Section 804 Importation Program: Overview of Final Rule and Implementation

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Who We Are

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Food and Drug Administration

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Chief of Staff
Julia Tierney, JD

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Legend:
*** Direct report to DHHS General Counsel
Who We Are

Center for Drug Evaluation and Research (CDER)

Office of Compliance

Office of Compounding Quality and Compliance

Office of Drug Security, Integrity, & Response

Office of Manufacturing Quality

Office of Program & Regulatory Operations

Office of Scientific Investigations

Office of Unapproved Drugs and Labeling Compliance

ODSIR
Introduction

• The Section 804 Importation Program is overseen by ODSIR’s Imports Compliance Branch in the Division of Global Drug Distribution and Policy.

• We will work with States and Indian Tribes that propose to develop SIPs. This presentation is intended to assist the States with the SIP process.

• We will cover ODSIR’s overall phased review approach.

• The presentation will focus primarily on preparing a complete Section 804 Importation Program (SIP) proposal for review.
Overview of the Final Rule

• The Final Rule, “Importation of Prescription Drugs” was published October 1, 2020 (85 FR 62094) and became effective November 30, 2020.

• Under the final rule, section 804 of the FD&C Act will be implemented through time-limited Section 804 Importation Programs (SIPs).

• The rule allows FDA-authorized programs to import certain prescription drugs from Canada under specific conditions that ensure, as required by section 804, that the importation poses no additional risk to the public’s health and safety while achieving a significant reduction in the cost of covered products to the American consumer.
Section 804 Importation Program Overview

Review of Requirements

Proposal Evaluation (Consults)

SIP Proposal Decision

Pre-Import Request

Importation

No Foreign Seller within 6 months

If not authorized


If not granted

Submit a new Pre-Import Request in order to continue

If granted

Subject to Denial. If a new SIP Proposal is submitted, process restarts.
What Constitute Completeness of a SIP Proposal?

- To be considered complete, a SIP proposal should provide all required information pursuant to the Final Rule with emphasis on SIP proposal submission requirement (21 CFR § 251.3).
  - ODSIR performs a review of the SIP proposals to ensure all required elements are addressed.
    - This review verifies that all required elements are addressed before we perform a substantive review.
    - This is not an adequacy review.
  - SIPs should be as specific as possible with supporting documentation for processes and plans.

- FDA may notify a SIP Sponsor, via a request for information (RFI), if FDA believes there are missing or incomplete elements in the proposal.
## 21 CFR § 251.3 SIP Proposal Submission Requirements

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(i) Name of SIP Sponsor and Co-Sponsor, if any  
(ii) Name and contact information for a point of contact person  
(iii) **Signature of the SIP Sponsor and Co-Sponsor**, if any |
| 21 CFR § 251.3(c)(2) | A table of contents |
| 21 CFR § 251.3(c)(3) | An introductory statement that includes an overview of the SIP Sponsor’s SIP Proposal  
- **Specific requirements are under 251.3(d)** |
| 21 CFR § 251.4(c)(4) | The SIP Sponsor’s importation plan  
- **Specific requirements are under 251.3(e)** |
# 21 CFR § 215.3(d) Overview of the SIP Proposal

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  i. Statutory testing requirements  
  ii. Supply chain security  
  iii. Labeling requirements  
  iv. Post-importation pharmacovigilance and other requirements  
  v. Significant reduction in the cost to the American consumer |
## 21 CFR § 215.3(e) Importation Plan

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| 21 CFR § 215.3(e)(11) | SIP Sponsor’s plan on  
  i. Storage, handling, and distribution practices of supply chain participants  
  ii. Supply chain security  
  iii. Importer’s screening process for violative drug products  
  iv. Importer’s responsibilities to submit adverse event, field alert, and other reports |
| 21 CFR § 215.3(e)(12) | Education plan about the eligible prescription drugs imported under the SIP |
| 21 CFR § 215.3(e)(13) | Recall plan |
| 21 CFR § 215.3(e)(14) | Return plan |
| 21 CFR § 215.3(e)(15) | Compliance plan |
| 21 CFR § 215.3(e)(16) | Trade secrets or commercial or financial information handling |
# 21 CFR § 251, Subpart C - Certain Requirements for Section 804 Importation Programs

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Review Timeframe

• The Final Rule does not provide a timeframe for review of a SIP proposal.

• The timeframe for review is dependent upon the inclusion of all requirements of the rule in the SIP proposal.

• The Agency anticipates providing feedback regarding the SIP proposal’s adherence to the requirements within six months from the submission.
Where to send questions or requests regarding a SIP Proposal?

• States and tribes interested in working with the agency on a SIP proposal can contact FDA’s Intergovernmental Affairs Staff at IGA@fda.hhs.gov to begin the conversation.

• States and tribes may submit a SIP proposal for agency review or ask questions about an existing proposal by email to SIPDrugImportsandRFP@fda.hhs.gov.