

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 BURDEN¹

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.

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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.

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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.