

(4) Increasing knowledge and understanding of health risk factors.

(5) Developing mechanisms that support better information dissemination, education, prevention, and service delivery to individuals from disadvantaged backgrounds, including individuals who are members of racial and ethnic minority groups.

(6) Ensuring that the National Center for Health Statistics, Centers for Disease Control and Prevention, collects data on the health status of each minority group.

(7) With respect to individuals who lack proficiency in speaking the English language, entering into contracts with public and nonprofit private providers of primary health services for the purpose of increasing the access of individuals to such services by developing and carrying out programs to provide bilingual or interpretive services.

(8) Supporting a national minority health resource center to carry out the following:

(A) Facilitate the exchange of information regarding matters relating to health information and health promotion, preventive health services, and education in the appropriate use of health care;

(B) Facilitate access to information;

(C) Assist in the analysis of issues and problems relating to such matters;

(D) Provide technical assistance with respect to the exchange of such information (including facilitating the development of materials of such technical assistance).

(9) Carrying out programs to improve access to health care services for individuals with limited proficiency in speaking the English language. Activities under the preceding sentence shall include developing and evaluating model projects.

II. Nominations

The Office of Minority Health (OMH) is requesting nominations for voting members to serve on the Advisory Committee. The Committee is to consist of 12 voting members appointed by the Secretary from among racial and ethnic minorities, defined as Black or African American, Hispanic/Latino, American Indian/Alaska Native, Asian American, and Native Hawaiian or Pacific Islander, who have expertise regarding issues of minority health. The racial and ethnic minority groups will be equally represented among the voting members. The membership will also be diverse in terms of gender, HIV status, disability, age, culture, sexual orientation, geography, and points of view. Employees or officers of the Federal Government may not serve as voting

members, except that the Secretary may appoint employees of the DHHS to serve as ex-officio, non-voting members.

OMH is seeking nominations of persons from a wide-array of fields including but not limited to: public health and medicine, health administration and financing, behavioral and social sciences, immigration and rural health, health law and economics, cultural and linguistic competency, and biomedical ethics and human rights. Demonstrated expertise in minority health, in subject areas such as access to care, data collection and analysis, health professions development, cultural competency, and eliminating disparities in cancer, cardiovascular diseases, infant mortality, HIV infection/AIDS, child and adult immunization, diabetes, substance abuse, homicide, suicide, unintentional injuries, and other diseases and health conditions is also required.

Nominations must state that the nominee is willing to serve as a member of the Advisory Committee and appears to have no conflict of interest that would preclude membership. Candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Members are appointed for a term of four years except that the Secretary shall initially appoint a portion of members to one, two, and three year terms. The Chair, selected by the Secretary from among the voting members of the Committee, will serve a term of two years. Committee members will be compensated for the time spent in Committee meetings (including travel time) as well as per diem costs.

Any interested person may nominate one or more qualified persons. Self-nominations will also be accepted.

Nomination forms may be obtained from the Office of Minority Health Resource Center, P.O. Box 37337, Washington, D.C. 20013-7337, telephone 1-800-444-6472, TDD 301-230-7199, e-mail: info@omhrc.gov. Nomination forms may also be downloaded from the Office of Minority Health Resource Center web site, <http://www.omhrc.gov>. All nominations and curricula vitae for the Advisory Committee should be set to Monica Farrar at the address in this notice.

Dated: January 27, 2000.

Nathan Stinson, Jr.,
Deputy Assistant Secretary for Minority Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-00-22]

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 for other forms of information technology. Send comments to Seleda Perryman, CDC Assistance Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Implementation of data collection described in Evaluation Guidance for CDC Funded Health Department HIV Prevention Programs To Be Implemented From 2000 to 2003—New—The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention (NCHSTP) proposes a collection of standardized HIV evaluation data from health department grantees to ensure delivery of the best possible HIV prevention services. The CDC needs standardized evaluation data from

health department grantees for the following reasons: (1) To determine the extent to which HIV prevention efforts have contributed to a reduction in HIV transmission, (2) to improve programs to better meet that goal (3) to help focus technical assistance and support and (4) to be accountable to stakeholders by informing them of progress made in HIV prevention nationwide.

CDC formed evaluation workgroups and panels consisting of expert evaluation consultants, health department representatives, representatives of the National Alliance of State and Territorial AIDS Directors, and CDC staff in order to assess and summarize existing health department evaluation data collections. An extensive review of published and unpublished evaluation data led to the conclusion that even though there is information suggesting a very large number of Americans who receive HIV prevention services, but there were no standardized and scientifically valid evaluation data on HIV prevention services. Based on these findings, the workgroups and panels have concluded that there is a need to monitor intervention plans, implementation, and outcomes on the national, state, and local levels for public health management purposes.

CDC and its prevention partners have specifically identified the types of standardized evaluation data they need

to be accountable for the use of federal funds and to conduct systematic analysis of HIV prevention to improve policies and programs. Generally, evaluation data that are needed (but not yet available at the national level) include the types and quality of HIV prevention interventions provided by CDC health department grantees and their grantees, the characteristics of clients targeted and reached by the interventions, and the effects of interventions on client behavior and HIV transmission.

In 1998, the 5-year Cooperative Agreement with state and territorial health departments in CDC Program Announcement 99004 HIV Prevention Projects specified health department evaluation activities and referenced the proposed data collection. The announcement states that the Evaluation Guidance is designed to assist grantees in implementing evaluation activities listed in announcement 99004. Below is a listing of these evaluation activities. In addition, the proposed evaluation data collection forms are sub-categorized under each 99004 evaluation activity.

- (1) Evaluating HIV Prevention Community Planning
 - CPG Membership Survey
 - Table of Estimated Expenditures Form
- (2) Designing and Evaluating Intervention Plans
 - Aggregate Intervention Plan Data Collection Form for the following types of interventions:

- Individual-Level
- Group-Level
- Outreach
- Prevention Case Management
- Partner Counseling and Referral Services Health Communication/ Public Information Other Interventions

(3) Monitoring and Evaluating the Implementation of HIV Prevention Programs

—Aggregate Process Evaluation Data Collection Form for the following types of intervention:

- Individual-Level
- Group-Level
- Outreach
- Prevention Case Management
- Partner Counseling and Referral Services Health Communication/ Public Information Other Interventions

(4) Evaluating Linkages between the Comprehensive HIV Prevention Plan, CDC funding application and resource allocation

- Data Collection Form for Linkages between the CDC funding application and the Comprehensive HIV Prevention Plan
- Data Collection Form for Linkages between Resource Allocation and the Comprehensive HIV Prevention Plan

Ten health departments pilot tested the instruments. The following table was developed from that experience.

| Respondents | Number of respondents | Number of responses/respondent | Average burden per response (in hours) | Total burden (in hours) |
|----------------------------------|-----------------------|--|--|-------------------------|
| Health department grantees. | 390 | 18 (total number of data collection forms). | 1.0 | 7020 |
| Total | | | | 7020 |

The CDC anticipates 2 persons per health department jurisdiction (total # of jurisdictions = 65) to prepare and submit Evaluation Guidance data collection forms annually for the next 3 years (65 × 2 = 130 respondents; 130 × 3 years = 390 total respondents.) Therefore, the total response burden is estimated at 7020 hours (309 × 18 forms.) The total cost to respondents is estimated at \$140,400 assuming a working wage for assigned health department personnel of \$20.00 over the 3-year period.

Dated: January 28, 2000.
Nancy Cheal,
Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0236]

Guidance for Industry on Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry

entitled “Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products.” This guidance provides assistance to sponsors of abbreviated new drug applications (ANDA’s) by recommending study designs and scoring systems that can be used to test skin irritation and sensitization during development of transdermal products. Skin irritation and sensitization should be assessed because the condition of the skin may affect the absorption of a drug from a transdermal system, thus affecting the efficacy or safety of the product. This guidance does not address the actual bioequivalence studies