(6) Collecting and submitting the information and documentation to FDA about the imported drug(s) pursuant to section 804(d) of the Federal Food, Drug, and Cosmetic Act, in addition to information about the Foreign Seller, as set forth in § 251.19; and

(7) Submitting the adverse event, field alert, and other reports, and complying with drug recalls, in accordance with § 251.18.

(b) If the Importer is also relabeling the eligible prescription drug, the Importer must also:

(1) Register with FDA as a repackager or relabeler under section 510(b) of the Federal Food, Drug, and Cosmetic Act, in accordance with § 207.25 of this chapter;

(2) Obtain a labeler code from FDA and propose an NDC for each eligible prescription drug pursuant to § 207.33 of this chapter; and

(3) List each eligible prescription drug pursuant to § 207.53 of this chapter.

(c) If the Importer is not itself relabeling the eligible prescription drug, the Importer must:

(1) Obtain its own labeler code from FDA under § 207.33(c) of this chapter;

(2) Ensure that the eligible prescription drug incorporates the NDC the Importer proposed for assignment, which must include the Importer's labeler code; and

(3) Ensure that the entity relabeling an eligible prescription drug on its behalf proposes an NDC pursuant to § 207.33 of this chapter and lists each eligible prescription drug pursuant to § 207.53 of this chapter.

§ 251.13 Labeling of eligible prescription drugs.

(a) Upon the request of a SIP Sponsor or Importer, the manufacturer of an eligible prescription drug must provide an Importer written authorization for the Importer to use, at no cost, the FDA-approved labeling for the drug. If the manufacturer fails to do so within 30 calendar days of receiving the Importer's request, FDA may deem this authorization to have been given.

(b) In addition to the exemption provided in subpart D of part 201 of this chapter, an eligible prescription drug imported for purposes of this part is exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if all the following conditions are met:

(1) The Importer or the manufacturer certifies that the drug meets all labeling requirements under the Federal Food, Drug, and Cosmetic Act, including the requirements of this part. The Importer of an eligible prescription drug must either:

(i) Propose an NDC for the drug following the procedures in § 207.33 of this chapter and list the drug following the procedures in § 207.53 of this chapter; or

(ii) Take responsibility to ensure that the entity performing relabeling on its behalf lists each eligible prescription drug and incorporates the NDC the Importer proposed for assignment in accordance with the applicable requirements of part 207 of this chapter.

(2) The drug must be:

(i) In the possession of a person (or his or her agents or employees), including Foreign Sellers and Importers, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs;

(ii) In the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or

(iii) In the possession of a practitioner licensed by law to administer or prescribe such drugs.

(3) The drug is to be dispensed in accordance with section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(4) At the time the drug is sold or dispensed, the labeling of the drug must be the same as the FDA-approved labeling under the applicable NDA or ANDA, except that the labeling must bear conspicuously:

(i) The Importer's NDC for the eligible prescription drug, and such NDC must replace any other NDC otherwise appearing on the label of the FDA-approved drug;

(ii) The lot number assigned by the manufacturer of the eligible prescription drug, on the carton labeling and on the container label;

(iii) The name and place of business of the Importer;

(iv) The statement: ''[This drug was/These drugs were] imported from Canada without the authorization of [Name of Applicant] under the [Name of SIP Sponsor] Section 804 Importation Program.'' If the SIP maintains a website, the statement could also include the website address. This statement must appear in the HOW SUPPLIED/STORAGE AND HANDLING section for products subject to §§ 201.56(d) and 201.57 of this chapter, or in the HOW SUPPLIED section for products subject to §§ 201.56(e) and 201.80 of this chapter. The statement also must be included on the immediate container label and outside package;

(v) For products subject to §§ 201.56(d) and 201.57(c)(17)(iii) of this chapter, the NDC(s) assigned to the eligible prescription drug in accordance with the procedures in § 207.33 of this chapter must be included in the HOW SUPPLIED/STORAGE AND HANDLING section in place of the NDC(s) assigned to the FDA-approved versions of the drug. The NDC(s) also must be included on the immediate container label and outside package;

(vi) For products subject to §§ 201.56(d) and 201.57(a)(11)(ii) of this chapter, the Adverse Reaction Contact Reporting Statement under the Adverse Reactions heading in the Highlights of Prescribing Information. This statement must include the Importer's name and the telephone number of the firm to provide a structured process for reporting suspected adverse events; and

(vii) For products subject to §§ 201.56(e) and 201.80(k)(3) of this chapter, the NDC(s) assigned to the eligible prescription drug in accordance with the procedures in § 207.33 of this chapter. The NDC(s) must be included in the HOW SUPPLIED section in place of the NDC(s) assigned to the FDA-approved versions of the drug. The NDC(s) also must be included on the immediate container label and outside package.

(c) The Importer is responsible for relabeling the drug, or arranging for it to be relabeled, to meet the requirements of this part. The relabeling and associated limited repackaging activities must meet applicable requirements, including applicable current good manufacturing practice requirements under parts 210 and 211 of this chapter. Except for repackaging that is necessary to perform the relabeling described in this part, further repackaging of drugs imported pursuant to a SIP is prohibited. Repackaging the container closure of a drug is not permitted under this part.

(d) The Importer may submit to FDA, in electronic format via the ESG or to an alternative transmission point identified by FDA, under § 251.8, a supplemental proposal to modify the labeling of an eligible prescription drug, for example if the eligible prescription drug's container is too small to fit the additional information required by this section.

§ 251.14 Supply chain security requirements for eligible prescription drugs.

(a) *SIP Sponsor*. A sponsor of an authorized SIP must ensure that:

(1) Each drug imported under the SIP is HPFB-approved and labeled for sale in Canada by the manufacturer before it reaches the Foreign Seller;

(2) For each drug that is imported under the SIP and that is manufactured outside Canada, the drug was authorized for import into Canada by the manufacturer and was not transshipped through Canada for sale in another country;

(3) For each drug imported under the SIP, the drug was sold by the manufacturer directly to a Foreign Seller;

(4) For each drug imported under the SIP, the Foreign Seller ships the drug directly to the Importer in the United States;

(5) For each drug imported under the SIP, the Foreign Seller identified in the SIP meets applicable supply chain security requirements of this part;

(6) The Importer identified in the SIP meets the applicable requirements of this part and in sections 582(c) and (d) of the Federal Food, Drug, and Cosmetic Act; and

(7) Returned eligible prescription drugs are properly dispositioned in, and not exported from, the United States.

(b) *Manufacturer*. For each transaction of the eligible prescription drug, the manufacturer must provide to the Importer, within 30 calendar days of receiving the Importer's request, a copy