Dated: December 19, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–32850 Filed 12–27–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0282]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of Participation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by January 29, 2003.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Notice of Participation (OMB Control Number 0910–0191)—Extension

The regulations in § 12.45 (21 CFR 12.45), issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. Section 12.45 also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or in the case of a hearing before a Public Board of Inquiry (21 CFR 13.25), concerning disclosure of data and information by participants. In accordance with § 12.45(e), the presiding officer may omit a participant's appearance. The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation. The respondents are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit groups and institutions.

In the **Federal Register** of July 18, 2002 (67 FR 47387), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	340	1	340	3	1,020

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The agency bases this estimate on past notices filed in which each notice of participation took an estimated 3 hours to complete.

Dated: December 20, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–32849 Filed 12–27–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0509]

International Conference on Harmonisation; Draft Guidance on the M4 Common Technical Document—Quality: Questions and Answers/ Location Issues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Common Technical Document—Quality: Questions and Answers/ Location Issues.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In the **Federal Register** of October 16, 2001 (66 FR 52634), FDA announced the availability of an ICH guidance entitled ''M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use'' (M4 CTD). This draft guidance provides further clarification for preparing the quality components of an application file in the CTD format (M4Q: The CTD-Quality). The draft guidance addresses: (1) The relationship between linked sections for certain parameters (such as polymorphism and particle size), and (2) 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.

DATES: Submit written or electronic comments on the draft guidance by February 28, 2003.

ADDRESSES: 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 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug

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.

[FR Doc. 02–32852 Filed 12–27–02; 8:45 am]

BILLING CODE 4160–01–S

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