

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 An extensive review of published and unpublished evaluation data led to the conclusion that even though there is information suggesting a very large number of Americans who receive HIV prevention services,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 ( $65 \times 2 = 130$  respondents;  $130 \times 3$  years = 390 total respondents.) Therefore, the total response burden is estimated at 7020 hours ( $309 \times 18$  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

necessary for a particular transdermal product.

**DATES:** Submit written comments on agency guidances at any time.

**ADDRESSES:** Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Mary M. Fanning, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5845.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a guidance for industry entitled "Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products." Transdermal products have properties that may lead to skin irritation and/or sensitization. The delivery system, or the system in conjunction with the drug substance, may cause these reactions. Skin irritation and skin sensitization studies are designed to detect irritation and sensitization under conditions of maximal stress and may be used during the assessment of transdermal drug product for ANDA's.

A draft guidance entitled "Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products" was published in the **Federal Register** of February 26, 1999 (64 FR 9516). Eight comments were received between February and April of 1999, and this guidance has been revised after careful consideration of those comments.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on skin irritation and sensitization testing of generic transdermal drug products. 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, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management

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

Dated: January 24, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-R-1500]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Health Insurance Common Claims Forms and Supporting Regulations in 42 CFR 414.40, 424.32, and 424.44; *Form No.:* HCFA-1500, 1490U, and 1490S (OMB # 0938-0008); *Use:* This form is a standardized form for use in the Medicare/Medicaid programs to apply for reimbursement for covered services; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-

for-profit institutions; *Number of Respondents:* 1, 321, 417; *Total Annual Responses:* 717,876,097; *Total Annual Hours:* 44,460,460.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 24, 2000.

**John P. Burke,**

*Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-1957]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of