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]

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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