the Federal Food, Drug, and Cosmetic Act;

(4) Continued implementation of the SIP is reasonably likely to pose additional risk to the public's health and safety;

(5) Confidential manufacturer information was disclosed in violation of § 251.16;

(6) Continued implementation of the SIP is not reasonably likely to result in a significant reduction in the cost of the drugs covered by the SIP to the American consumer;

(7) Continued monitoring of the SIP imposes too much of a burden on FDA or HHS resources for carrying out this part or is inconsistent with FDA or HHS prioritization of resources;

(8) Continued implementation of the SIP is otherwise inappropriate; or

(9) Grounds exist for suspension under paragraph (a) or (b) of this section and FDA determines it should revoke, either instead of, or after, suspension.

§ 251.8 Modification or extension of authorized importation programs.

(a) A supplemental proposal to modify or extend an authorized SIP must be submitted in electronic format via the ESG, or to an alternative transmission point identified by FDA, for FDA's consideration.

(b) FDA's review and authorization of a supplemental proposal to modify or extend an authorized SIP is governed by this part. In reviewing a supplemental proposal, FDA may take into account information learned subsequent to authorization of the SIP.

(c) FDA may authorize a supplemental proposal from a SIP Sponsor to add additional Foreign Sellers or additional Importers to an authorized SIP if FDA determines the SIP Sponsor has adequately demonstrated that the SIP has consistently imported eligible prescription drugs in accordance with section 804 of the Federal Food, Drug, and Cosmetic Act and this part. Each supply chain under a SIP must be limited to one manufacturer, one Foreign Seller, and one Importer.

(d) If FDA authorizes changes to a SIP, the Importer must submit a new Pre-Import Request in accordance with § 251.5.

(e) A SIP Sponsor must not make any changes or permit any changes to be made to a SIP without first securing FDA's authorization.

(f) A SIP Sponsor may request that FDA extend the authorization period of an authorized SIP. Such a request must be submitted at least 90 calendar days before the SIP's authorization period will expire. To be eligible for an extension of the authorized SIP, a SIP must be up to date on all of the information and records-related requirements of section 804 of the Federal Food, Drug, and Cosmetic Act and this part. FDA may extend the authorization period for up to 2 years at a time.

Subpart C—Certain Requirements for Section 804 Importation Programs

§ 251.9 Registration of Foreign Sellers.

(a) Any Foreign Seller(s) designated in a SIP Proposal must be registered with FDA before FDA will authorize the SIP Proposal.

(b) To register, a Foreign Seller must provide the following information:

(1) Name of the owner or operator; if a partnership, the name of each partner; if a corporation, the name of each corporate officer and director, and the place of incorporation;

(2) All names of the Foreign Seller, including names under which the Foreign Seller conducts business or names by which the Foreign Seller is known;

(3) Physical address and telephone number(s) of the Foreign Seller;

(4) Registration number, if previously assigned by FDA;

(5) A unique facility identifier in accordance with the system specified under section 510 of the Federal Food, Drug, and Cosmetic Act;

(6) All types of operations performed by the Foreign Seller;

(7) Name, mailing address, telephone number, and email address of the official contact for the establishment; and

(8) Name, mailing address, telephone number, and email address of:

(i) The U.S. agent;

(ii) The Importer to which the Foreign Seller plans to sell eligible prescription drugs; and

(iii) Each SIP Sponsor with which the Foreign Seller works.