ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees at the Oak Ridge Institute for Nuclear Studies, Oak Ridge, Tennessee, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Oak Ridge Institute for Nuclear Studies.

Location: Oak Ridge, Tennessee.

Job Titles and/or Job Duties: All medical division employees.

Period of Employment: June 1, 1950 through June 25, 1956.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV.*

Dated: October 31, 2005.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 05–22030 Filed 11–3–05; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0422]

Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Shortages Data Collection System (Formerly the Emergency Medical Device Shortage Program Survey)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Emergency Shortages Data Collection System (formerly the Emergency Medical Device Shortage Program Survey).

DATES: Submit written or electronic comments on the collection of information by January 3, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Emergency Shortages Data Collection System (Formerly the Emergency Medical Device Shortage Program Survey)—21 CFR Part 20 (OMB Number 0910–0491)—Extension

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)), the FDA Commissioner is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. Section 510 of the act (21 U.S.C. 360) requires that domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution register their establishments and list the devices they manufacture with the FDA. Section 522 of the act (21 U.S.C. 360(l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process.

Subsequent to the events of September 11, 2001, FDA's Center for Devices and Radiological Health (CDRH) began planning for handling medical device shortage issues associated with counter-terrorism. One of the activities related to the planning was that CDRH would establish a data collection system as a supplemental source for available product. Because of events on September 11, 2001, local and State governments have obtained stockpiles of backup supplies within their jurisdiction to cover an emergency for the first 12 hours following a terrorist attack. The second 12 hours will have additional medical devices supplied by the Centers for Disease Control's Strategic National Stockpile and the National Acquisition Center. However, if additional supplies are needed in the first 12 hours, the Department of Health and Human Services (HHS) will request that FDA provide the number of medical devices readily available to meet demands. HHS has an established

transportation and delivery mechanism in place to provide these emergent needs to the local and State authorities.

The Emergency Medical Device Shortage Survey was established in 1992 to collect data to assist FDA in implementing an emergency medical device shortage program that would find resources to supplement the needed supplies. In 2004, CDRH changed the process for the data collection and the name was changed to the Emergency Shortages Data Collection System. Because of the confidentiality aspect of the information, the information is only available to those on the FDA Emergency Shortage Team (EST) and senior management with a need-to-know. The need-to-know personnel include 5 EST members, the EST Leader, the EST data entry technician, and 5 senior managers.

The Emergency Shortages Data Collection System will be updated every 4 months to keep information current. CDRH learned that medical device manufacturers have a high rate of turnover in personnel and in corporate structures due to mergers with larger companies. In addition, with the constant advances in technology, some of these manufacturers are forced to discontinue product lines or add product lines to their inventory. This new data collection system process will update information on a regular basis ensuring more accurate information in an emergency/disaster.

The process consists of one scripted telephone call to the designated shortage person at the four or five largest manufacturers of specific medical devices that may be needed by first responders in a national emergency. At the current time, the list contains 67 products from 65 manufacturers. If other products or new technology are deemed necessary to add at a later date, then the EST will conduct the appropriate search to find the four or five largest manufacturers of that product line and request the manufacturer's voluntary inclusion into the program.

The Emergency Shortages Data Collection System will only include those medical devices that are expected to be in demand but in short supply in an emergency/disaster. The data collection system includes life-saving and life-sustaining products (i.e., mechanically powered ventilators) as well as products that would require frequent changes resulting in rapidly depleted supplies (i.e., face masks and gloves).

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
65	3	195	.5	98

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

FDA based these estimates on past experience with direct contact with the medical device manufacturers. FDA estimates that approximately 65 manufacturers would be contacted by electronic mail three times per year to get updated information at their facility. Further, it is estimated that the manufacturers may require up to 30 minutes to check if information received previously is still current and send electronic mail back to FDA.

Dated: October 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21973 Filed 11–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0516]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; 2005 Food Safety Survey; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of October 24, 2005 (70 FR 61455). The document announced an approval by the Office of Management and Budget. The document was published with an incorrect expiration date for OMB control number 0910–0345. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In FR Doc. 05–21157, appearing on page 61455 in the **Federal Register** of Monday, October 24, 2005, the following correction is made:

1. On page 61455, in the second column, in the **SUPPLEMENTARY INFORMATION** section, beginning on line 13, the sentence ''The approval expires on February 30, 2008.'' is corrected to read ''The approval expires on February 29, 2008.''

Dated: October 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21974 Filed 11–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002E–0020] (formerly Docket No. 02E–0020)

Determination of Regulatory Review Period for Purposes of Patent Extension; ZOMETA; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 28, 2003 (68 FR 9690). The document announced that FDA had determined the regulatory review period for ZOMETA. A Request for Revision of Regulatory Review Period was filed for the product on May 4, 2005. FDA reviewed its records and found that the effective date of the investigational new drug application (IND) was incorrect due to a clerical error. Therefore, FDA is revising the determination of the regulatory review period to reflect the correct effective date for the IND.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–13), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.