

**The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities—(OMB Control Number 0910-0494)—Extension**

Due to a terrorist event during the fall of 2001, approximately 1,200 decontamination workers were placed on long-term antibiotic therapy to protect them from environmental anthrax spores. Through the services of a contractor the FDA is currently administering a survey to all 1,200 decontamination workers to collect important health information pertaining to long term use of antibiotics. This information is critical to the agency's mission in protecting the public health and failure of the FDA to adequately follow up on these workers will reduce the agency's ability to apply lessons learned from the current situation to provide guidance during future public health emergencies should they occur. This could result, not only, in the loss of time and dollars but also in the loss of life if patients stop taking their medicines because they think the drug

therapy is responsible for a health problem when in fact it is not. This type of population is likely to never be available for assessment again until a future terrorist event occurs. It would be unacceptable for FDA not to obtain drug experience information from this group to assist in any future public health response to a terrorist attack.

FDA is requesting an extension of the OMB approval of a survey to help FDA's Center for Drug Evaluation and Research evaluate the long-term antibiotic drug therapy in persons involved in anthrax remediation activities. The reason for the extension is to allow for more time to complete the survey, which has been delayed for two reasons. The first reason relates to the delays in cleaning up some of the contaminated sites. Primarily the cleanup of the Brentwood Post Office in Washington, DC, which accounts for approximately 400 of the decontamination workers, was delayed. The clean up at Brentwood is almost complete and it is anticipated that final medical examinations of the Brentwood cleanup workers can begin in earnest in

the February/March 2003 timeframe. Once the final medical examination is completed then Market Facts, the contractor hired to conduct the survey, can begin to administer the questionnaire to these workers. The second reason is the result of having to obtain authorization from approximately 35 subcontractor firms (who employed the decontamination workers) to release contact information on the remediation workers. To date, only contact information for approximately 300 workers has been released and further efforts are on going to obtain permission to release the remaining information. The medical service subcontractor is working diligently to obtain the necessary authorizations.

In the **Federal Register** of January 17, 2003 (68 FR 2561), the agency requested comments on the proposed collections of information. The agency received no comments to the notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Type of Survey	No. of Respondents	Annual Frequency/Response	Total Annual Responses	Hours per Response	Total Hours
Telephone	1,200	1	1,200	.25	300
<b>Total</b>					<b>300</b>

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated annual reporting burden is based on the Centers for Disease Control and Prevention's administration, in 2001 and 2002, of a similar questionnaire to individuals who were exposed to anthrax spores dispersed during a terrorist event.

Dated: March 26, 2003.

**William K. Hubbard,**  
Associate Commissioner for Policy and Planning.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01D-0435]

**International Conference on Harmonisation; Guidance on Electronic Common Technical Document Specification; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "M2 eCTD: Electronic Common Technical Document Specification." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle management, and archiving of the electronic submission. The guidance is intended to assist industry in transferring electronically their marketing applications for human drug and biological products to a regulatory authority.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the 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 (HFMA-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. Submit written comments on the 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>. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**  
*Regarding the guidance:* Robert Yetter, Center for Biologics Evaluation and

Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373, or Timothy M. Mahoney, Center for Drug Evaluation and Research (HFD-73), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3540.

*Regarding the ICH:* Janet Showalter, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0865.

#### 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 is 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 the **Federal Register** of June 14, 2002 (67 FR 40948), FDA announced the availability of a second draft guidance entitled "Electronic Common Technical Document Specification." The notice gave interested persons an opportunity to submit comments by August 1, 2002.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in September 2002.

The eCTD guidance describes the recommended method for industry-to-agency electronic transfer of marketing applications for human drug and biological products. The guidance defines the means for industry-to-agency transfer of regulatory information that will facilitate the creation, review, life cycle management, and archiving of the electronic submission. The guidance is intended to assist industry in transferring their marketing applications for human drug and biological products to a regulatory authority. The guidance includes the following changes:

- The Document Type Definition (DTD) and specification version numbers were harmonized to 3.0.
- Throughout the guidance, references to Common Technical Document (CTD) sections were updated to reflect the current CTD specifications.
- Path names in Appendix 4 were abbreviated to avoid exceeding maximum path character limits.
- The Glossary of Terms was updated.
- Technical errors discovered during testing were corrected.

This guidance represents 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 guidance at any time. 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 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: March 25, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 02E-0150]

##### Determination of Regulatory Review Period for Purposes of Patent Extension; GYNECARE INTERGEL

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for GYNECARE INTERGEL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

**ADDRESSES:** Submit written comments and petitions 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>.

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3460.