

**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
Total					300

<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 (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. 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