whether BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness.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 FDA's review shows that the product was withdrawn from sale because of reports of serious adverse events, including deaths.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literature, FDA has determined under § 314.161 that BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety or effectiveness.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the agency has determined, under § 314.161, that BREVIBLOC (esmolol HCl) Injection, 250 mg/mL, 10-mL ampule, was withdrawn from sale for reasons of safety.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,