ELECTRONIC ELEMENTS FOR SF 88—Continued

Item	Placement*
28t. Audiometer—Right Ear—2000–2048	
28t. Audiometer—Right Ear—3000–3096	
28t. Audiometer—Right Ear—4000–4096	
28t. Audiometer—Right Ear—6000–6144	
28t. Audiometer—Left Ear—500–512	
28t. Audiometer—Left Ear—100–1024	
28t. Audiometer—Left Ear—2000–2048	
28t. Audiometer—Left Ear—3000–3096	
28t. Audiometer—Left Ear—4000–4096	
28t. Audiometer—Left Ear—6000–6144	
28u. Psychological and Psychomotor (Tests used and score)	
29. Notes (Continued) and Significant or Interval History	
30. Summary of Defects and Diagnoses (List diagnoses with item numbers)	
31. Recommendations—Further Specialist Examinations Indicated (Specify)	
32. Physical Profile—P	
32. Physical Profile—U	
32. Physical Profile—L	
32. Physical Profile—H	
32. Physical Profile—E	
32. Physical Profile—S	
33. Examinee—Is Qualified for (Checkbox)	
33. Examinee—Is Qualified for Explanation	
33. Examinee—Is Not Qualified for (Checkbox)	
33. Examinee—Is Not Qualified for Explanation	
34. Physical Category—A	
34. Physical Category—B	
34. Physical Category—C	
34. Physical Category—E	
35. If Not Qualified, List Disqualifying Defects by Item Number	
36. Typed or Printed Name of Physician	
36. Signature of Physician	
37. Typed or Printed Name of Physician	
37. Signature of Physician	
38. Typed or Printed Name of Dentist or Physician (Indicate which)	
38. Signature of Dentist or Physician	
39. Typed or Printed Name of Reviewing Officer or Approving Authority	
39. Signature of Reviewing Officer or Approving Authority	

*If no specific placement, data element may be in any order.

FOR FURTHER INFORMATION CONTACT: CDR Katherine Ciacco Palatianos, Indian Health Service, Department of Health and Human Services, Rockville, MD 20857 or e-mail at *kciacco@hqe.ihs.gov.*

Dated: March 21, 2003.

Katherine Ciacco Palatianos,

Chairperson, Interagency Committee on Medical Records.

[FR Doc. 03–7927 Filed 4–1–03; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0354]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities

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: Fax written comments on the information collection provisions by May 2, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to *sshapiro@omb.eop.gov* or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

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[1]

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

[1]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.

[FR Doc. 03–7821 Filed 4–1–03; 8:45 am]

BILLING CODE 4160–01–S

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