

Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* Charles P.

Hoiberg, Center for Drug Evaluation and Research (HFD-800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5918; or Christopher C. Joneckis, Center for Biologics Evaluation and Research (HFM-20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0833.

*Regarding the ICH:* Janet J. Showalter, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug

Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In October 2001, FDA made available the ICH guidance M4 CTD, which describes a harmonized format for new product applications (including applications for biotechnology-derived products) for submission to the regulatory authorities in the three ICH regions. The M4 CTD guidance was made available in four parts as follows: (1) A description of the organization of the M4 CTD; (2) the Quality section; (3) the Safety, or nonclinical, section; and (4) the Efficacy, or clinical, section.

In September 2002, the ICH Steering Committee agreed that a draft guidance entitled "Common Technical Document—Quality: Questions and Answers/Location Issues" should be made available for public comment. The draft guidance is the product of the CTD-Quality Implementation Working Group of the ICH. Comments about this draft will be considered by FDA and the CTD-Quality Implementation Working Group.

The draft guidance provides further clarification for preparing the quality components of an application in the CTD-Quality format. The draft guidance addresses the relationship between linked sections for certain parameters, such as polymorphism and particle size.

The draft guidance also addresses location issues by indicating the section in which to place requested information. The draft guidance is intended to ease the preparation of paper and electronic submissions, facilitate regulatory reviews, and simplify the exchange of regulatory information among regulatory authorities.

This draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 and regulations.

**II. Comments**

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any mailed 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: December 23, 2002.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01P-0542]

**Determination That Diazepam Autoinjector Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that Diazepam Autoinjector (diazepam for injection) 5 milligrams per milliliter

(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.*

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## 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](mailto: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