

variable drugs is expected to occur rarely. In these instances, FDA believes that all relevant statistical issues have been sufficiently resolved and that no important public health risk will arise if the criterion is used to allow market access.

This guidance replaces the following guidances: (1) "Guidelines for the Evaluation of Controlled Release Drug Products" (April 1984); (2) "Oral Extended (Controlled) Release Dosage Form: In Vivo Bioequivalence and In Vitro Dissolution Testing" (September 1993); (3) "Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design" (July 1992); (4) the preliminary draft guidance on "In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches" (October 1997), and (5) the draft guidance on "BA and BE Studies for Orally Administered Drug Products—General Considerations." This guidance supersedes any prior guidance, or any relevant part of a prior guidance issued to assist sponsors in meeting the requirements in part 320.

This level 1 guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). This guidance document represents the agency's current thinking on BA and BE studies for orally administered 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 an approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may 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: October 19, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4561-N-67]

Notice of Submission of Proposed Information Collection to OMB; Uniform Physical Standards and Physical Inspection Requirements for Certain HUD Housing, Administrative Process for Assessment of Insured and Assisted Properties

AGENCY: Office of the Chief Information Officer, 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.

DATES: *Comments Due Date:* November 27, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0369) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed

forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Uniform Physical Standards and Physical Inspection Requirements for Certain HUD Housing, Administrative Process for Assessment of Insured and Assisted Properties.

OMB Approval Number: 2502-0369.

Form Numbers: None.

Description of the Need for the Information and its Proposed Use: The uniform physical condition standards are intended to ensure that HUD program participants carry out their legal obligations to maintain HUD properties in a condition that is decent, safe, sanitary, and in good repairs.

Respondents: Business or Other For-Profit.

Frequency of Submission: Annually.
Reporting Burden:

| Number of respondents | × | Frequency of response | × | Hours per response | = | Burden hours |
|-----------------------|---|-----------------------|---|--------------------|---|--------------|
| 7,100 | | 1 | | 9 | | 153,900 |

Total Estimated Burden Hours: 153,900.
Status: Reinstatement, with change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: October 20, 2000.

Wayne Eddins,
*Departmental Reports Management Officer,
 Office of the Chief Information Officer.*
 [FR Doc. 00-27608 Filed 10-26-00; 8:45 am]
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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4561-N-68]

Notice of Submission of Proposed Information Collection to OMB; 2000 Survey of Homeless Residential Service Providers

AGENCY: Office of the Chief Information Officer, 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.

DATES: Comments Due Date: November 27, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the

information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: 2000 Survey of Homeless Residential Service Providers.

OMB Approval Number: 2502-XXXX.

Form Numbers: None.

Description of the Need for the Information and its Proposed Use: The 2000 Survey of Homeless Residential Service Providers will provide information about the current operation of programs assisting homeless persons in 16 jurisdictions in order to improve HUD's ability to assess the success of homeless service programs and grantees

Frequency of Submission: One-time.
Reporting Burden:

| | Number of respondents | × | Frequency of response | × | Hours per response | = | |
|-------------------------------|-----------------------|---|-----------------------|---|--------------------|---|-----|
| <i>Reporting Burden</i> | 900 | | 1 | | 1 | | 900 |

Total Estimated Burden Hours: 900.
Status: New.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: October 20, 2000.

Wayne Eddins,
*Departmental Reports Management Officer,
 Office of the Chief Information Officer.*
 [FR Doc. 00-27609 Filed 10-26-00; 8:45 am]
BILLING CODE 4210-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4561-N-69]

Notice of Submission of Proposed Information Collection to OMB; Multifamily Default Status

AGENCY: Office of the Chief Information Officer, 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.

DATES: Comments Due Date: November 27, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502-0041) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov;

telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of