and run the grant day-to-day. Administrative expenses will be capped at .5 percent for the State and 5 percent for the local partner.

The State of Louisiana, in consultation with its local partner, has flexibility subject to approval by the Centers for Medicare & Medicaid Services (CMS) in determining the funding allocation methodology to grantee clinics/subawardees, as long as it includes a standardization of ''units of care'' across all grantee clinics, and includes a base award and supplementary payments that meet the intent of the grant.

This award was made based on the authority granted by section 6201 of the Deficit Reduction Act (DRA). In particular, section 6201(a)(4) of the DRA provides authority to the Secretary, Department of Health and Human Services (DHHS), to make payments to States to restore access to health care in communities impacted by Hurricane Katrina.

Under the authority of section 6201(a)(4) of the DRA of 2005, the Secretary has invoked his authority to restore health care in impacted communities affected by Hurricane Katrina by offering this unique funding opportunity to stabilize primary health care access to the Greater New Orleans area, which is facing inadequate primary care access as a result of Hurricane Katrina and its subsequent floods.

Louisiana is the only State with the knowledge and ability to administer a grant designed to affect impacted Louisiana communities. For this reason, the Secretary has directed CMS to offer a single-source award to the State of Louisiana to help strengthen and increase primary care access to the Greater New Orleans area and by helping to increase the supply of health care providers negatively impacted as a result of this hurricane.

FOR FURTHER INFORMATION CONTACT: Wendy J. Taparanskas, Ph.D., Health Insurance Specialist, Finance, Systems, and Budget Group, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, Mail Stop S3–13–15, 7500 Security Boulevard, Baltimore, MD 21244, (410) 786–5245.

Authority: Section 6201(a)(4) of the Deficit Reduction Act of 2005 (DRA).

Dated: August 30, 2007.

Herb B. Kuhn,

Acting Deputy Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–17560 Filed 9–5–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0218]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Pilot Program for Medical Products (Formally Medical Device Adverse Event Reporting Program)

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 October 9, 2007.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0471. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1427.

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:

Adverse Event Pilot Program for Medical Products—21 U.S.C. 360(i) (OMB Control Number 0910–0471)—Extension

Under section 519 of the Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360(i)), FDA is authorized to require: Manufacturers to report medical device related deaths, serious injuries, and malfunctions; and user facilities to report device-related deaths directly to manufacturers and FDA, and to report serious injuries to the manufacturer. Section 213 of the FDA Modernization Act of 1997 (FDAMA), amended section 519(b) of the act (21 U.S.C. 360 i(b)) relating to mandatory reporting by user facilities of deaths and serious injuries and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a ''. . . subset of user facilities that constitutes a representative profile of user reports'' for device related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the act. The current universal reporting system remains in place during the pilot stages of the new program, and until FDA implements the new national system by regulation. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high quality data on medical devices in clinical use. This system is called the Medical Product Safety Network (MedSun).

FDA is continuing to conduct a pilot of the MedSun system before the agency issues a regulation to change from universal mandatory reporting for medical device user facilities to reporting by a representative sample of facilities. This data collection has been ongoing since February 20, 2002, and this notice is for continuation of this data collection.

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on the 3500A Form related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and to pilot a few additional questions which will permit FDA to better understand the cause of the reported adverse event. During the pilot program, participants will be asked to complete an annual outcome measures form to aid FDA in evaluating the effectiveness of the program. Participation in this pilot is voluntary and currently includes 400 facilities and over 100 beds. The use of an interactive electronic data collection system is easier and more efficient for the participating user facilities to use than the alternative paper system. The paper form takes approximately 1 hour to complete and the electronic version takes approximately 45 minutes or less to complete. Much of the data which must be filled in by hand on the paper system is automatically filled in by the electronic version.

In addition to collecting data on the electronic adverse event report form, MedSun also collects data electronically in the Device-Safety Exchange (DS-X).

This data collection is also voluntary, and is an FDA moderated site. MedSun sites may send in ''success stories'' describing quality improvement initiatives they have implemented to improve patient safety with medical products and also may send in medical product related questions to which other sites may respond. The maximum time it takes to enter a story, or write or respond to a question, is 30 minutes.

In the **Federal Register** of June 13, 2007 (72 FR 32670), FDA published a 60-day notice requesting public comment on the information collection provisions. In response to that notice, no comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
519(b) Facilities participating in the electronic reporting of adverse event programs.	400	15	6,000	.75	4,500
Section 519 (b) Facilities participating in DS-X (not used by all sites)	200	5	1,000	.50	500
Total					5,000

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

The burden estimate for the electronic reporting of adverse events is based on the number of facilities currently participating in MedSun (400) and the number of sites (50), expected to be added to the program over the next 3 years. The current average number of reports per site is seven reports annually. For purposes of the renewal for this data collection, we are estimating an average of 15 reports per site annually. This increase is expected because MedSun is working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, electrophysiology laboratories, and the hospital laboratories. Thus, the total annual responses is calculated to be 6,000 (400 facilities x 15 data entries = 6,000). The participating MedSun reporters tell FDA that it typically takes 20 to 45 minutes to fill out the on-line form. Using the high end of that time frame, the total burden estimate for facilities participating in the electronic reporting of adverse event programs, is estimated to be 4,500 hours (6,000 report entries x .75 hours = 4,500 hours).

Determination of burden estimate for the DS-X portion of MedSun: All sites do not use this part of the software. To determine the total annual responses for DS-X, 200 participants are multiplied by the number of times each will access DS-X. Thus the total annual responses are calculated to be 1,000 reports (200 x 5 = 1,000). It typically takes an average of 30 minutes to enter data into the DS-X, given that there are various types of data entries which are possible, some of which are lengthier than others. The number of burden hours for DS-X is determined by multiplying the expected 1,000 times the site will be accessed by the average amount of time it takes to make a DS-X entry (30 minutes). Thus the total burden estimate for DS-X is calculated to be 500 hours (1,000 x 0.5 = 500). Therefore, the combined total burden estimate for MedSun and DS-X is calculated to be 5,000 hours (4,500 + 500 = 5,000).

Dated: August 29, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–17562 Filed 9–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0329]

Determination That MILTOWN (Meprobamate) Tablets and Five Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the six drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the drug products, and it will allow FDA to continue to approve ANDAs that refer to the products.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855,301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).