TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	264	1	264	3	792

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

Dated: March 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3819 Filed 3–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0422]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information 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 collection of information by April 17, 2006.

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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Emergency Shortages Data Collection System (Formerly the Emergency Medical Device Shortage Program Survey)—(OMB Control 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 Commissioner of Food and Drugs 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 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 FDA's Emergency Shortage Team (EST) and senior management with a need-to-know. The need-to-know personnel include five EST members, the EST leader, the EST data entry technician, and five 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).

In the **Federal Register** of November 4, 2005 (70 FR 67177), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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 facilities. 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: March 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3820 Filed 3–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005E–0238]

Determination of Regulatory Review Period for Purposes of Patent Extension; TYSABRI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TYSABRI 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 human biological product.

ADDRESSES: Submit written or electronic comments and petitions to the Division of Dockets Management (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 V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product TYSABRI (natalizumab). TYSABRI is indicated for the treatment of patients, with relapsing forms of multiple sclerosis, to reduce the frequency of clinical exacerbations. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TYSABRI (U.S. Patent No. 5,840,299) from Athena Neurosciences, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of TYSABRI represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TYSABRI is 2,924 days. Of this time, 2,740 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: November 23, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 23, 1996.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: May 24, 2004. FDA has verified the applicant's claim that the product license application (BLA) for TYSABRI (BLA 125104) was initially submitted on May 24, 2004.

3. *The date the application was approved*: November 23, 2004. FDA has verified the applicant's claim that BLA 125104 was approved on November 23, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and