IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 8:22-cv-1981-TPB-JSS

STATE OF FLORIDA, et al.,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION, et al.,
Defendants.

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR A PROTECTIVE ORDER

On November 29, Defendants moved for a protective order "prohibiting [Plaintiffs] from moving to compel compliance with previously served discovery requests or serving any additional requests unless such discovery has been expressly authorized by the Court." Motion 2, ECF No. 29.

Defendants are wrong that Plaintiffs are not entitled to discovery on their claim for agency inaction. Discovery is appropriate, well-supported by caselaw, and necessary for the Court's merits review of Plaintiffs' agency inaction claim. But, in any event, Defendants are not entitled to a protective order, much less the sweeping protective order they seek shutting down all discovery in this case.

The Court has already scheduled a case management conference for December 13, at which time the Court may wish to resolve the parties' dispute about whether Plaintiffs are entitled to discovery on their agency inaction claim—an issue that was addressed at length in the parties' Case Management Report. *See* ECF No. 27 at 1–5 (explaining parties' competing discovery positions); Notice, ECF No. 28 (scheduling December 13 conference). In the meantime, Defendants suffer no harm—a prerequisite for a protective order—because they are free to serve objections to any discovery they believe is inappropriate, and Plaintiffs have not indicated that they intend to move to compel responses to the previously served discovery requests or serve additional discovery requests before the December 13 conference.

The Court should deny Defendants' request for a protective order preemptively shutting down the normal discovery process for the entirety of this litigation.

ARGUMENT

I. Discovery is Appropriate on Plaintiffs' Agency Inaction Claim.

Defendants assert that Plaintiffs' Administrative Procedure Act ("APA") agency inaction claim is exempt from discovery because it is allegedly "an action for review on an administrative record." L.R. 3.02(d)(2); *see* Motion 6, ECF No. 29. But Plaintiffs' APA claim alleges agency *inaction*, and courts routinely hold that such claims are not resolved on an administrative record

because there is no final agency action in the first place, and thus no administrative record to "support" any such action.

As one court aptly explained: "When it comes to agency inaction under 5 U.S.C. § 706(1), 'review is not limited to the record as it existed at any single point in time, because there is no final agency action to demarcate the limits of the record.' … Therefore, 'there may well be reason for discovery, since agency delay is not necessarily a discrete event resulting from a decision based upon some sort of administrative record, but may be simply ... after-the-event justifications [] which may need to be explored by plaintiffs.'" *W. Watersheds Project v. Pool*, 942 F. Supp. 2d 93, 100–01 (D.D.C. 2013) (citations omitted). Many courts have agreed. *See Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 560 (9th Cir. 2000); *Tribe v. Bureau of Land Mgmt.*, 2022 WL 1778525, at *5 (E.D. Cal. June 1, 2022); *Gona v. USCIS*, 2021 WL 1226748, at *2 (D.D.C. Apr. 1, 2021); *Red Wolf Coal. v. U.S. Fish & Wildlife Serv.*, 210 F. Supp. 3d 796, 802 (E.D.N.C. 2016); *Nat'l Law Ctr. on Homelessness & Poverty v. U.S. Dep't of Veterans Affairs*, 842 F. Supp. 2d 127, 130 (D.D.C. 2012); *Sierra Club v. U.S. Dep't of Transp.*, 245 F. Supp. 2d 1109, 1119 (D. Nev. 2003); *Cobell v. Babbitt*, 91 F. Supp. 2d 1, 38 (D.D.C. 1999).[1]

[1] Defendants' extensive citation to *Sierra Club v. U.S. Dep't of Energy*, 26 F. Supp. 2d 1268 (D. Colo. 1998), is unpersuasive. *See* Motion 9–10, ECF No. 29. Although the plaintiff there alleged agency inaction, there was no claim of unlawful delay, as here, which requires additional information about the decision-making process itself. The

Discovery is often appropriate in agency inaction cases for the additional reason that courts need more information than any sparse administrative record could provide. For example, "an isolated administrative record would not allow the Court to determine whether the agency adheres to a rule of reason in adjudicating [plaintiffs'] applications," making discovery "necessary to resolve [the APA] inaction claim." *Gona*, 2021 WL 1226748, at *2. That consideration is a key part of Plaintiffs' APA inaction claim here. *See* Am. Compl. ¶¶ 90–95, ECF No. 7; *see also* Part II, *infra*.

Defendants cite several cases stating that an administrative record is the "focal point" for review, Motion 6, ECF No. 29, or that discovery is presumptively unavailable in APA cases, *id.* at 12–13, but those cases involved challenges to final agency action, not claims of agency inaction, *see, e.g.*, *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 732 (1985); *Marllantas, Inc. v. Rodriguez*, 806 F. App'x 864, 866 (11th Cir. 2020); *Pres. Endangered Areas of Cobb's Hist., Inc. v. U.S. Army Corps of Engineers ("PEACH")*, 87 F.3d 1242,

court also acknowledged that "indications of agency policy preferences, and past conduct of the agency" would be relevant "to determine whether an agency unlawfully withheld agency action required by law," but the discovery requests in that case were not relevant to those issues. By contrast, Plaintiffs in this case have requested information, for example, about "past conduct of the agency" diverting foreign drugs to the United States pursuant to other programs, *see* Part II, *infra*, which *Sierra Club* does not foreclose. And even if *Sierra Club* stood for the broad proposition Defendants' assert—which it does not—it is outweighed by the many cases concluding discovery is appropriate when assessing agency action unlawfully withheld or unreasonably delayed.

1246 (11th Cir. 1996); *Wall v. Centers for Disease Control & Prevention*, No. 6:21-cv-975, 2021 WL 4948142, at *2 (M.D. Fla. Oct. 7, 2021) ("[A]ll parties agree this case is an action for review of an administrative record."); *Comprehensive Cmty. Dev. Corp. v. Sebelius*, 890 F. Supp. 2d 305, 312 (S.D.N.Y. 2012) ("[C]ourts have consistently recognized that, for the purpose of judicial review *of agency action*, deliberative materials antecedent to the agency's decision fall outside the administrative record." (emphasis added)).[2]

The rationale for precluding discovery in cases challenging final agency action is that a court should generally not "conduct its own investigation and substitute its own judgment for the administrative agency's decision." *PEACH*, 87 F.3d at 1246. But Plaintiffs do not ask this Court to second-guess final agency action. Rather, they ask the Court to compel the agency to take final agency action in the first place. Thus, contrary to Defendants' view, Plaintiffs

[2] Defendants' assertion that Plaintiffs "must first file a motion seeking authorization to conduct discovery," Motion 12, ECF No. 29 (quoting *Wall*, 2021 WL 4948142, at *2), is unpersuasive. It relies on an unpublished decision that in no way implicates agency inaction, and where all parties agreed review should be on the administrative record. *See Wall*, 2021 WL 4948142, at *2. In fact, that decision involved a 206-page complaint with 23 separate causes of action, *see Wall v. Centers for Disease Control & Prevention*, No. 6:21-cv-975, 2021 WL 3008588, at *1 (M.D. Fla. June 29, 2021), where the court had already "found that the motions to dismiss … are both clearly meritorious and completely dispositive of the claims" so "there is good cause to stay discovery." *Wall*, 2021 WL 4948142, at *1. The best case Defendants muster in support of their position is so clearly inapposite that it supports the reasonableness of Plaintiffs' position here.

are not asking this Court to "conduct a *de novo* inquiry" and "reach its own conclusions based on such an inquiry." ECF No. 27 at 4.

Defendants' position is also contrary to the U.S. Department of Justice's adamant assertions elsewhere that APA inaction claims are *not* resolved on an administrative record. *See Varghese v. Blinken*, 2022 WL 3016741, at *2 n.3 (D.D.C. July 29, 2022) ("The government maintains that [the required submission of a certified list of the administrative record] does not apply because this case concerns 'agency inaction, not agency action.' The Court agrees with the government. Because the agency here allegedly 'failed to act, there is no administrative record for a federal court to review.'") (cleaned up); *Arab v. Blinken*, ___ F. Supp. 3d ___, 2022 WL 1184551, at *4 n.2 (D.D.C. Apr. 21, 2022) (same); *Thakker v. Renaud*, 2021 WL 1092269, at *5 n.10 (D.D.C. Mar. 22, 2021) (same); *Desai v. USCIS*, 2021 WL 1110737, at *5 n.7 (D.D.C. Mar. 22, 2021) (same); *Palakuru v. Renaud*, 521 F. Supp. 3d 46, 50 n.6 (D.D.C. 2021) (same). It seems the federal government's position changes based on whether it suits the particular litigation. But the government cannot have it both ways.

Defendants' decision to file an Answer in this case, rather than a motion to dismiss, also demonstrates that the issues in this case are factual in nature, confirming the need for discovery on Plaintiffs' APA inaction claim.

Discovery is warranted for yet an additional reason: There is evidence of Defendant Food & Drug Administration ("FDA") engaging in improper behavior by sending a 15-page single-spaced "Request for Information" to Plaintiff AHCA (copy attached as Exhibit A). The timeline of FDA's interactions with Plaintiffs demonstrates the extremely unusual timing of this RFI. Florida's SIP Proposal was originally submitted in November 2020, and it contained all necessary information, except for details about the foreign seller that would obtain prescription drugs in Canada and resell them to Florida. Am. Compl. ¶ 49, ECF No. 7. The FDA's own regulations allow the foreign seller information to be submitted up to six months after the proposal itself, 21 C.F.R. § 251.4, and Florida submitted that last piece of information in April 2021. Am. Compl. ¶ 52, ECF No. 7. In August and November 2021, the FDA asked several minor clarifying questions, which Plaintiffs promptly answered. *Id.* ¶¶ 57–58.

Since then, for an entire year, the FDA has made no further requests for information from Plaintiffs, despite Florida officials persistently asking the FDA for progress on evaluating Florida's SIP Proposal. *Id.* ¶¶ 55, 59–72. Yet on the eve of the parties filing the Case Management Report with this Court, the FDA apparently decided there are actually dozens of items missing from Florida's SIP Proposal. The RFI seeks to deflect attention from Defendants' extensive delay by purporting to put the ball back in Plaintiffs' court.

Moreover, suddenly conjuring so many supposed defects after nearly two years—during which time the FDA sought only minor clarifications—strongly suggests a desire by Defendants to avoid judicial scrutiny of their inaction and suggests the agency recognizes its delay has been unreasonable.

A review of the RFI confirms that it is a stall tactic. Many of the requests are the direct result of the FDA's own dilatory behavior, which has led to outdated information (e.g., "The SIP Sponsor is encouraged to adopt more recent price and utilization data and to provide data covering a longer time period."; "Repacker/relabeler registration included in the SIP Proposal is expired."; "Please ensure that your proposed labeling is based on the most recent version of the FDA-approved labeling."; "Please provide the current ISO 17025 accreditation certificates for the four laboratories identified in the SIP Proposal."; "[P]lease submit the latest version of the FDA-approved labeling….").

Other requests in the RFI generically ask Florida to "describe" or "provide" information about compliance with certain requirements but provide no explanation for why prior submissions were inadequate. Another asks for information from the "Orange Book," which is the FDA's *own* publication and thus is easily available to the FDA. Although other requests provide more specifics, it is unclear why it took the FDA so long to make these inquiries based on materials submitted by Florida long ago—unless, of course, the FDA's

goal all along has been to stall as long as possible. Moreover, the RFI does not even state that it is an exhaustive list, meaning the FDA could keep this process going indefinitely to give the false appearance of making progress on Florida's SIP Proposal.

If the FDA truly believed any of this information was necessary, the FDA would have asked for it a year ago. By waiting to send this list only after Plaintiffs sued and on the eve of the parties filing their Case Management Report, the FDA's actions indicate that it is trying to avoid scrutiny of its nearly two-year-long delay in adjudicating Florida's SIP Proposal.

Defendants argue that a strong showing of bad faith is required to obtain discovery in an APA case, but that is only in final agency action cases, where (as discussed above) courts generally cannot substitute their own judgment for the agency's, and thus inquiries into final agency actions and thought processes are generally disfavored. *See PEACH*, 87 F.3d at 1246. But that is not the rule in agency inaction cases, where a court must evaluate the propriety of an agency's delay. Under the *TRAC* factors used to evaluate agency delay and inaction cases, improper agency behavior is not required, but its presence is a strong indication of unreasonable agency delay, *see TRAC v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984), and thus it is fair game for discovery in an agency inaction case like this one.

For all these reasons, discovery is appropriate on Plaintiffs' agency inaction claim, and Plaintiffs have already begun the discovery process to ensure it does not delay the resolution of this matter. In particular, on October 25, Plaintiffs served interrogatories, requests for production, and requests for admissions on Defendants (these documents were also served via certified mail sent October 27); and on November 15, Plaintiffs served initial disclosures on Defendants.

II. Plaintiffs' Discovery Requests Seek Information Targeting the *TRAC* Factors.

Defendants challenge the relevance of only a small handful of the discovery requests Plaintiffs served. *See* ECF Nos. 29-1, 29-2, 29-3. Defendants argue that these few requests seek "immaterial" information that is "not discoverable" because it "explore[s] the mindset and inner workings of agency officials." Motion 15, ECF No. 29. This implicitly concedes the relevance of the other discover requests. But Defendants are also wrong about the few requests to which they object, which seek only factual information directly relevant to the *TRAC* factors used to determine whether agency action has been unreasonably delayed.[3]

[3] The *TRAC* factors are: (1) "the time agencies take to make decisions must be governed by a rule of reason"; (2) "where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason"; (3) "delays that might be reasonable in the sphere of economic regulation are less tolerable when

For example, Defendants suggest that agency records reflecting or referencing "whether additional information is needed to evaluate [Florida's SIP] proposal" is irrelevant or will probe officials' "mindset," Motion 14, ECF No. 29 (citing Request for Production 4), but whether Defendants genuinely need more information from Plaintiffs for review of Florida's SIP Proposal—or instead have largely been stalling for nearly two years—is directly relevant to the *TRAC* factors subjecting agency inaction to "a rule of reason," *TRAC*, 750 F.2d at 80, looking to whether there has been "impropriety," *id.*, and also inquiring into whether "human health and welfare are at stake," *id.*

Defendants likewise label as immaterial an interrogatory asking for a list of steps they have taken "to implement Executive Order 14036's directive that defendants work with states to develop Section 804 prescription drug importation programs." Motion 15, ECF No. 19 (quoting Interrogatory 11). Defendants do not explain how a listing of historical facts could probe officials' "mindset," and, in any event, Defendants' *bona fide* implementation (or not) of that Executive Order speaks directly to the *TRAC* factors asking about impropriety and subjecting an agency to a "rule of reason" analysis. If the FDA

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human health and welfare are at stake"; (4) "the effect of expediting delayed action on agency activities of a higher or competing priority"; (5) "the nature and extent of the interests prejudiced by delay"; and (6) "the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed." *TRAC*, 750 F.2d at 80.

is not implementing the sitting President's own directive for these prescription drug reimportation proposals, it is strong evidence that the FDA is not conducting its review of Florida's SIP Proposal in a reasonable manner.

Defendants also object to an interrogatory asking for a list of drugs the FDA has "diverted into the U.S. market" to alleviate or mitigate drug shortages, Motion 15, ECF No. 29 (quoting Interrogatory 14), but again a listing of historical facts does not "explore the mindset and inner workings of agency officials," *id.* at 15. The material is relevant because the FDA has suggested that its delay is partially due to a lack of information about the safety of prescription drugs imported from Canada, *see* RFI 10, ECF No. 27-1, but that explanation would be demonstrably unreasonable and improper if the FDA is routinely authorizing drugs to be imported from Canada pursuant to other programs. If Defendants are suggesting that this interrogatory is irrelevant because they in fact have no safety concerns about Florida's SIP Proposal, then Plaintiffs would be willing to withdraw the interrogatory in exchange for a short stipulation on the matter from Defendants.

The propriety and relevance of the information and documents sought by Plaintiffs' discovery requests is confirmed by the fact that Defendants muster only these unpersuasive objections to a handful of discovery requests. Discovery in this case would thus be beneficial for the Court's review of Defendants' inaction and delay under the *TRAC* factors. If Defendants object

to specific discovery requests, the proper course would be to timely lodge those objections and confer with Plaintiffs, rather than file a motion for a protective order asking for the preclusion of all discovery.

Finally, Defendants contend that a forthcoming administrative record "may" prove adequate, Motion 11, ECF No. 29, recognizing the distinct possibility it will not. This concession is reinforced by Defendants' contention that even those discovery requests directly relevant to *TRAC* factors allegedly seek information that is "immaterial," *id.* at 15, making it clear that Defendants' administrative record will not include the information the Court needs for its review under the *TRAC* factors. Accordingly, discovery is not just appropriate but also necessary.

III. Plaintiffs' Discovery Requests Were Not Premature.

In passing, Defendants suggest that Plaintiffs' discovery requests were premature, *see* Motion 8 n.2, ECF No. 29, but Defendants served their discovery requests nearly a week after the Rule 26(f) conference, which traditionally marks the beginning of discovery in this Court, *see, e.g., Taser Int'l, Inc. v. Phazzer Electr., Inc.*, No. 6:16-cv-366, 2022 WL 1238472, at *2 (M.D. Fla. Feb. 16, 2022) ("Discovery is normally barred prior to a Rule 26(f) conference."); *see also* Case Management Report, ECF No. 27 at 1 (Rule 26(f) conference held October 19); ECF No. 29-1 at 10, ECF No. 29-2 at 8, ECF No. 29-3 at 9 (discovery requests served on October 25).

It appears Defendants believe the parties' October 19 case management conference was not a Rule 26(f) conference, but the Case Management Report—the substance of which consumed nearly the entirety of that conference—expressly says it is being submitted "under Rule 26(f)(2)," ECF No. 27 at 10, which provides the required "content" for a Rule 26(f) conference.

Because Plaintiffs' discovery requests were served after the Rule 26(f) conference, they were not premature.

IV. A Protective Order Is an Improper Remedy.

For several reasons, there is no need for the drastic relief of a protective order preemptively shutting down the normal discovery process in this case.

First, Defendants can show no harm from Plaintiffs' discovery requests. "'Generally, a party moving for a protective order must make a specific demonstration of facts in support of the request, as well as of the harm that will result without a protective order.'" *Gov't Emps. Ins. Co. v. Glassco Inc.*, No. 8:19-cv-1950-KKM-JSS, 2020 WL 13357816, at *2 (M.D. Fla. July 31, 2020). On November 15, Plaintiffs offered to extend the discovery response deadline if Defendants needed additional time to prepare substantive responses, but Plaintiffs stated that if Defendants objected to discovery altogether, they should lodge a "timely objection." Defendants remain free to serve objections to any discovery requests they believe are inappropriate. But Defendants instead chose to seek a protective order even though the Court may resolve the

parties' discovery disputes at the December 13 conference. Nor have Plaintiffs indicated that they intend to move to compel responses or serve additional requests before the December 13 conference. Without any harm, Defendants are not entitled to a protective order.

Second, even if the Court declines to authorize certain discovery requests at the December 13 hearing, other discovery requests may be appropriate, and it would be improper to preemptively preclude Plaintiffs from serving *any* discovery requests for the entirety of the litigation, as Defendants request. Rather, the appropriate mechanism for resolving such disputes, should they arise, is for Defendants to timely object and then consult with Plaintiffs, who may then choose to move to compel responses (or not). That is the standard mechanism for addressing discovery disputes. It is unnecessary and inappropriate to seek a protective order shutting down all discovery at this early stage.

CONCLUSION

The Court should deny Defendants' motion for a protective order.

Dated: December 1, 2022

Respectfully submitted,

ASHLEY MOODY
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CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2022, I filed the foregoing via the Court's CM/ECF system, which will serve all counsel.

/s/ R. Trent McCotter
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Ex. A

November 16, 2022

Simone Marstiller, Secretary
Florida Agency for Health Care Administration
2727 Mahan Drive, Mail Stop #20
Tallahassee, FL 32308

Re: Florida Agency for Health Care Administration Section 804 Importation Program Proposal

Dear Secretary Marstiller,

This letter responds to the Section 804 Importation Program (SIP) Proposal that was initially submitted by the Florida Agency for Health Care Administration on November 23, 2020, and subsequently revised on: April 19, 2021, September 15, 2021, and November 15, 2021.

FDA welcomes your interest in pursuing a SIP and appreciates the efforts you have made to seek authorization of your proposal. Consistent with the July 2021 Executive Order on Promoting Competition in the American Economy, FDA is committed to working with States such as Florida and Indian Tribes that propose to develop SIPs under section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the final rule on Importation of Prescription Drugs (see 85 FR 62094; 21 CFR part 251). To assist you with this process, numerous subject matter experts at FDA and other components of HHS have carefully and thoroughly reviewed your revised SIP Proposal and prepared this letter, which identifies additional information that will help FDA complete our evaluation of your SIP Proposal. You may submit the requested information, which is detailed below in the order presented in 21 CFR part 251, to your current SIP Proposal or in a new SIP Proposal, along with all other required information. We look forward to continuing to work with you toward our shared goal of achieving a significant reduction in the cost of prescription drugs to the American consumer without posing additional risk to the public's health and safety.

Information on the Eligible Prescription Drugs:

- 251.3(d)(4) The overview of the SIP Proposal must include…the approved NDA or ANDA number.
    - Please ensure that your SIP Proposal includes the correct application number for each product. On page 12 of the SIP Proposal, the application number for the drug Genvoya is listed as ANDA 207561. The correct application number is NDA 207561.

- 251.3(e)(1) Identify…the manufacturer(s) of the finished dosage form and the active ingredient or ingredients of each eligible prescription drug that the SIP Sponsor seeks to import, if known or reasonably known…

  - Please clarify if the manufacturing facilities of the Health Products and Food Branch of Health Canada (HPFB)-approved and FDA-approved drugs are the same, if known or reasonably known. If different, the manufacturing location of the HPFB-approved product should be a location listed in the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA).

- 251.3(e)(5) …The SIP Sponsor's importation plan must also include as much of the information that is required by §251.5 about the HPFB-approved product and its FDA-approved counterpart as is available, including the name and quantity of the active ingredient, the inactive ingredients, and the dosage form.
  - The SIP Proposal appears to include information about the name and quantity of active ingredients, inactive ingredients, and dosage forms, but does not indicate if this information is applicable for both the HPFB-approved products and FDA-approved counterparts. Please clarify whether this information is the same for both versions. Also, please ensure that the information provided is accurate and as complete as possible given the information that is available. For example, for the drug Tradjenta, only mannitol is listed as an inactive ingredient, and for the drug Triumeq, lamivudine is not listed as an active ingredient. In addition, please note that there are instances where the proprietary names of FDA-approved drugs and HPFB-approved drugs are different. For example, Farxiga is the name of the FDA-approved drug and Forxiga is the name of the HPFB-approved drug.
  - For the list of drugs that follows, please clarify if you are planning to import all strengths and dosage forms that are approved in the U.S. or just those that are listed in the SIP Proposal: Biktarvy, Descovy, Epclusa, Harvoni, Intelence, Isentress, Kaletra, Mavyret, and Spiriva Respimat.

- 251.3(e)(6) Provide adequate evidence that each HPFB-approved drug's FDA-approved counterpart drug is currently commercially marketed in the United States.
  - You must provide supporting information to demonstrate that, for each HPFB-approved drug you are proposing to import, the FDA-approved counterpart drug is currently commercially marketed in the U.S. We recommend, at a minimum, including information from FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) to show that each drug product is listed in the Active Section.

Information on the Statutory Testing Requirements:

- 251.3(d)(11)(i) The overview of the SIP Proposal must include a summary of how the SIP Sponsor will ensure that the imported eligible prescription drugs meet the Statutory Testing requirements.
  - The SIP Proposal says that the State intends to partner with manufacturers that will perform required testing on each imported drug, but also suggests that for certain categories of drugs (for example, drugs that the SIP Proposal says are

"produced in the same facilities, on the same manufacturing lines, and contain identical specifications and standards") it will not be necessary to perform Statutory Testing on these products. Please clarify that the manufacturer or the Importer will arrange for drugs imported under the SIP to be tested by a qualifying laboratory. Laboratory testing requirements must include that a statistically valid sample of the HPFB-approved drug be subjected to testing to confirm that the HPFB-approved drug meets the FDA-approved drug's specifications and standards, which include the analytical procedures and methods and the acceptance criteria. We also note that to test for degradation, a stability-indicating assay provided by the manufacturer must be conducted on the sample of the drug that is proposed for import.

- Further, the SIP Proposal lacks a summary of the State's specific plans to ensure that drugs imported under the SIP meet the FDA-approved drug's specifications and standards.

- 251.3(e)(7) The SIP Sponsor's importation plan must describe, to the extent possible, the testing that will be done to establish that the HPFB-approved drug meets the conditions in the NDA or ANDA for the HPFB-approved drug's FDA-approved counterpart. The SIP Sponsor's importation plan must also identify the qualifying laboratory that will conduct the Statutory Testing for the Importer, if the Importer is responsible for conducting the Statutory Testing, and it must establish that the laboratory is qualified in accordance with § 251.15 to conduct the tests.
  - The SIP Proposal briefly states that appropriate testing will be performed on certain drug products that will be imported. However, it only contains a listing of kinds of analytical testing and examination that are to be used in determining a drug's characteristics and compliance with specifications and standards. The SIP Proposal is general in nature and lacks information, for either the HPFB-approved drug or the FDA-approved counterpart, related to the specific testing that will be done to establish that the HPFB-approved drug meets the conditions in the NDA or the ANDA for the FDA-approved counterpart (per § 251.3(e)(7)).
  - To the extent possible, relevant information must be provided that allows the FDA to confirm that the characteristics of the proposed imported drug conform to those of the FDA-approved drug. To the extent possible, please provide a description of and information about specific testing, analytical procedures and methods, and related acceptance criteria that will ensure that the HPFB-approved drug meets the conditions in the NDA or ANDA for the HPFB-approved drug's FDA-approved counterpart (per §§ 251.3(e)(7) and 251.16(d)).
  - We acknowledge that the SIP Proposal has stated that each of the four qualifying laboratories is ISO 17025 certified and provided each laboratory's certificate number. However, based on the information provided in the SIP Proposal, FDA is unable to verify that these accreditations are current. Please provide the current ISO 17025 accreditation certificates for the four laboratories identified in the SIP Proposal.
  - Please note that the acceptability of the qualifying laboratories could change. If a laboratory is inspected and receives an OAI (Official Action Indicated)

classification; or, if the ISO 17025 accreditation for one of the labs expires, that laboratory would no longer be considered acceptable. We recommend that the state develop a plan to assure the ongoing compliance of these laboratories and a contingency plan if one, or more, of these laboratories is no longer acceptable.

Information on History of Violations:

- 251.3(e)(2) Include an attestation and information statement containing a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the responsible individual(s)… or an attestation that the responsible individual(s)… has not been involved in, or convicted of, any such violations.
    - Please provide information specified in this section of the final rule for the responsible individuals identified in the SIP Proposal.

- 251.3(e)(3) Include a list of all disciplinary actions, to include the date of and parties to any action imposed against the responsible individual(s)…by State, Federal, or Canadian regulatory bodies…for the previous 7 years prior to submission of the SIP Proposal.
    - Please provide information specified in this section of the final rule for the responsible individuals identified in the SIP Proposal.

General Information Regarding the SIP:

- 251.3(e)(4)(ii) The State and Federal inspectional history for the Importer for the previous 5 years or, if the Importer has been licensed for less than 5 years, for the duration of its period of licensure.
    - In the SIP Proposal, LifeScience Logistics is associated with more than one address. Please explain what the role is for each address associated with LifeScience Logistics, LLC, and verify if there is inspectional history and current FDA registration for any address where SIP activities will occur.

- 251.3(e)(10) Explain how the SIP Sponsor will ensure that all the participants in the SIP comply with the requirements of section 804 of the FD&C Act and the final rule.
    - Please indicate the planned frequency of onsite inspections of the Importer's Florida warehouse.

- 251.3(e)(15)(iii) The SIP Sponsor's importation plan must include the SIP's compliance plan, which must include the creation of written compliance policies, procedures, and protocols.
    - Please provide specific written compliance policies, procedures, and protocols that have been created as part of the SIP's compliance plan.

- 251.3(e)(15)(iv) The SIP Sponsor's importation plan must include the SIP's compliance plan, which must include the provision of education and training to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related obligations.
    - Please provide the frequency of education and training under this requirement.

- 251.3(e)(15)(vi) The SIP Sponsor's importation plan must include the SIP's compliance plan, which must include the adoption of processes and procedures for uncovering and addressing noncompliance, misconduct, or conflicts of interest.
    - Please provide processes and procedures for uncovering and addressing conflict of interest.

- 251.3(e)(16) The SIP Sponsor's importation plan must explain how the SIP Sponsor will ensure that any information that the manufacturer supplies to authenticate a prescription drug being tested and confirm that the labeling of the prescription drug complies with labeling requirements under the FD&C Act, and any trade secrets or commercial or financial information that is privileged or confidential that the manufacturer supplies for the purposes of testing or otherwise complying with the FD&C Act and the final rule, are kept in strict confidence and used only for the purposes of testing or otherwise complying with the FD&C Act and the final rule.
    - Please provide a written policy regarding handling trade secrets or commercial or financial information that is privileged or confidential.

Information on Cost Savings:

- 251.3(d)(11)(v) The overview of the SIP Proposal must include a summary of 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.
- 251.3(e)(9) The SIP Sponsor's importation plan must 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.
    - Additional information is required to meaningfully evaluate the SIP Proposal's major finding that "Following full implementation, Florida is projecting over $150 million dollars in annual savings." Our evaluation approach starts by attempting to replicate the spending and cost-savings projections of the SIP Proposal, based on the data and assumptions included in the cost-savings analysis. As drafted, the SIP Proposal does not include the details necessary to enable this first step of cost savings evaluation. Additionally, we need the sponsor to identify the sources of their pricing and spending data, explain any assumptions, and confirm that the costs included in the analysis are comprehensive. Our evaluation will

also attempt to verify these sources of data, consider the reasonableness of these assumptions, and determine whether the cost-savings analysis is consistent with the other elements of the SIP Proposal and process outlined in the statute and final rule.

   a. The SIP Proposal does not contain a projection of the total expenditures the SIP Sponsor anticipates under the 'Plan Scenario' if the SIP Proposal is authorized and implemented.
   b. The SIP Proposal does not contain a projection of the total expenditures the SIP Sponsor anticipates under a 'Baseline Scenario' if the SIP Proposal is not authorized and implemented.
   c. The SIP Proposal should project cost savings for each year as the difference between the baseline costs anticipated under the Baseline Scenario and the 'Plan Scenario'.

- For the 'Plan Scenario', the SIP Proposal should contain annual projections of the anticipated total expenditures for each year of the proposed SIP, and identify the calendar year, or specific 12-month period covered, for each year of the analysis.
   a. The SIP Proposal reports a projection of total cost savings covering only one year, and does not identify the calendar year, or specific 12-month period for this projection.
   b. The SIP Proposal indicates "[W]hat Florida's population can save annually once the importation program's benefit fully matures should amount to the hundreds of millions", without identifying when the SIP Sponsor anticipates these cost savings.
- For the Baseline Scenario, the SIP Proposal should contain annual projections of the total expenditures covering at least the following: (1) the time period corresponding to the projections under the 'Plan Scenario', and (2) the time period between the most recent complete year of drug pricing data referenced in the SIP Proposal used to support the 'Plan Scenario' projections and the beginning of the 'Plan Scenario' projections. For example, if the SIP Proposal would be implemented in calendar years 2023 and 2024, and the most recent complete year of drug pricing data is calendar year 2018, the annual projection of the total expenditures under the Baseline Scenario should cover at least calendar years 2018 through 2024.
- 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.
- The SIP Proposal should contain price and quantity projections for each drug under the 'Plan Scenario' and Baseline Scenario. The product of the price and quantity projections should be consistent with the drug-specific expenditure projections for each scenario.
   a. The SIP Proposal includes price information for the Baseline Scenario for 37 drugs in 2018, and no other years.

b. The SIP Proposal includes price, quantity, and drug-specific expenditure data for the Baseline Scenario for 6 drugs in 2018 and no other years.
c. The SIP Proposal presents a table with “an example of the analysis conducted to determine the potential cost savings under the SIP using a sample of drugs used to treat HIV/AIDS,” referencing data that “represents utilization and costs for one quarter of 2018”. This example analysis, which contains several required elements, partially characterizes a ‘Counterfactual Scenario’ that the SIP Proposal was in effect in 2018; however, it does not include price, quantity, or drug-specific expenditure projections for the Baseline Scenario or ‘Plan Scenario’ for years covered under the SIP Proposal.

- 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.
  a. The analysis contained in the SIP Proposal references data for 6 drugs covering one quarter of 2018.
  b. As noted above, the November 11, 2021 version of the SIP Proposal does not contain price and quantity projections for each drug under the ‘Plan Scenario’ and Baseline Scenario for the years covered by the SIP Proposal. Revisions to this SIP Proposal should contain a narrative to justify that the drug pricing data are sufficient to project annual expenditure projections for each drug under the ‘Plan Scenario’ and Baseline Scenario.
- The SIP Proposal should explain the sources and magnitude of the uncertainty of the ‘Plan Scenario’ and Baseline Scenario projections.
  a. The SIP Proposal suggests the SIP Sponsor has identified a source of uncertainty in the cost saving projections, reporting that "For the first year, the State is conservatively projecting that it can save between approximately $80 to $150 million." The SIP Proposal should explain the sources of the uncertainty that support this range of cost-savings estimates.
- 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.
  a. The SIP Proposal should provide adequate citations of data sources used in the compiling of the underlying estimates for all quantitative elements, especially for the drug pricing and drug utilization elements.
  b. The SIP Proposal should explicitly report the magnitude of the markup to be applied to the listed Canadian price that the SIP Sponsor believes is likely to cover additional costs of importation and processing under the SIP. The SIP Proposal should provide sufficient justification for this assumption.
  c. The SIP Proposal should include estimates of other costs of implementation anticipated by the SIP Sponsor, including the costs of 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.

- The 'Plan Scenario' and Baseline Scenario projections should be consistent with reasonable assumptions of potentially related trends.
    a. For example, when projecting drug utilization, the SIP Sponsor could consider population growth rates; and when projecting drug-specific prices, the SIP Sponsor could consider trends in overall drug prices.
    b. The SIP Sponsor should consider accounting for drug-specific price and utilization trends in the Baseline Scenario. The SIP Proposal should document any drugs that are anticipated to lose marketing exclusivity during the time period covered in the Baseline Scenario, as indicated in FDA's Orange Book. For each of these products, the SIP Proposal should clearly state whether the SIP Sponsor anticipates any impact on the drug-specific price from this loss of exclusivity.
- In addition to addressing the above issues, please note the following:
    a. The SIP Sponsor must provide information about how the program 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. Note that, in response to public comment (85 FR 62101, Response 21), FDA indicated the following:
    "FDA intends to determine whether a reduction in cost is significant in the context of considering a specific proposal. The information needed to demonstrate anticipated cost savings to the American consumer will be dependent on the specific mechanisms which the SIP Proposal is using to reduce costs for American consumers. The SIP Proposal should clearly articulate the mechanism by which the proposal will reduce costs to consumers and provide relevant information given that context. 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. If the cost savings do not go to consumers directly, because, for example, they accrue to a healthcare provider or payor, the SIP Proposal would need to show that the SIP will result in a significant reduction in the cost of covered products to the American consumer. We anticipate that some SIP Sponsors may seek to import drugs to be used by patients in State-run programs in which consumers do not directly pay the cost of drugs. In such cases, a SIP Sponsor could submit information about whether cost-sharing expenses are reduced for the participants, or whether the program will result in cost savings that are passed on to consumers in other ways, such as increasing the number of people covered by a State program, or increasing the availability of drugs covered by the program."
    b. The SIP Sponsor is encouraged to adopt more recent price and utilization data and to provide data covering a longer time period.
    c. The SIP Sponsor is encouraged to provide 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. In particular the framework should include:

- Details of how the assumed markup to be added to the purchase price of Canadian drugs can be measured over the life of the SIP to enable more accurate future estimates of cost savings related to a renewal of the SIP.
- Details of how actualized savings can be measured ex-post implementation of the SIP and compared to initial projections of savings to the American consumer to provide a clear ex-post analysis of the original projections.

Information on the Recall Plan:

- 251.18(e)(3)(iii) The recall plan must include sufficient procedures for the SIP Sponsor to specify the depth to which the recall will extend (e.g., wholesale, intermediate wholesale, retail or consumer level) if not specified by FDA.
    - Please provide information specified in this section of the final rule.

- 251.18(e)(3)(iv) The recall plan must include sufficient procedures for the SIP Sponsor to notify the public about any hazard(s) presented by the recalled drug when appropriate to protect the public health.
    - Please provide information specified in this section of the final rule.

- 251.18(e)(3)(v) The recall plan must include sufficient procedures for the SIP Sponsor to conduct effectiveness checks to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action.
    - Please provide information specified in this section of the final rule.

Information on the Adverse Event Reporting Requirements:

- 251.3(d)(11)(iv) The overview of the SIP Proposal must include a summary of how the SIP Sponsor will ensure that the post-importation pharmacovigilance and other requirements of the FD&C Act and the final rule are met.
    - Please describe how the Importer will fulfill its post-importation pharmacovigilance obligations.

- 251.3(e)(11)(iv) The SIP Sponsor's importation plan must describe the procedures the SIP Sponsor will use to ensure that the requirements of the final rule are met, including the steps that will be taken to ensure that the Importer fulfills its responsibilities to submit adverse event, field alert, and other reports required by the SIP, the FD&C Act, or the final rule.
    - Please describe how the Importer will fulfill its responsibilities for, among other things, the surveillance, receipt, evaluation, reporting to FDA, and recordkeeping of adverse events.

Information on the Supply Chain Security Requirements:

- 251.3(e)(11) The SIP Sponsor's importation plan must describe the procedures the SIP Sponsor will use to ensure that the requirements of this part are met, including the steps that will be taken to ensure that the:
    - (i) Storage, handling, and distribution practices of supply chain participants, including transportation providers, meet the requirements of part 205 of this chapter and do not affect the quality or impinge on the security of the eligible prescription drugs
        - Please provide evidence of LifeScience Logistics licensure as a wholesale distributor in accordance with part 205.
    - (ii) Supply chain is secure
        - Please provide more information on the steps the SIP sponsor will take to ensure applicable supply chain security requirements are met. Areas not addressed or lacking specificity include:
            - Compliance with requirements on the SIP Sponsor, manufacturer, foreign seller, and importer under 21 CFR 251.14, including verification and product identifier requirements described therein.
            - Evidence that the wholesale drug distributor (WDD) is authorized (e.g., evidence of LifeScience Logistics licensure and annual reporting to FDA).
            - SIP participants' compliance with section 582 of the FD&C Act, as applicable (see e.g., 21 CFR 251.14(d)(2), (d)(6)).
            - LifeScience Logistics authorized as repackager – Repacker/relabeler registration included in the SIP Proposal is expired.

- 251.3(e)(14) The SIP Sponsor's importation plan must include the SIP's return plan, including an explanation of how the SIP Sponsor will ensure that product that is returned after distribution in the United States is properly dispositioned in the United States, if it is a non-saleable return, in order to protect patients from expired or unsafe drugs, and an explanation of how the SIP Sponsor will prevent the non-saleable returned eligible prescription drugs from being exported from the United States. In the event that a returned eligible prescription drug may be considered saleable, include an explanation for how the returned product will be determined to be saleable and under what circumstances such eligible prescription drugs may be re-distributed in the United States.
    - Please describe the return plan for ensuring non-saleable returned products (e.g., damaged, expired) are properly dispositioned in the U.S., including:
        - How the importer or designee will ensure non-saleable returned product is properly dispositioned in the United States.
        - How non-saleable returned product will be removed from the pharmaceutical distribution supply chain.

- Please describe how returned products will be determined to be saleable and under what circumstances such eligible prescription drugs may be re-distributed in the United States.

Information on the Proposed Labeling:

- Consistent with 21 CFR 251.3(e)(8), the SIP Sponsor's importation plan must include a copy of the FDA-approved drug labeling for the FDA-approved counterpart of the eligible prescription drug, a copy of the proposed labeling that will be used for the eligible prescription drug, and a side-by-side comparison of the FDA-approved labeling and the proposed labeling, including the Prescribing Information, carton and container labeling, and patient labeling (e.g., Medication Guide, Instructions for Use, patient package inserts), with all differences annotated and explained. The SIP Proposal must also include a copy of the HPFB-approved labeling.
  - You have provided the proposed Prescribing Information (PI) and FDA-approved patient labeling for your proposed imported drug followed in sequence by the PI and FDA-approved patient labeling for the source drug. Please provide a side-by-side comparison of the FDA-approved PI for the source drug and the proposed PI for the imported drug with all differences annotated and explained. Similarly, provide a side-by-side comparison of the FDA-approved patient labeling for the source drug and the proposed patient labeling for the imported drug with all differences annotated and explained.
  - Some of the images for the proposed carton and container labeling are clear; however, others are not clear. Please ensure that the images of all the proposed carton and container labeling are clear and legible. For example, the images of the carton labeling for Combivent Respimat are illegible.
  - For some of the proposed imported drugs, you submitted some of, but not all, the approved labeling and the proposed labeling. Please ensure that all approved and proposed labeling is provided in the SIP Proposal including all the carton and container labeling. For example, for Combivent Respimat, the carton labeling was provided, but not the inhaler label.
  - If your SIP Proposal does not include all the package sizes available for the FDA-approved counterpart, then please revise the HOW SUPPLIED/STORAGE AND HANDLING section of the proposed PI to delete package sizes that are not being imported. For example, the proposed PI for Latuda and Januvia include the bottle or package sizes and NDC numbers of the FDA-approved drug that are not being imported under the SIP Proposal. Thus, please remove such information from the PI.
  - Please ensure that your proposed labeling is based on the most recent version of the FDA-approved labeling.
    - The FDA-approved labeling for the NDA drug products can be found on Drugs@FDA. If such labeling is not available on Drugs@FDA, you may be

able to obtain the labeling from the manufacturers. You can also obtain it through a Freedom of Information Act (FOIA) request.
    - The FDA-approved labeling for Abbreviated New Drug Application (ANDA) drug products are typically not posted on Drugs@FDA. The labeling for FDA-approved ANDA drug products can be obtained through a FOIA request. You may also be able to obtain it from the manufacturers.
  - Please ensure that references to other labeling that appear in the Importer's labeling are linked to the importer's labeling.
    - For example, the proposed Instructions for Use for Combivent Respimat lists a link to the website that includes the FDA-approved source drug labeling, not the importer's labeling.

- Consistent with 251.13(b)(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, with certain exceptions.
  - Please ensure that the design of the container and carton labeling is the same as the FDA-approved carton and container labeling given that different corporate trade dress, format, and organization is not permitted under 251.13(b)(4). Several of your proposed carton and container have different corporate trade dress, format, and organization than the source drug's carton and container labeling.
    - Manufacturer's copyright references or logos should not be removed.
    - Some of your proposed container labels include the following country of origin phrase: 'Made in XXXX'. Please fill in the information.
    - Please ensure that the proposed labeling does not contain any additional statements not permitted in the final rule. For example, the proposed Emtricitabine and Tenofovir Disoproxil Fumarate Tablets container label states "Do not cover ALERT box with pharmacy label" which is not included in the FDA-approved label.
  - You proposed to change the term 'distributed by' to 'originally distributed by'. However, the term "originally distributed by" is not an allowable statement under 21 CFR 251.13(b)(4).
  - Please review all labeling for spelling and formatting errors. For example, the proposed Emtricitabine and Tenofovir Disoproxil Fumarate Tablets:
    - Container label states "Pharmicist" instead of "Pharmacist" and "See package interest" instead of "See package insert".
    - PI on page 46 states "A I brand" instead of "All brand".
    - The border lines for Table 2 on page 11 of PI are missing. Also, the Table reference should appear in smaller font under the Table. Currently, the legend appears in the same size font as the following paragraphs and may be misinterpreted to be a heading.
  - Although the labeling you submitted for several of the source drugs were the last FDA approved version, some were not. Given that the labeling of the imported drug must be the same as the FDA-approved labeling with some acceptable

differences, please submit the latest version of the FDA-approved labeling and ensure that the imported drug labeling is the same as the FDA-approved labeling except for the allowable exceptions.
    - The revision date should match the revision date of the latest FDA-approved labeling. When there is an update to the FDA-approved labeling in the future, the SIP labeling also needs to be updated.
    - Please ensure that the imprint code descriptions match the actual drug proposed to be imported. For example, for Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, the HPFB-approved drug labeling states that the tablets are light blue to blue, "TV" on one side and with "7607" on the other side. However, the proposed labeling states that the tablets are white to off-white with “TV” on one side and “C75” on the other side.

- Consistent with 251.13(b)(4)(i), please ensure that the Importer’s NDC replaces the NDC of the FDA-approved drug at the time of importation. For example, NDCs are not replaced in the HOW SUPPLIED/STORAGE AND HANDLING section of the proposed Epclusa PI.
    - At the time of importation, the Importer’s full NDC must replace any other NDC appearing on the label of the FDA-approved drug. Currently, the Importer’s NDC is listed as 42067-XXXX-XX.
        - The contents of linear barcode on the container and carton labeling should contain the importer’s NDC.

- Consistent with 251.13(b)(4)(iii), please ensure you add the name and place of business of the Importer to all proposed labeling including the PI, carton and container labeling, and patient labeling (e.g., Medication Guides (MGs), Instructions for Use (IFUs), Patient Package Inserts (PPIs)).
    - We recommend you add the importer’s information at the end of PI in addition to HOW SUPPLIED/STORAGE AND HANDLING section. We recommend you add the importer’s information at the end of the MG, IFU, and/or PPI.
        - The statement of the place of business should include the street address, city, State, and ZIP Code. The street address can be omitted if it is shown in a current city directory or telephone directory. If the importer’s street address is not shown in a current city directory or telephone directory, the street address of the importer should be added.
    - If the drug container is too small to fit the additional information required by this section or there is another reason to modify the labeling, you may submit a supplemental proposal to modify the labeling of an eligible prescription drug, in accordance with 251.13(d).

- Consistent with 251.13(b)(4)(iv), please ensure that correct firm names are listed in the statement for all labeling. For example, under HOW SUPPLIED/STORAGE AND HANDLING section of the proposed Latuda PI, Gilead Sciences is listed as the name of the applicant instead of the actual U.S. NDA holder, Sunovion Pharmaceuticals Inc.

  - Please ensure that the complete statement is used. For example, the carton labeling of Combivent Respimat is missing the phrase ‘under the [Name of SIP Sponsor] Section 804 Importation Program.’
  - Please ensure that 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” appears in the HOW SUPPLIED/STORAGE AND HANDLING section of the PI. For example, the statement appears in the PATIENT COUNSELING INFORMATION section of the Harvoni PI.

- Consistent with 21 CFR 251.13(c), please provide the written procedure for the relabeling process of your proposed imported prescription drugs.
  - If it is not possible to relabel a product without affecting the container closure system, such as a blister pack, then the product cannot be imported under a SIP as per the rule. The final rule does not allow repackaging of drugs that breaches the container closure system, such as a blister pack, which could introduce unnecessary risk of adulteration, degradation, and fraud for drugs imported under a SIP. The final rule also does not permit affixing a conforming label to the outside of the container closure system in lieu of relabeling the immediate container of the product. (i.e., repackaging the container closure is not permitted).
  - Farxiga, Tradjenta, Zepatier, Mavyret, Spiriva HandiHaler capsules are packaged in blister packs or dose packs according to the approved labeling. If relabeling these drug products would require breaching their container closure systems (e.g., breaking the foil on a blister pack), then that product cannot be imported under a SIP. Confirm that these products can be relabeled without breaching the container closure system. If not, remove any such drugs from the SIP.
  - Wixela is packaged in a moisture-protective foil pouch according to the approved labeling. The labeling also states that Wixela should be stored inside the unopened moisture-protective foil pouch and only removed from the pouch immediately before initial use and discarded 30 days after opening the foil pouch. If relabeling the inhaler would require opening the foil pouch, then Wixela cannot be imported under a SIP.
  - Incruse Ellipta is packaged in a moisture-protective foil tray according to the approved labeling. The labeling states that once the tray is opened, the inhaler should be discarded after 6 weeks. If relabeling the inhaler would require opening the foil tray, then Incruse Ellipta cannot be imported under a SIP.

Please indicate if you intend to provide the additional required information or if you would like to withdraw the current submission and resubmit at a later time. When submitting additional or revised information or a revised proposal, please describe the changes that have been made since your previous submission. Please submit any questions, requests to meet, or any revisions to your SIP Proposal for agency review to SIPDrugImportsandRFP@fda.hhs.gov.

Sincerely,

S. Leigh Verbois, PhD
Director
Office of Drug Security, Integrity & Response
Office of Compliance
Center for Drug Evaluation and Research