(mg/mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for diazepam for injection 5 mg/mL.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Borgerding, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Diazepam Autoinjector is the subject of NDA 20–124. Diazepam Autoinjector is an automatic injection drug product indicated for the management of anxiety disorders and the treatment of epileptic and other convulsive seizures. FDA approved NDA 20–124, held by the U.S. Army (Army), on December 5, 1990. The Diazepam Autoinjector is manufactured for the Army by Meridian Medical Technologies, Inc. (MMT), and has always been listed in the ''Discontinued Drug Product List'' of the Orange Book because it is not commercially available.

On November 30, 2001, MMT submitted a citizen petition (Docket No. 01P–0542/CP1) under 21 CFR 10.30 requesting that the agency determine whether Diazepam Autoinjector was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Diazepam Autoinjector was not withdrawn from sale for reasons of safety or effectiveness. The Army has never commercially marketed Diazepam Autoinjector. In previous instances (see, e.g., 61 FR 25497, May 21, 1996 (addressing a relisting request for glyburide tablets)), FDA has concluded that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. There is no indication that the Army's decision not to market Diazepam Autoinjector commercially is a function of safety or effectiveness concerns, and the petitioner has identified no data or other information suggesting that Diazepam Autoinjector poses a safety risk. FDA's independent evaluation of relevant information has uncovered nothing that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA has determined that, for the reasons outlined previously, Diazepam Autoinjector was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list Diazepam Autoinjector (diazepam for injection) 5 mg/mL in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to Diazepam Autoinjector (diazepam for injection) 5 mg/mL may be approved by the agency.

Dated: December 19, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–32851 Filed 12–27–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4739–N–50]

Notice of Proposed Information Collection: Comment Request; Home Mortgage Disclosure Act (HMDA) Loan/Application Register

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, 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 Due Date:* February 28, 2003.

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: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8003, Washington, DC 20410 or *Wayne_Eddins@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Judith V. May, Director, Office of Evaluation, Office of Finance and Budget, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 755–7500 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting 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 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 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: Home Mortgage Disclosure Act (HMDA) Loan/Application Register.

OMB Control Number, if applicable: 2502–0539.

Description of the need for the information and proposed use: The HMDA Loan/Application Register collects information from mortgage lenders on application for, and originations and purchases of, mortgage and home improvement loans. Non-depository mortgage lending institutions are required to use the information generated as a running log throughout the calendar year, and send the information to HUD by March 1 of the following calendar year.

Agency form numbers, if applicable: FR HMDA–LAR.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated total number of hours needed to prepare the information collection is 177,777; the number of respondents is 1,800 generating approximately 1,800 annual responses; the frequency of response is on occasion and annually; and the estimated time needed to prepare the response varies from 10 hours to 15,000 hours with an average of 98.75 hours.

Status of the proposed information collection: Extension of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: December 20, 2002.

John C. Weicher,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 02–32833 Filed 12–27–02; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4739–N–51]

Notice of Proposed Information Collection: Comment Request; Request for Acceptance of Changes in Approved Drawings and Specifications

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, 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 Due Date:* February 28, 2003.

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: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, L'Enfant Plaza Building, Room 8003, Washington, DC 20410 or *Wayne_Eddins@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Vance T. Morris, Director, Office of Single Family Program Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–2121 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting 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 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 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: Request for Acceptance of Changes in Approved Drawings and specifications.

OMB Control Number, if applicable: 2502–0117.

Description of the need for the information and proposed use: Builders who request changes to HUD's accepted drawings and specifications for proposed construction properties as required by homebuyers, or determined by the builder use the information collection. The lender reviews the changes and amends the approved exhibits. These changes may affect the value shown on the HUD commitment. HUD requires the builder to use form HUD–92577 to request changes for proposed construction properties. HUD's collection of this information is for the purpose of ascertaining that HUD does not insure a mortgage on property that poses a risk to health or safety of the occupant.

Agency form numbers, if applicable: HUD–92577.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated total number of hours needed to prepare the information collection is 5,000; the number of respondents is 10,000 generating approximately 10,000 annual responses; the frequency of response is on occasion; and the estimated time needed to prepare the response is 30 minutes.

Status of the proposed information collection: Reinstatement, without change, of a previously approved collection for which approval has expired.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: December 20, 2002.

John C. Weicher,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 02–32834 Filed 12–27–02; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4734–N–74]

Notice of Submission of Proposed Information Collection to OMB: Hispanic-Serving Institutions Assisting Communities

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:* January 29, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding