Section 804 Importation Program: Overview of Final Rule and Implementation

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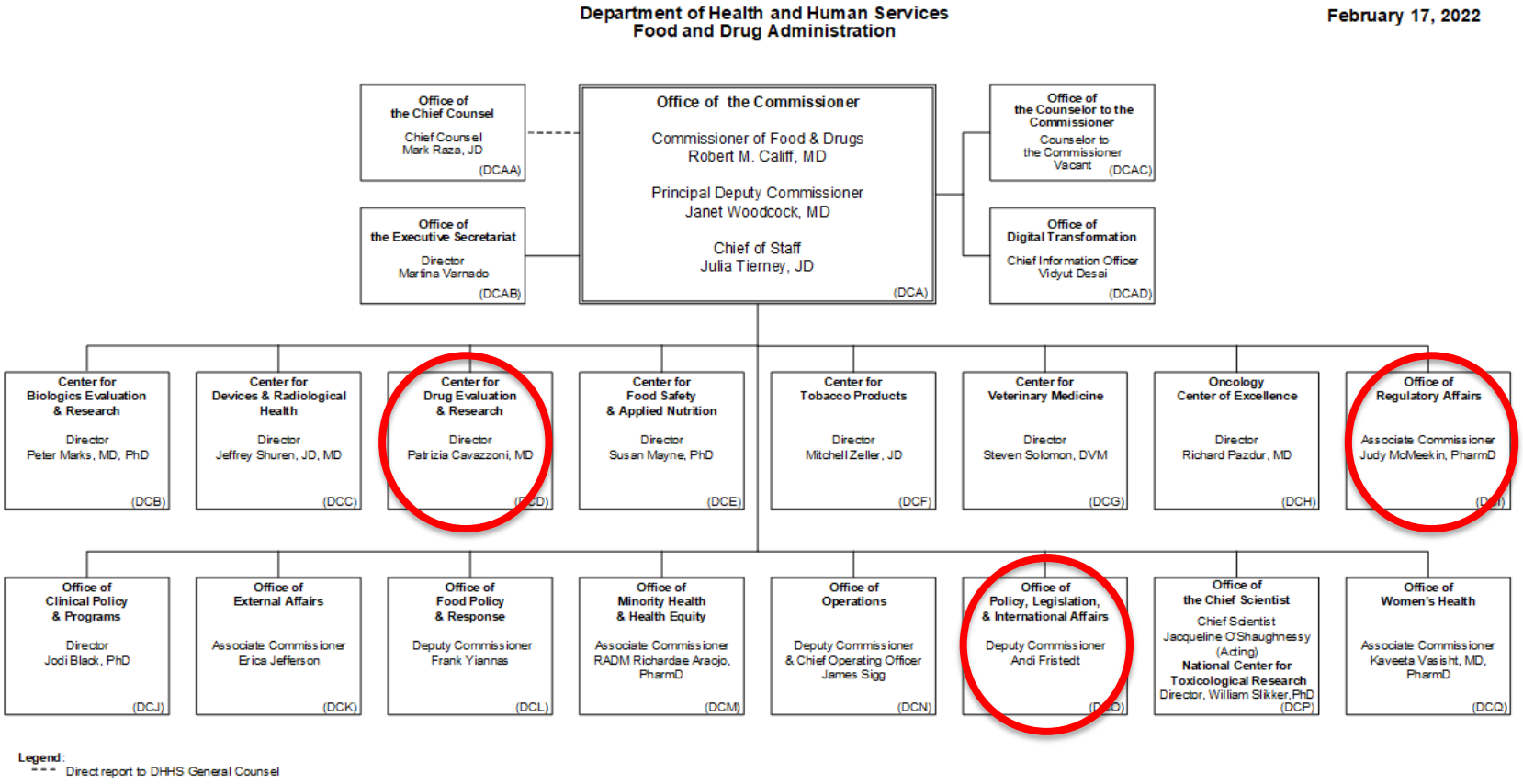
Who We Are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Food and Drug Administration
February 17, 2022
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Direct report to DHHS General Counsel

Who We Are

September 2021

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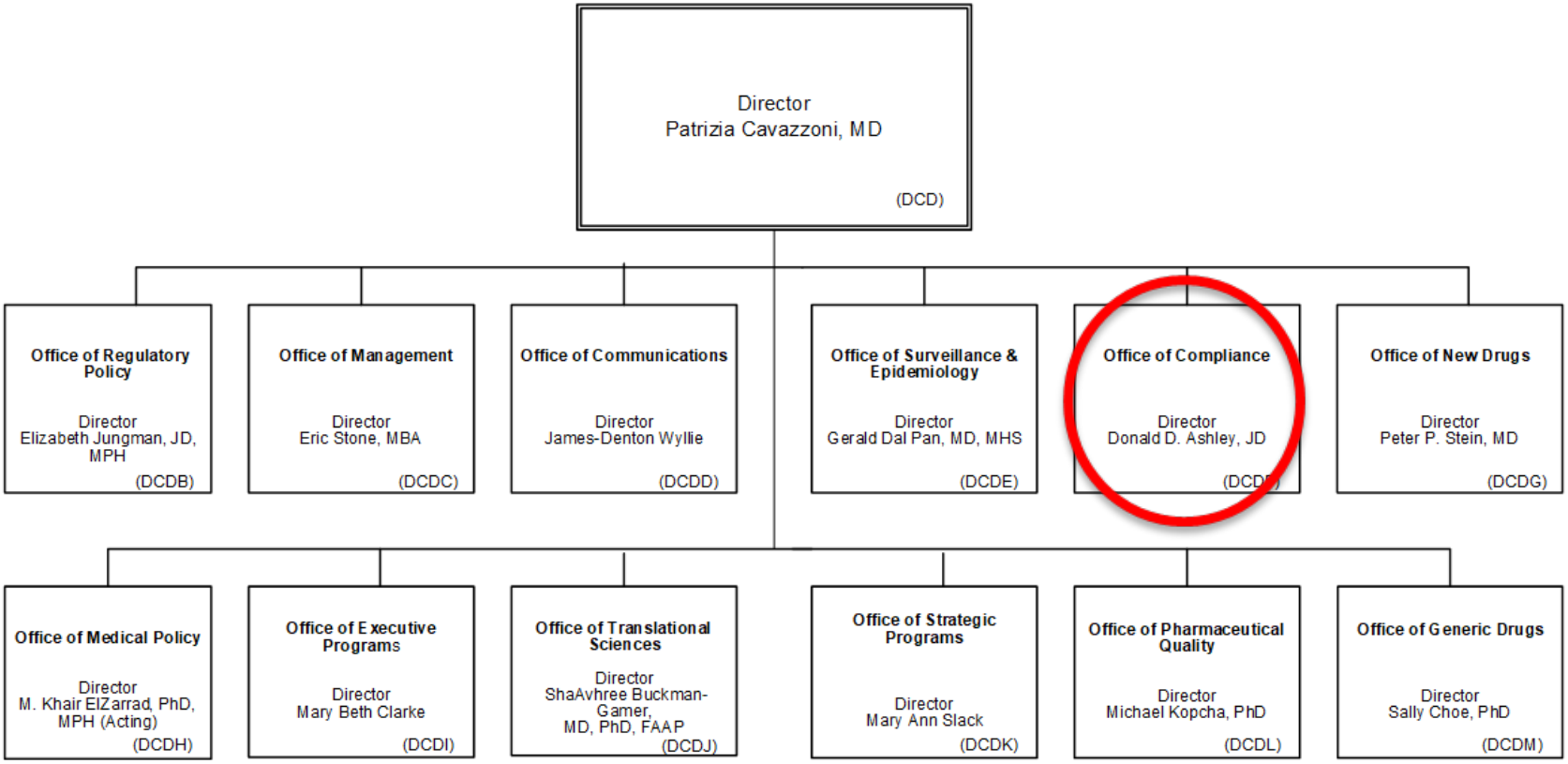

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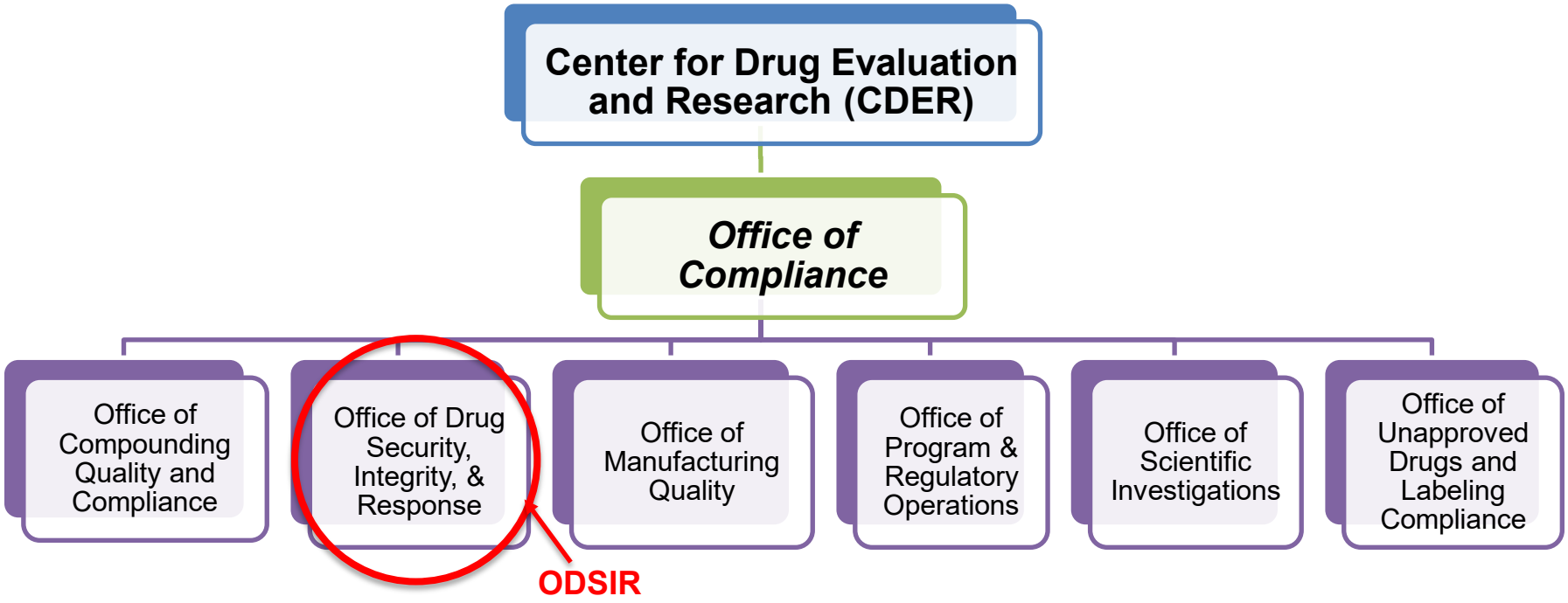
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ODSIR

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.

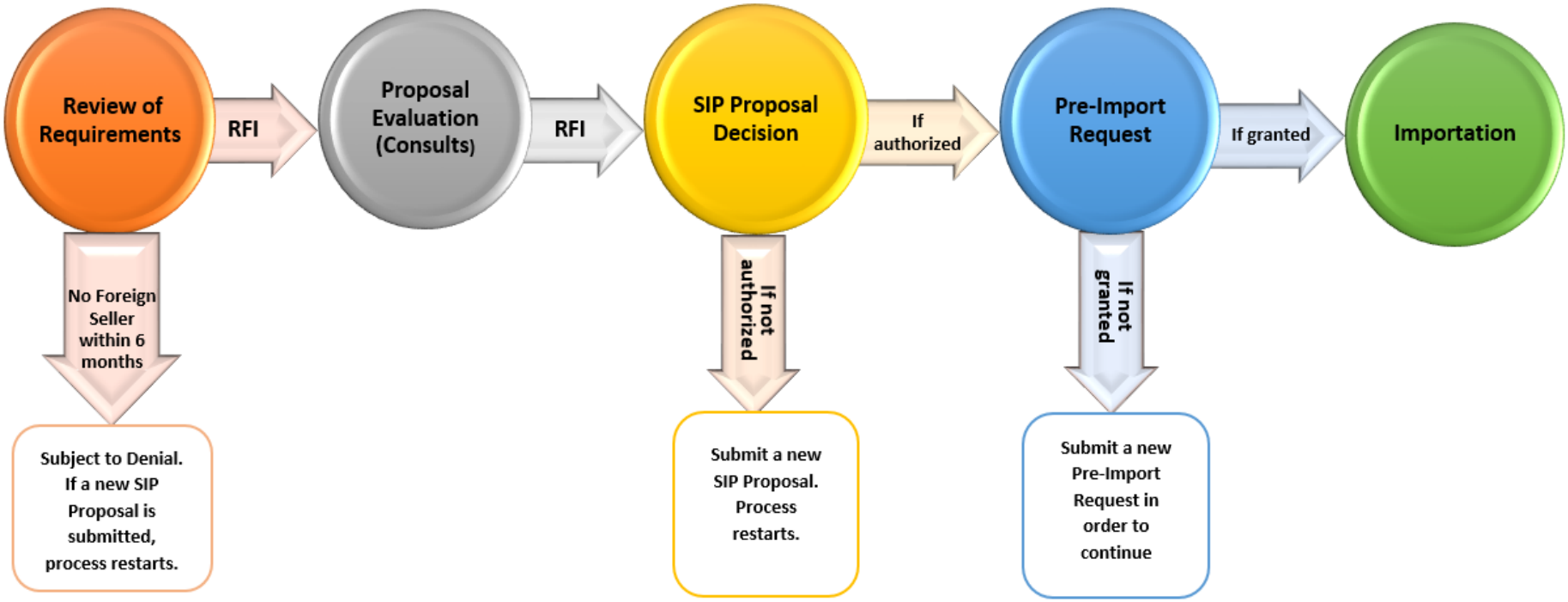
Overview of the Final Rule

- 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



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

Final Rule Section	Contents
21 CFR § 251.3(c)(1)	Cover sheet (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

Final Rule Section	Contents
21 CFR § 215.3(d)(1)	SIP and SIP Sponsor/Co-Sponsor information
21 CFR § 215.3(d)(2)	Responsible individual
21 CFR § 215.3(d)(3)	Name and DIN of each eligible prescription drug
21 CFR § 215.3(d)(4)	NDA/ANDA and applicant holder's information
21 CFR § 215.3(d)(5)	Manufacturer information – finished dosage form, if known or reasonably known
21 CFR § 215.3(d)(6)	Manufacturer information – active ingredient, if known or reasonably known
21 CFR § 215.3(d)(7)	Foreign Seller information
21 CFR § 215.3(d)(8)	Foreign Seller's Health Canada Drug Establishment License
21 CFR § 215.3(d)(9)	Importer information
21 CFR § 215.3(d)(10)	Repackager or relabeler information
21 CFR § 215.3(d)(11)	Summary of SIP Sponsor's plan on 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

Final Rule Section	Contents
21 CFR § 215.3(e)(1)	Information on SIP Sponsor/Co-Sponsor, responsible individual, NDA/ANDA applicant holder, manufacturers of finished dosage form and active ingredient or ingredients (if known or reasonably known), Foreign Seller (if known or reasonably known), and Importer
21 CFR § 215.3(e)(2)	Attestation and information statement of any past criminal convictions or violations regarding drugs or devices
21 CFR § 215.3(e)(3)	A list of all disciplinary actions
21 CFR § 215.3(e)(4)	The Health Canada inspectional history for the Foreign Seller and the State and Federal inspectional history for the Importer
21 CFR § 215.3(e)(5)	Information on eligible prescription drugs
21 CFR § 215.3(e)(6)	Evidence that each HPFB-approved drug's FDA-approved counterpart drug is currently commercially marketed in the United States
21 CFR § 215.3(e)(7)	Statutory testing plan and qualifying laboratory information
21 CFR § 215.3(e)(8)	Side-by-side comparison of the FDA-approved labeling and the proposed labeling with all differences annotated and explained

21 CFR § 215.3(e) Importation Plan (cont.)

Final Rule Section	Contents
21 CFR § 215.3(e)(9)	How the SIP will result in a significant reduction in the cost to the American consumer
21 CFR § 215.3(e)(10)	How the SIP Sponsor will ensure that all the participants in the SIP comply with the program requirements
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

Final Rule Section	Contents
21 CFR § 251.9	Registration of Foreign Sellers
21 CFR § 251.10	Reviewing and updating registration information for Foreign Sellers
21 CFR § 251.11	Official contact and U.S. agent for Foreign Sellers
21 CFR § 251.12	Importer responsibilities
21 CFR § 251.13	Labeling of eligible prescription drugs
21 CFR § 251.14	Supply chain security requirements for eligible prescription drugs
21 CFR § 251.15	Qualifying laboratory requirements
21 CFR § 251.16	Laboratory testing requirements

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.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