

cdcr/guidance/index.htm". Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Mary 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**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled "Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products."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 skin reactions. In the development of transdermal products, dermatologic adverse events are evaluated primarily with animal studies and safety evaluations in the context of large clinical trials generally associated with the submission of new drug applications. Separate skin irritation and skin sensitization studies also are used for this purpose. These later studies are designed to detect irritation and sensitization under conditions of maximal stress. These studies may be used during the assessment of transdermal drug products for ANDA's.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It 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 statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above).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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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: February 19, 1999.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

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

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Comments are invited on: (a) Whether the proposed collections of information are 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.

Proposed Project: Persistent Effect of Treatment in Cuyahoga County, Ohio—New—The Center for Substance Abuse Treatment (CSAT) is undertaking a major initiative to study the long-term course of substance abuse within the context of receipt of substance abuse treatment. It has often been observed that success in treating substance abuse may require multiple episodes of treatment. The Persistent Effects of Treatment Studies (PETS) will be a family of studies structured to provide data on a wide range of populations and treatment approaches over a three-year period following admission to a substance abuse treatment program in a community setting. The family of studies will be built on existing studies currently being conducted by other organizations (including Federal, State, and local governments) in order to minimize costs and response burden. Collectively, the PETS studies are expected to provide valuable insights into the factors that lead to long-term success in treatment of substance abuse.

Persistent Effects of Treatment in Cuyahoga County, Ohio, is the first of these studies. Under the aegis of an existing, CSAT-funded, Target Cities cooperative agreement, the county has built a strong substance abuse treatment information capability including standardized client intake assessment using the computerized Central Intake Assessment Instrument (CIAI-C), sound and comprehensive treatment information systems, and ongoing client follow-up at 6- and 12-months after treatment. This proposed project will build upon this foundation by conducting additional interviews at 24, 30, and 36 months after treatment admission using the computerized CIAI-C Followup version. At month 36, additional information needed to construct a natural history of substance use, treatment, criminal justice involvement, and employment for each subject over the previous 4-year period will be collected.

The estimated response burden over the three-year period of approval is summarized below.

	Number of respondents	Number of responses/respondent	Average burden/response (hours)	Total burden (hours)
CIAI-C Followup Interview .....	1,297	3	1.5	5,837
Natural History Interview .....	1,038	1	1.0	1,038
Total .....				6,875

**Note:** The annualized burden for this project is expected to be 2,292 hours over the three-year period of approval.

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 19, 1999.

**Richard Kopanda,**

*Executive Officer, Substance Abuse and Mental Health Services Administration.*

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BILLING CODE 4162-20-P

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4442-N-06]

**Notice of Proposed Information Collection for Public Comment**

**AGENCY:** Office of the Assistant Secretary for Policy Development and Research, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** Comments are due April 27, 1999.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: the Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW, Room 8226, Washington, DC 20410.

**FOR FURTHER INFORMATION CONTACT:** Ronald J. Sepanik, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW, Washington. Telephone (202)-708-1060, Ext. 5887 (this is not a toll-free number), or Jane Kneessi, Bureau of the Census, HHES Division, Washington, DC 20233, (301)-457-3235 (this is not a toll-free number). Copies of the proposed forms and other available documents to be submitted to OMB may be obtained from Mr. Sepanik or Ms. Kneessi.

**SUPPLEMENTARY INFORMATION:** The Department will submit the proposed information collection to OMB for review, as required by the Paperwork

Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

*Title of Proposal:* 1999 American Housing Survey—National Survey.

*OMB Control Number:* 2528-0017.

*Description of the need for the information and proposed use:* The 1999 American Housing Survey—National Sample (AHS-N) provides a periodic measure of the size and composition of the housing inventory in our country. Title 12, United States Code, Sections 1701Z-1, 1701Z-2(g), and 1701Z-10a mandate the collection of this information.

The 1999 survey is similar to previous AHS-N surveys and collects data on subjects such as the amount and types of housing in the inventory, the physical condition of the inventory, the characteristics of the occupants, the persons eligible for and beneficiaries of assisted housing by race and ethnicity, and the number and characteristics of vacancies.

Policy analysts, program managers, budget analysts, and Congressional staff use AHS data to advise executive and legislative branches about housing conditions and the suitability of policy initiatives. Academic researchers and private organizations also use AHS data in efforts of specific interest and concern to their respective communities.

The Department of Housing and Urban Development (HUD) needs the AHS data for two important uses.

1. With these data, policy analysts can monitor the interaction among housing needs, demand and supply, as well as changes in housing conditions and costs, to aid in the development of housing policies and the design of housing programs appropriate for

different target groups, such as first-time home buyers and the elderly.

2. With these data, HUD can evaluate, monitor, and design HUD programs to improve efficiency and effectiveness.

*Agency Form Numbers:* Computerized Versions of AHS-22 and AHS-23.

*Members of affected public:* Households.

*Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:*

*Number of respondents:* 61,000.

*Estimated responses per respondent:*

1 every two years.

*Time per respondent:* 34 minutes.

*Total hours to respond:* 34,567.

*Status of the proposed information collection:* Pending OMB approval.

**Authority:** Title 13 U.S.C. Section 9(a), and Title 12, U.S.C., Section 1701z-1 *et seq.*

Dated: February 18, 1999.

**Lawrence L. Thompson,**

*General Deputy Assistant Secretary for Policy Development and Research.*

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4445-N-03]

**Submission for OMB Review: Comment Request**

**AGENCY:** Office of the Assistant Secretary for Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone (202) 708-3055 (this is not a toll-free number). Copies of this proposed forms and other