, as well as customized communication protocols, patient education materials, incentives, and enablers. Finally, the study will produce

a valid interview instrument that TB clinics can adopt for their own assessments of TB beliefs and attitudes among the local communities they serve. There are no cost to respondents.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Foreign Born Persons (interviewed)	100	1	1	100
Total	100

Dated: October 11, 2001.

John Moore,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 28, 2001, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballrooms A and B, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kimberly Littleton Topper or Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or by e-mail at TopperK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss the implementation of the

pediatric rule with regard to study designs, ethical and developmental considerations, and extrapolation of findings from adult to pediatric cancer patients.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by November 16, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 16, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 28 and 29, 2001, from 8:30 a.m. to 5:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact: Nancy Chamberlin, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1076), Rockville, MD 20857, 301-827-7001, e-mail: CHAMBERLINN@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 28, 2001, the committee will: (1) Discuss the current status of, and future plans for, the FDA draft guidance entitled "ANDAs: Blend Uniformity Analysis;" (2) discuss and provide direction for the Process Analytical Technology Subcommittee; (3) discuss and provide comments on stability testing and shelf life; and (4) receive updates from subcommittees and on other Center for Drug Evaluation and Research guidance documents. On November 29, 2001, the committee will: (1) Receive updates on FDA research in dermatopharmacokinetics, and (2) discuss and provide comments on bioequivalence issues.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 15, 2001. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on November 28, 2001, and between approximately 11 a.m. and 12 noon on November 29,