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).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

NDA No.	Drug	Applicant
9–698	MILTOWN (meprobamate) Tablets, 200 milligrams (mg) and 400 mg	Medpointe Pharmaceuticals, 265 Davidson Ave., Suite 300, Somerset, NJ 08873–4120
17–481	VERMOX (mebendazole) Chewable Tablets, 100 mg	McNeil Consumer & Specialty Pharmaceuticals, 7050 Camp Hill Rd., Fort Washington, PA 19034–2999
18–226	BUMEX (bumetanide) Injection, 0.25 mg/milliliter	Roche Laboratories, Inc., 340 Kingsland St., Nutley, NJ 07110–1199
20–463	NASALCROM (cromolyn sodium) Spray, 5.2 mg/spray	Pfizer Consumer Healthcare, 201 Tabor Rd., Morris Plains, NJ 07950
21–203	TRICOR (fenofibrate) Tablets, 54 mg and 160 mg	Abbott Laboratories, 200 Abbott Park Rd., D–89J45–2, Abbott Park, IL 60064–6133
50–517	MEFOXIN (cefoxitin) for Injection, 10 grams/vial	Merck & Co., Inc., Sumneytown Pike, BLA–20, P.O. Box 4, West Point, PA 19486

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs for the products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: August 29, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–17566 Filed 9–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Free Clinic Federal Tort Claims Act (FTCA) Deeming Application (OMB No. 0915–0293): Revision

Under 42 U.S.C. 233(o), and HRSA BPHC PIN 2004–24, the FTCA Free Clinic Program requires requesting free clinics to submit annual, renewal, and supplemental applications for the process of deeming qualified volunteer health care clinicians for FTCA malpractice insurance coverage. It is proposed that the FTCA application forms attached to the current PIN 2004–24 will be modified in several ways. These modifications include adding or clarifying the requirement to include the following information or data: (1) The annual number of the free clinic's patient visits which are covered by the FTCA malpractice coverage, (2) a list of any restrictions, suspensions, or disciplinary actions related to the medical licenses of the relevant volunteer health care clinicians, (3) clarifying the requirement to include a copy of the clinic's IRS 501(c)(3) documentation, (4) clarifying the need to detail any medical malpractice claims filed against any of the relevant volunteer health care clinicians or against the clinic for at least the last 10 years, and (5) a clarification of the need to file future annual renewal applications by August 1. It is anticipated that these modifications will add only incrementally to the time and effort required by the current OMB approved FTCA application forms.

The estimated annual burden is as follows: