RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

July 6, 2022

ONLINE SUBMISSION ONLY
(https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm)

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Freedom of Information Act Request.

Dear FOIA Officer:

I submit this request under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and 21 C.F.R. Part 20, to the Food and Drug Administration ("FDA") on behalf of the Florida Agency for Health Care Administration ("AHCA" or the "Requester").

Requested Records

The Requester requests records from January 1, 2019, to the present related to Florida's Section 804 Importation Program ("SIP") proposal. Specifically, the Requester requests the following records[1]:

1. Records relating to Florida's SIP proposal.

2. Records relating to Canadian drug importation programs, including SIP proposals, for the following states: Colorado, New Mexico, New Hampshire, Vermont, and Maine.

3. Records relating to the Canadian drug importation program and private pharmaceutical stakeholders, including pharmaceutical companies, lobbying groups, and advocacy groups, including the Pharmaceutical Research and Manufacturers of America (PhRMA).

4. Records relating to the development of the SIP review and approval process, including the development of the standards for ascertaining "cost savings to the American consumer." 21 C.F.R. §§ 251.3(d)(11)(v), 251.3(e)(9).

5. Records relating to the "risk" to the American public's health and safety. 21 C.F.R. § 251.7(c)(4).

6. Records relating to standards for laboratory testing. *See* 21 C.F.R. § 251.16(a) ("The manufacturer or the Importer must arrange for drugs imported under an authorized SIP to be tested by a qualifying laboratory.").

[1] Records include, but are not limited to, briefings, reports, memoranda, legal opinions, policy statements, talking points, notes, tape recordings, electronic records (including email, whether through .gov email addresses or private third-party services such as Gmail), and any other materials.

7. Records related to Tab A hereto, which is an FDA presentation titled "Section 804 Importation Program: Overview of Final Rule and Implementation," dated March 31, 2022.

8. Records relating to a completeness review. *See* slide 8 of Tab A hereto (""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).").

9. Records relating to a substantive review and the timeline for such a review. *See* slide 8 of Tab A hereto ("This review verifies that all required elements are addressed before we perform a substantive review.").

10. Records related to Tab B hereto, which is an FDA presentation titled "Projecting Cost Savings for the American Consumer," dated March 31, 2022.

11. Records relating to the Canadian drug importation program and HHS guidelines for Regulatory Impact Analysis. *See* slide 3 of Tab B hereto ("The HHS Guidelines for Regulatory Impact Analysis discuss this widely used framework for collecting, organizing, and evaluating data on the anticipated consequences of regulatory actions.").

12. Records relating to "analytic approaches." *See* slide 3 of Tab B hereto ("Other analytical approaches may be appropriate. Note that the SIP Proposal's cost-saving 'explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.' The SIP Proposal's discussion of assumptions should include an explanation of the analytic approach adopted by the SIP Sponsor.").

13. Records relating to "measuring prices." *See* slides 9-12 of Tab B hereto.

14. Records relating to the basis or bases for denial of a SIP proposal. 21 C.F.R. 251.4(a).

I urge the FDA to process this request consistent with the Department of Justice's policy directing a presumption of disclosure under FOIA.[2]

Request for Expedited Processing

The Requester requests that the FDA provide expedited processing of this FOIA request because "there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity."[3]

First, the Requestor is "primarily engaged in disseminating information to the general public and not merely to a narrow interest group."[4] AHCA is a state agency with a mission of facilitating "Better Health Care for All Floridians." As part of that mission, AHCA is "responsible for the

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[2] *See* Dep't of Justice Office of Info. Policy, *Memorandum from The Attorney General*, https://www.justice.gov/ag/page/file/1483516/download (2022).

[3] 21 C.F.R. § 20.44(a)(2).

[4] *Id.* § 20.44(c)(1).

administration of the Florida Medicaid program, licensure and regulation of Florida's health facilities, and for providing information to Floridians about the quality of care they receive."[5] Dissemination of information about government activities, particularly with respect to healthcare, is a critical and substantial component of AHCA's mission. Because doing so is vital to its work, AHCA will disseminate any information obtained through this request to the public, contributing to the public's enhanced understanding of the Canadian drug importation program and the FDA's role in implementing the program.

Second, there is "an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly."[6] Here, the requested records will shed light on the role of the FDA in implementing a program of great interest and importance to the people of Florida. The availability of essential, low-cost drugs is a matter of great public interest and concern in Florida and across America, especially because many vulnerable citizens need these drugs but cannot afford to pay for them. Moreover, the need for this information is urgent. Outpatient prescription drug prices have increased exponentially and continue to rise.[7] At the same time, many Americans cannot afford essential drugs, "forcing them to choose whether to maintain their health, pay the rent or mortgage, or put food on the table."[8] As the U.S. Department of Health and Human Services recently recognized, being forced to make that choice sometimes has dire health consequences: "High drug prices result in access and affordability challenges for many Americans. Twenty-four percent of adults taking prescription drugs say they are hard to afford, and nearly 10 percent of adults report not taking medication as prescribed in order to save money. *Some have died as a result.*"[9] Given this tragic choice many American face, information about what the FDA is doing to implement a government program designed to address skyrocketing drug prices should be disseminated quickly.

Third, this FOIA request "specifically concerns identifiable operations or activities of the Federal Government."[10] Here, the requested records will shed light on the operations or activities of the FDA, an agency of the federal government, in implementing the Canadian drug importation program.

As required by federal regulation,[11] I hereby certify that the above information is true and correct to the best of my knowledge and belief.

Request for a Public Interest Fee Waiver

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[5] *See* AHCA Website, https://ahca.myflorida.com (2022)

[6] *Id.* § 20.44(c)(2).

[7] *See* Agency for Healthcare Research and Quality Website, *Medical Expenditure Panel Survey Household Component*, https://datatools.ahrq.gov/meps-hc?type=tab&tab=mepshcpd (2022).

[8] *See* U.S. Dep't of Health and Human Serv., Comprehensive Plan for Addressing High Drug Prices, https://www.aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf?_ga=2.444 37804.947374691.1656625467-1666649285.1656625467 (2021).

[9] *Id.* at pg. 5 (emphasis supplied).

[10] *Id.* § 20.44(c)(3).

[11] *Id.* § 20.44(d).

The Requester requests a waiver of search, review, and duplication fees because disclosure of the requested records (1) "is likely to contribute significantly to public understanding of the operations or activities of the Government,"[12] and (2) "is not primarily in the commercial interest of the requester."[13]

Regarding the public understanding prong, *first*, the request concerns "identifiable operations or activities of the federal government."[14] As described above, the requested records will shed light on the operations or activities of the FDA in implementing the Canadian drug importation program.

Second, the request seeks "meaningful information about Government operations or activities that is not already public knowledge."[15] Here, the information is meaningful because the availability of quality, low-cost drugs is a matter of great public interest and concern in Florida, as elsewhere, and this information will bring greater public understanding to the Canadian drug importation program and the FDA's efforts to implement that program. In addition, this information is not already public knowledge. To date, neither the FDA nor any other government agency has released the information sought in this FOIA request.

Third, the requested information "will advance the understanding of the general public as distinguished from a narrow segment of interested persons," the Requester has the "knowledge or expertise as may be necessary to understand the information," and the Requestor's "intended use of the information would be likely to disseminate the information to the public."[16] As described above, AHCA is a state agency "responsible for the administration of the Florida Medicaid program, licensure and regulation of Florida's health facilities, and for providing information to Floridians about the quality of care they receive."[17] By definition, AHCA has the knowledge and expertise to understand the information sought and to facilitate its public dissemination quickly and effectively. And, as described, AHCA will disseminate this information to the public.

Lastly, "the public's understanding of the Government's operations [would] be substantially greater as a result of the disclosure."[18] As stated, the Requester intends to disseminate any information obtained through this request to the public, contributing to the public's enhanced understanding of the Canadian drug importation program and the FDA's role in implementing the program. To date, the FDA has not released any of the information sought in this FOIA request. Because the disclosure will be the first such disclosure to the public about an important government program, the public's understanding of the FDA's operations will be substantially greater than it is currently.

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[12] 5 U.S.C. § 552(a)(4)(A)(iii); 21 C.F.R. § 20.46(a)(1).

[13] 5 U.S.C. § 552(a)(4)(A)(iii); 21 C.F.R. § 20.46(a)(2).

[14] 21 C.F.R. § 20.46(b)(1).

[15] 21 C.F.R. § 20.46(b)(2).

[16] 21 C.F.R. § 20.46(b)(3).

[17] *See* AHCA Website, https://ahca.myflorida.com (2022)

[18] 21 C.F.R. § 20.46(b)(4).

Regarding the commercial interest prong, the Requester does not have any commercial interest in the disclosure of the requested records.[19] AHCA does not seek to commercially benefit from this information. Nor could it possibly do so. Rather, the dissemination of information to the public will be at no cost and for the purpose of educating the public and promoting AHCA's mission.

Request for Records in Electronic Format

The Requester requests that responsive electronic records be provided electronically in their native file format, if possible.[20] Alternatively, the Requester requests that the records be provided electronically in text-searchable PDF, in the best image quality in the FDA's possession, and in separate, Bates-stamped files. The Requester further requests that you provide an estimated date on which you will finish processing this request.[21]

* * *

If this FOIA request is denied in whole or in part, please provide the reasons for the denial, pursuant to 5 U.S.C. § 552(a)(6)(A)(i). In addition, please release all segregable portions of otherwise exempt material in accordance with 5 U.S.C. § 552(b).

Please do not hesitate to contact either me, or Assistant Deputy Secretary Jason C Weida, should you have any questions.

Sincerely,

Simone Marstiller
Secretary

cc: Assistant Deputy Secretary Jason C. Weida (by email only)
Email: Jason.Weida@ahca.myflorida.com
Phone: 850-412-4118

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[19] 21 C.F.R. § 20.46(c).

[20] *See* 5 U.S.C. § 552(a)(3)(B); *Scudder v. Cent. Intelligence Agency*, 25 F. Supp. 3d 19 (D.D.C. 2014) ("When an agency already creates or converts documents in a certain format . . . requiring that it provide documents in that format to others does not impose an unnecessarily harsh burden, absent specific, compelling evidence as to significant interference or burden." (quoting *TPS, Inc. v. Dep't of Defense*, 330 F.3d 1191 (9th Cir. 2003))).

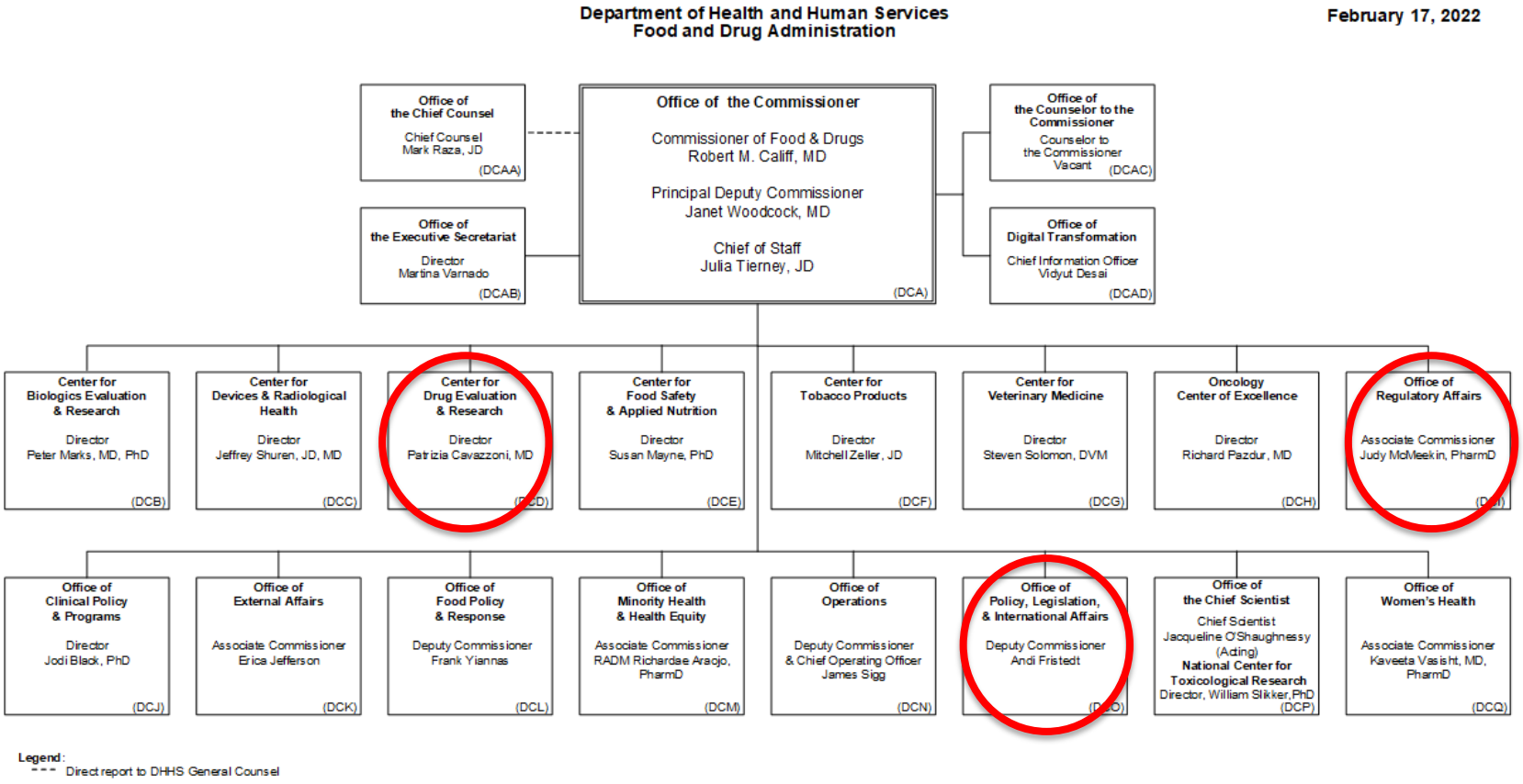
[21] *See* 5 U.S.C. § 552(a)(6)(B).

TAB A

Section 804 Importation Program: Overview of Final Rule and Implementation

Carole Jones
Director, Division of Global Drug Distribution and Policy
Office of Drug Security, Integrity and Response
Center for Drug Evaluation and Research, Office of Compliance
U.S. Food and Drug Administration

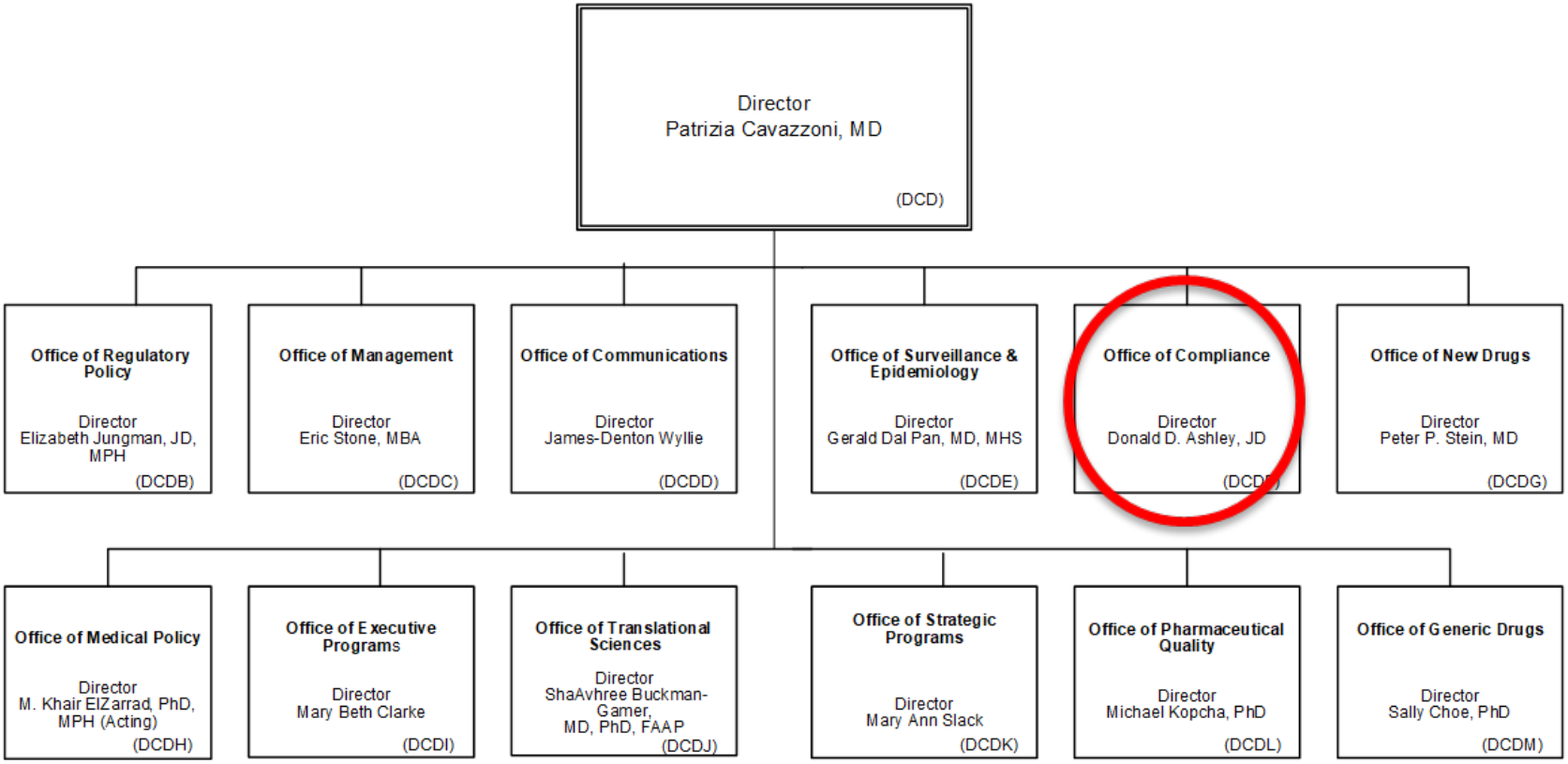
Who We Are


Department of Health and Human Services
Food and Drug Administration
February 17, 2022
Office of the Chief Counsel
Chief Counsel
Mark Raza, JD
(DCAA)
Office of the Executive Secretariat
Director
Martina Varnado
(DCAB)
Office of the Commissioner
Commissioner of Food & Drugs
Robert M. Califf, MD
Principal Deputy Commissioner
Janet Woodcock, MD
Chief of Staff
Julia Tierney, JD
(DCA)
Office of the Counselor to the Commissioner
Counselor to the Commissioner
Vacant
(DCAC)
Office of Digital Transformation
Chief Information Officer
Vidyut Desai
(DCAD)
Center for Biologics Evaluation & Research
Director
Peter Marks, MD, PhD
(DCB)
Center for Devices & Radiological Health
Director
Jeffrey Shuren, JD, MD
(DCC)
Center for Drug Evaluation & Research
Director
Patrizia Cavazzoni, MD
(DCD)
Center for Food Safety & Applied Nutrition
Director
Susan Mayne, PhD
(DCE)
Center for Tobacco Products
Director
Mitchell Zeller, JD
(DCF)
Center for Veterinary Medicine
Director
Steven Solomon, DVM
(DCG)
Oncology Center of Excellence
Director
Richard Pazdur, MD
(DCH)
Office of Regulatory Affairs
Associate Commissioner
Judy McMeekin, PharmD
(DCI)
Office of Clinical Policy & Programs
Director
Jodi Black, PhD
(DCJ)
Office of External Affairs
Associate Commissioner
Erica Jefferson
(DCK)
Office of Food Policy & Response
Deputy Commissioner
Frank Yiannas
(DCL)
Office of Minority Health & Health Equity
Associate Commissioner
RADM Richardae Araojo, PharmD
(DCM)
Office of Operations
Deputy Commissioner & Chief Operating Officer
James Sigg
(DCN)
Office of Policy, Legislation, & International Affairs
Deputy Commissioner
Andi Fristedt
(DCO)
Office of the Chief Scientist
Chief Scientist
Jacqueline O'Shaughnessy
(Acting)
National Center for Toxicological Research
Director, William Slikker, PhD
(DCP)
Office of Women's Health
Associate Commissioner
Kaveeta Vasisht, MD, PharmD
(DCQ)
Legend:
Direct report to DHHS General Counsel

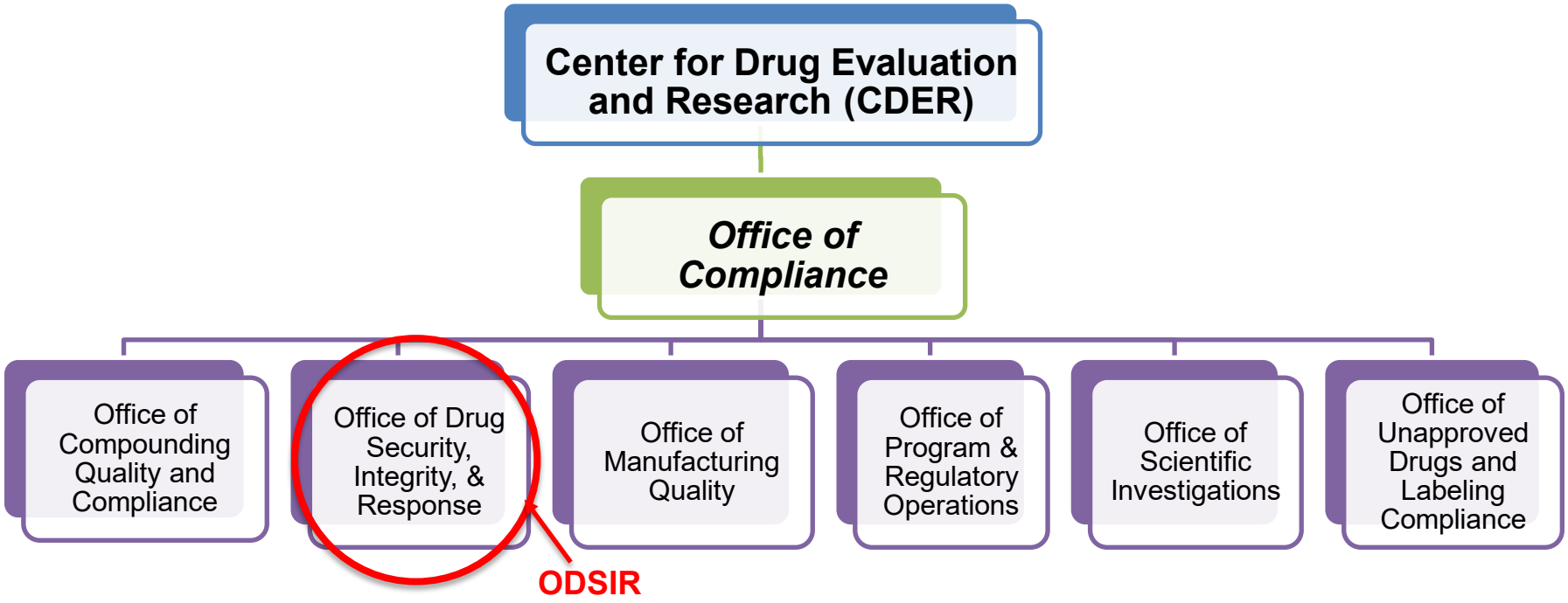
Who We Are

September 2021

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research



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.

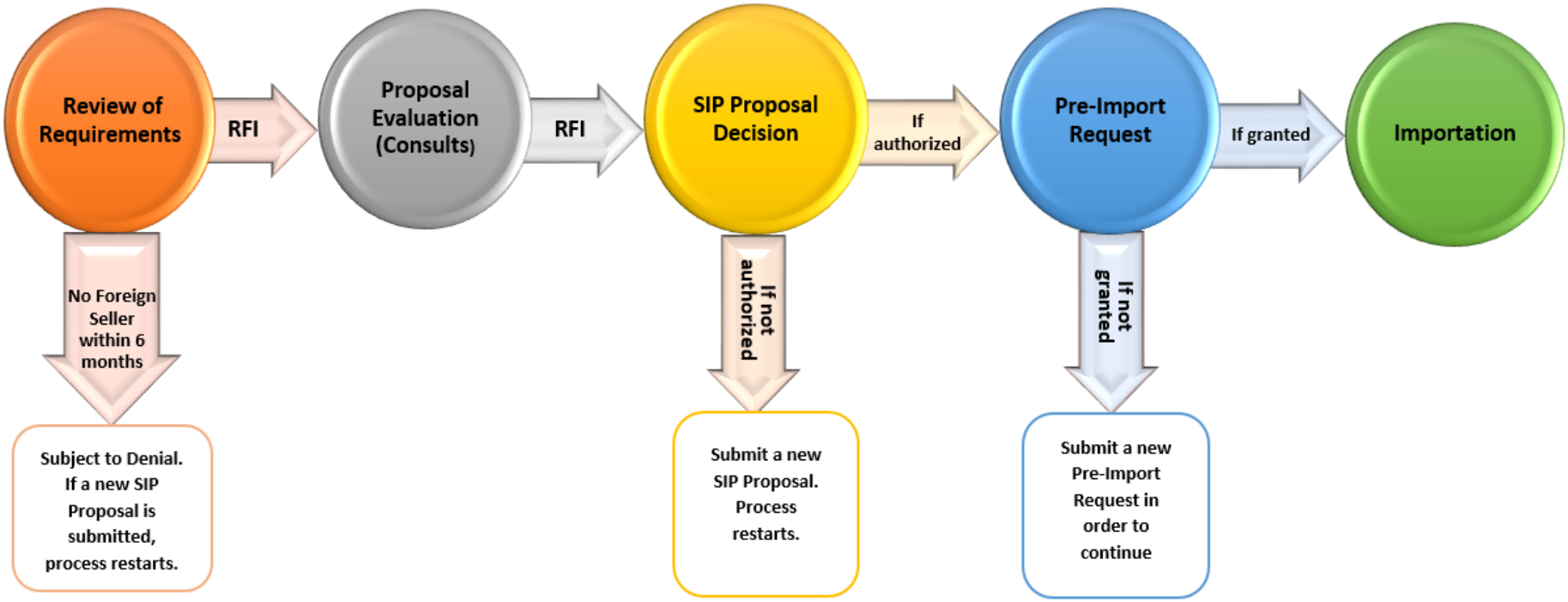
Overview of the Final Rule

- 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



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.


FDA
U.S. FOOD & DRUG
ADMINISTRATION

TAB B

Projecting Cost Savings for the American Consumer

Aaron Kearsley

Senior Economist and Acting Director

Division of Science and Public Health Policy

Office of Science and Data Policy

April 31, 2022

Aaron.Kearsley@hhs.gov

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Evaluation

§ 251.3 SIP proposal submission requirements

- (e) The SIP Sponsor's importation plan must:

  …

- (9) Explain how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP Sponsor seeks to import. The explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation.

Analysis of Cost Savings

- Discussion today draws on principles HHS identifies as best practices for benefit-cost analysis
- The HHS *Guidelines for Regulatory Impact Analysis* discuss this widely-used framework for collecting, organizing, and evaluating data on the anticipated consequences of regulatory actions
- Other analytical approaches may be appropriate. Note that the SIP Proposal's cost-saving "explanation must include any assumptions and uncertainty, and it must be sufficiently detailed to allow for a meaningful evaluation." The SIP Proposal's discussion of assumptions should include an explanation of the analytic approach adopted by the SIP Sponsor.

Measuring Total Cost Savings

- Terminology
  - **Plan Scenario**: a projection of the total expenditures the SIP Sponsor anticipates if the SIP Proposal is authorized and implemented
  - **Baseline Scenario**: a projection of the total expenditures the SIP Sponsor anticipates if the SIP Proposal is not authorized and implemented
  - **Cost Savings**: the difference between the total expenditures under the Plan Scenario and the Baseline Scenario

Measuring Total Cost Savings

- Plan Scenario should cover:
  - Annual projections of the anticipated total expenditures for each year for at least the first two years of the SIP
  - Identify the calendar year, or specific 12-month period covered for each year of the analysis
- For example, an SIP Sponsor could identify that the projections cover 2023 and 2024

Measuring Total Cost Savings

- Baseline Scenario should cover:
  - time period covered under the Plan Scenario
  - time period between the most recent year of drug pricing data the Plan Scenario projections
- For example, if the SIP covers 2023 and 2024 and the drug pricing data are from 2020, the Baseline Scenario should cover 2020-2024

Measuring Cost Savings

- The SIP Proposal should contain expenditure projections for each drug under the Plan Scenario and Baseline Scenario
  - The sum of these drug-specific expenditure projections should be consistent with the total expenditure projections for each scenario
  - These drug-expenditure projections should include quantity and per-unit price estimates

Measuring Prices

- The SIP Sponsor should adopt an analytic approach for estimating cost savings that is appropriate in the context of the specific Proposal
- When measuring drug price:
  - "To demonstrate expected cost savings, a SIP Sponsor could compare **anticipated acquisition costs or consumer prices per unit** of each eligible prescription drug that the SIP Sponsor is seeking to import. A SIP Sponsor could also compare the current **retail cash price** of the drugs." (85 FR 62101)

Measuring Prices

- It is generally not sufficient to identify differences in drug prices between the United States and Canada
- The SIP Proposal should demonstrate that the SIP Sponsor will be able to leverage these drug price differences for the eligible prescription drugs identified in the SIP Proposal and and that the SIP will result in cost savings for the American consumer
- Critically, the SIP Proposal should assess cost savings from comparable price measures for the Baseline Scenario and Plan Scenario

Measuring Prices

- The SIP Proposal should include all costs associated with implementation anticipated by the SIP Sponsor:
  - Importer price markups
  - Other transportation and logistical costs not captured by the importer price markup
  - Costs associated with drug samples, testing, and other requirements under Section 804 and the Importation of Prescription Drugs Final Rule
- The SIP Proposal should account for these costs when reporting the projected cost savings

Analytic Principles

- The analysis contained in the SIP Proposal should be transparent and contain enough information about the data and methods to facilitate the reproducibility of its major findings
- The SIP Proposal should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates
- The SIP Proposal should provide adequate citations of data sources used in the compiling of the underlying estimates for all quantitative elements
- The SIP Proposal should reference drug pricing data that are sufficient to project annual expenditures projections for each drug under the Plan Scenario and Baseline Scenario

Additional Considerations

- The Plan and Baseline Scenario projections should be consistent with reasonable assumptions of potentially related trends
- The SIP Sponsor could consider providing a framework for ex-post quantitative evaluation of the SIP Proposal projections, should the SIP Sponsor seek to renew the SIP at the conclusion of two years