TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.93		2,000	1	2,000	0.5	1,000
Totals						309,333

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in table 1 of this document.

Dated: April 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10576 Filed 5–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0284]

Determination That BREVIBLOC (Esmolol Hydrochloride) Injection, 250 Milligrams/Milliliter, 10-Milliliter Ampule, Was Withdrawn From Sale for Reasons of Safety or Effectiveness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that BREVIBLOC (esmolol hydrochloride (HCl)) Injection, 250 milligrams (mg)/milliliter (mL), 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness. This determination means the agency will not accept or approve abbreviated new drug applications (ANDAs) for esmolol HCl injection, 250 mg/mL, 10-mL ampule.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

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 applicants 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 under a new drug application (NDA). ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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 (the 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 removed 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 (section 505(j)(7)(C) of the act; 21 CFR 314.162).

FDA will not approve an ANDA if the listed drug has been withdrawn from sale for safety or effectiveness reasons (section 505(j)(4)(I) of the act). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. A drug that has been withdrawn from the market for safety or effectiveness reasons is not a listed drug (21 CFR 314.3(b)). FDA may not approve an ANDA that does not refer to a listed drug.

BREVIBLOC (esmolol HCl)) Injection is the subject of NDA 19–386, held by Baxter Healthcare Corp. (Baxter). BREVIBLOC is a beta$_1$-selective adrenergic receptor-blocking agent with a short duration of action. BREVIBLOC is approved for the treatment of supraventricular tachycardia. BREVIBLOC is also indicated for treatment of intraoperative and postoperative tachycardia and/or hypertension.

Baxter currently markets 4 product presentations of BREVIBLOC Injection—10-mg/mL and 20-mg/mL ready-to-use vials and 10-mg/mL and 20-mg/mL premixed injection bags. Baxter has discontinued marketing the following two product presentations of BREVIBLOC (esmolol HCl) Injection:

- In 2003, Baxter discontinued BREVIBLOC (esmolol HCl) Injection, 10 mg/mL (formulation without sodium chloride), and FDA determined that this presentation of BREVIBLOC Injection was not withdrawn from sale for reasons of safety or effectiveness (69 FR 47155, August 4, 2004).
- In 2007, Baxter discontinued BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule. In a letter dated June 28, 2007, Baxter informed the agency that the company had decided to cease manufacture and distribution of BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, because the product demonstrated a higher risk of medication errors that may potentially result in serious outcomes. Baxter observed that serious adverse events were associated with the following medication errors:
- Mixups between the ready-to-use 10-mg/mL vial and the 250-mg/mL, 10-mL ampule concentrate;
- Use of undiluted 250-mg/mL, 10-mL ampule concentrate;
- Dilution calculation errors with the 250-mg/mL, 10-mL ampule concentrate; and
- Administration of the wrong drug.

In a Dear Healthcare Professional letter dated August 20, 2007, Baxter stated that their decision to cease manufacture of BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was made after thorough review of adverse event reports, clinical usage studies, input from clinicians, and initiatives to reduce medication errors.

In a citizen petition dated March 27, 2008 (Docket No. FDA–2008–P–0284), submitted under 21 CFR 10.30 and in accordance with 21 CFR 314.122 and 314.161, Bedford Laboratories (Bedford) requested that the agency determine

whether BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness. Bedford noted that Baxter has publicly stated that the product was discontinued due to safety issues surrounding medication errors and asked the agency to determine the cause of the discontinuation.

We have carefully reviewed our files for records concerning the withdrawal from sale of BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, including the NDA file for this drug product. We have also independently evaluated relevant literature and data for possible postmarketing adverse event reports. FDA's review shows that the product was withdrawn from sale because of reports of serious adverse events, including deaths.

Although the application holder has made several labeling revisions (including a warning sticker on the ampule) and issued Dear Healthcare Provider letters to reduce the potential for medication errors, there have been additional reports of medication errors. In addition, alternative presentations of the product are available that are not associated with the same potential for medication errors.

After considering the citizen petition (and comments submitted) and reviewing agency records concerning the drug product, analyses of adverse event reports, and relevant literature, FDA has determined under § 314.161 that BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness. FDA has reviewed the latest approved labeling for BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, and has determined that this labeling is inadequate to reduce medication errors to an acceptable level. FDA has determined that Human Factors studies (i.e., Failure Mode and Effects Analysis and usability studies to test the product in a typical practice setting) are necessary before this product could be considered for reintroduction to the market.

Therefore, the agency has determined, under § 314.161, that BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety. BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, will be removed from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule.

Dated: April 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10559 Filed 5–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2010 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award a Single Source Grant to the grantee of the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately $620,000 for up to three years to the grantee of the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention. This is not a formal request for applications. Assistance will be provided only to the current grantee of the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SM–10–018.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 520A of the Public Health Service Act, as amended.

Justification: Only an application from the grantee for the Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention will be considered for funding under this announcement. Three-year funding has become available to assist because this funding supplement is intended to support the technical assistance needs of Project LAUNCH grantees to be newly funded in FY 2010. The current grantee provides technical assistance to the other cohorts for Project LAUNCH and is in a unique position to address the grant implementation needs of communities to be funded this fiscal year. There is no other potential organization with the required access and expertise.

Eligibility for this program supplement is restricted to the current grantee, Technical Assistance Center for Mental Health Promotion and Youth Violence Prevention. This supplement will serve to maximize efficiencies created under the current services infrastructure. It would be inefficient and duplicative to fund additional technical assistance services for Project LAUNCH grantees through a second organization.

Contact: Shelly Hara, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8–1095, Rockville, MD 20857; telephone: (240) 276–2321; E-mail: *shelly.hara@samhsa.hhs.gov.*

Toian Vaughn,

SAMHSA Committee Management Officer.

[FR Doc. 2010–10502 Filed 5–4–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451] (formerly Docket No. 2004N–0226)

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 023" (Recognition List Number: 023), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of "Modifications to the List of Recognized Standards, Recognition List Number: 023" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66,