

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug

is voluntarily withdrawn from sale, and ANDAs that refer to the listed drug have been approved.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has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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.*

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## 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:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Free Clinic FTCA Application .....	150	1	150	16	2,400
Total .....	150	.....	150	.....	2,400

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 29, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

**Project: Underage Drinking Prevention: Town Hall Meeting Feedback Form—New**

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Substance Abuse Prevention (CSAP) is proposing a 2008 Underage Drinking Prevention: Town Hall Meetings (THM) Initiative. In 2006, approximately 1,510 THMs were held by 1,262 community-based organizations (CBO) throughout the Nation. Each of the THMs strived to increase the understanding and awareness of underage alcohol use and its consequences by encouraging individuals, families, and communities to address the problem. The local THMs gave communities the opportunity to come together to learn more about the new research on underage alcohol use and its impact on both the individuals and the community. They also discussed how their communities can best prevent underage alcohol use.

To help guide decision making and planning for future THMs, SAMHSA/CSAP plans to conduct a process assessment of the THMs to be held in 2008. CBOs that agree to participate in this initiative will be asked to provide feedback about the implementation and results of the THMs in their community. This information collection is being

implemented under the authority of Section 501(d) (4) of the Public Health Service Act (42 U.S.C. 290aa).

The contractor conducting this information collection will distribute a brief feedback form to all participating organizations. The form includes 14 items about the THM, including where, when, and who conducted the meeting, number of attendees, format of meeting, participants in the presentations, actions planned, media coverage of the meeting, composition of the audience, responses of the attendees, materials provided in the town hall meetings, and indications of increased awareness and increased involvement. In addition to distributing the feedback form, the contractor will be responsible for collecting, compiling, analyzing, and reporting on information requested through this feedback form.

The feedback form will be completed by an estimated 1,200 employees from CBOs. The paper form will take an average of 10 minutes (.167 hours) to review instructions, complete the form, and mail it in a self-addressed, stamped envelope. This burden estimate is based on comments from several potential respondents who reviewed the form and provided comments on how long it would take them to complete it.

Form name	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Feedback Form .....	1,200	1	.167	200

Written comments and recommendations concerning the proposed information collection should be sent by October 9, 2007 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: August 29, 2007.

**Elaine Parry,**

*Acting Director, Office of Program Services.*

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**DEPARTMENT OF HOMELAND SECURITY**

[Docket No. DHS-2007-0067]

**Science and Technology Directorate; Submission for Review; New Information Collection Request for Support of SBIR/STTR Company Registration Form, Research Topic Recommendation Form, Ask a Question Form, Collaboration Opportunity Form, Reviewer Opportunity Form, E-mail Mailing List Signup Form, E-mail Mailing List Removal Form, Proposal Coversheet Form, Cost Proposal Form**

**AGENCY:** Science and Technology Directorate, DHS.

**ACTION:** 30-day Notice and request for comment.

**SUMMARY:** The Department of Homeland Security (DHS) invites interested persons to comment on the following forms for the Small Business Innovation Research (SBIR) program: Company Registration (DHS FORM 10022), Research Topic Recommendation (DHS FORM 10018), Ask a Question (DHS FORM 10020), Collaboration Opportunity (DHS FORM 10021), Reviewer Opportunity (DHS FORM 10019), E-mail Mailing List Signup (DHS FORM 10016), E-mail Mailing List Removal (DHS FORM 10024), Proposal Coversheet (DHS FORM 10017), Cost Proposal (DHS FORM 10023) forms and