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January 5, 2024

Re: Docket No. FDA-2021-P-0034

Dear Dr. Dohm, Ms. Karetnick, and Ms. Wood:

This letter responds to your citizen petition, received on January 8, 2021 (Petition), and your supplement to the Petition (Supplement), received on September 18, 2023, both submitted on behalf of the Pharmaceutical Research and Manufacturers of America, the Partnership for Safe Medicines, and the Council for Affordable Health Coverage. The Petition requests that the Food and Drug Administration (FDA or Agency) "refrain from authorizing [the State of Florida's Section 804 Importation Program (SIP)] Proposal and disclose the identities of Foreign Sellers for public comment" (Petition at 1).

We have carefully considered your Petition, the Supplement, the comments submitted to the docket, and other relevant information available to the Agency, including information provided by Florida in connection with its SIP Proposal, as amended. Based on our review of these materials, and for the reasons stated below, your Petition is denied.

I. BACKGROUND

A. Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) and FDA's Regulation

The continued rise of prescription drug prices has raised concerns among policymakers, healthcare professionals, and American consumers. Contributing to public frustration on this issue is the disparity between prices that Americans pay for brand name medications as compared with other developed countries. As a result of these price differentials, some American

consumers have sought to import drugs from other countries in an effort to obtain treatments that may be otherwise inaccessible to them because of cost. However, products purchased from other countries often have not been approved by the FDA for use and sale in the United States. The FDA cannot ensure the safety and effectiveness of medicine that American consumers purchase during trips outside the United States, from storefront businesses that offer to buy foreign medicine, or from websites selling drugs from foreign sources.

There has been interest for many years in allowing the importation of less expensive drugs from Canada to help American consumers benefit from lower prices. Section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides, among other things, a pathway for the importation of prescription drugs from Canada under certain circumstances. Section 804(l)(1) of the FD&C Act states that this pathway can become effective only if the Secretary of Health and Human Services (the Secretary) certifies to Congress that the implementation will "(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer." The Secretary made this certification to Congress, with regard to the commercial importation provisions in section 804(b) through (h) of the FD&C Act (21 U.S.C. 384(b) through (h)), concurrent with the issuance by FDA and the Department of Health and Human Services (HHS) of the final rule on Importation of Prescription Drugs (85 FR 62094, October 1, 2020). The Secretary's certification was based on the requirements and safeguards in the final rule, which are codified at 21 CFR parts 1 and 251.

The final rule, which was effective as of November 30, 2020, 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. Under the final rule, section 804 of the FD&C Act will be implemented through time-limited Section 804 Importation Programs (SIPs), which will be authorized by FDA and managed by States or Indian Tribes, or in certain future circumstances by pharmacists or wholesale distributors (SIP Sponsors). A SIP can be cosponsored by a State, Indian Tribe, pharmacist, or wholesale distributor.

SIP Sponsors must specify the eligible prescription drugs that will be included in the SIP. To be eligible, a drug needs to be approved by the Government of Canada's Health Canada's Health Products and Food Branch (HPFB) and, but for the fact it bears the HPFB-approved labeling when marketed in Canada, needs to otherwise meet the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for a drug that is currently commercially marketed in the United States, including those conditions relating to the drug substance, drug product, production process, quality controls, equipment, and facilities.

A SIP Proposal must identify the Foreign Seller in Canada that will purchase the eligible prescription drug directly from its manufacturer, and the Importer in the United States that will buy the drug directly from the Foreign Seller. Each supply chain under a SIP must be limited to three entities, i.e., one manufacturer, one Foreign Seller, and one Importer.

A Foreign Seller must be licensed to wholesale drugs by Health Canada and registered with FDA as a Foreign Seller, and the Importer must be a wholesale distributor or pharmacist licensed to operate in the United States. Both the Foreign Seller and the Importer will be subject to the

supply chain security requirements in the final rule and under the FD&C Act. Among other things, the Foreign Seller has to ensure that a section 804 serial identifier (SSI), which is an alphanumeric serial number unique to each package or homogenous case, is affixed to or imprinted on each package and homogenous case of the drugs. The Importer has to ensure that a product identifier meeting the requirements of section 582 of the FD&C Act (21 U.S.C. 360eee-1) (i.e., a product identifier that includes a National Drug Code, unique alphanumeric serial number of up to 20 characters, lot number, and expiration date, in both human- and machine-readable format) is affixed to or imprinted on each package and homogenous case of eligible prescription drugs received from the Foreign Seller. The lot number that is included as part of the product identifier is the number that was assigned by the manufacturer of the eligible prescription drug; separately, section 804(d)(1)(H) of the FD&C Act requires that the Importer shall submit it to FDA. The Importer also has to maintain records linking the product identifier affixed to or imprinted on a package and homogenous case to the SSI that the Foreign Seller assigned. The Foreign Seller must maintain records associating the SSI with the drug identification number (DIN) from the HPFB and all the records the Foreign Seller received from the manufacturer upon receipt of the original shipment intended for the Canadian market.

After FDA has authorized a SIP Proposal, the Importer must submit a Pre-Import Request to FDA at least 30 calendar days before the scheduled date of arrival or entry for consumption of a shipment containing an eligible prescription drug covered by the SIP, whichever is earlier. Entry and arrival of a shipment containing an eligible prescription drug is limited to the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA.

In accordance with section 804(e)(1) of the FD&C Act, FDA's regulations require the manufacturer or the Importer to conduct testing of the eligible prescription drugs for authenticity, degradation, and to ensure that the eligible prescription drugs are in compliance with established specifications and standards (statutory testing). If the manufacturer does not perform the statutory testing required under section 804 of the FD&C Act, the Importer must arrange for statutory testing by a qualifying laboratory in the United States and must also ensure that the drug complies with all labeling requirements under the FD&C Act. If such testing is performed by the Importer, section 804(e)(2) requires that the manufacturer of the eligible prescription drug supply the information the Importer needs to authenticate the drug and to confirm that its labeling complies with all labeling requirements under the FD&C Act. FDA's regulations require that the manufacturer provide the Importer with all information needed to conduct the statutory testing including, among other things, any testing protocols that the manufacturer has developed and a stability-indicating assay so the drug can be tested for degradation.

Pursuant to section 804(c)(3) of the FD&C Act, FDA's regulations also set forth post-importation requirements. Each SIP Sponsor is required to provide FDA with data and information about its SIP, including the SIP's cost savings to the American consumer. An Importer is required to submit adverse event, field alert, and other reports to a drug's manufacturer and to FDA. If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor is responsible for effectuating the recall. Each SIP must have a written recall plan that describes the procedures to perform a recall of the product and specifies who will be responsible for performing those procedures.

A SIP Sponsor may request that FDA extend the authorization period of an authorized SIP (21

CFR 251.8(f) (§ 251.8(f))). To be eligible for an extension, a SIP must be up to date on all of the information and records-related requirements of section 804 of the FD&C Act and FDA's regulations. FDA may extend the authorization period for up to 2 years at a time. Such a request must be submitted at least 90 calendar days before the SIP's authorization period will expire.

Additionally, a SIP Sponsor may propose to modify an authorized SIP (§ 251.8). In reviewing a proposal to modify a SIP, among other things, FDA may consider information learned subsequent to authorization of the SIP (§ 251.8(b)). A SIP Sponsor must not make or permit any changes to a SIP without FDA's authorization (§ 251.8(e)). If FDA authorizes changes to a SIP, the Importer must submit a new Pre-Import Request in accordance with § 251.5 (§ 251.8(d)).

FDA may suspend or revoke a SIP, in whole or in part, including with respect to one or more drugs in the SIP, at any time, under any circumstances set forth in the FD&C Act and FDA's regulations, including circumstances in FDA's discretion (§§ 251.7 and 251.18). An eligible prescription drug cannot be shipped into the United States under section 804 and FDA's regulations, and is subject to refusal of admission into the United States, if FDA has suspended the SIP or revoked its authorization.

An article that is imported or offered for import into the United States in violation of section 804 of the FD&C Act or 21 CFR part 251 is subject to refusal under section 801 of the FD&C Act (§ 251.21(a)). The importation of a prescription drug in violation of section 804 of the FD&C Act; the falsification of any record required to be maintained or provided to FDA under section 804; or any other violation of 21 CFR part 251 is a prohibited act under section 301(aa) of the FD&C Act (§ 251.21(b)).

On July 14, 2021, the Executive Order on Promoting Competition in the American Economy (86 FR 36987) directed FDA to work with States and Indian Tribes that propose to develop SIPs in accordance with section 804 of the FD&C Act and FDA's implementing regulations to reduce the cost of covered products to the American consumer without imposing additional risk to public health and safety.

B. Florida's SIP Proposal

The Florida Agency for Health Care Administration (Florida or the State) initially submitted a SIP Proposal to FDA on November 23, 2020. The State subsequently revised its SIP Proposal several times, on April 19, 2021, September 15, 2021, November 15, 2021, April 21, 2023, October 20, 2023, and November 16, 2023, including in response to FDA's requests for information. Your original Petition, dated January 7, 2021, referenced and discussed Florida's original November 2020 SIP Proposal, as did the comments submitted to the docket. Your supplement, dated September 18, 2023, referenced and discussed Florida's April 2023 SIP Proposal.

Numerous subject matter experts at FDA and other components of the Department of Health and Human Services (HHS) carefully and thoroughly reviewed Florida's SIP Proposal. FDA has determined that Florida's SIP Proposal, as amended, meets the requirements of section 804 of the FD&C Act and FDA's regulations, and therefore Florida has demonstrated that it meets the statutory obligation to ensure that importation under section 804 will significantly reduce the

cost of covered products to the American consumer without posing additional risk to the public's health and safety. On this basis, FDA authorized the SIP for a period of 2 years beginning when the Importer, or its authorized customs broker, files an electronic import entry for consumption for its first shipment of drugs under the SIP, in accordance with § 251.6(a)-(b).

FDA is committed to working with States and Indian Tribes that seek to develop successful section 804 importation proposals. Congress has given FDA, as part of the Agency's mission to promote and protect the public health, responsibility for implementing laws intended to strike a balance between encouraging and rewarding innovation in drug development and facilitating robust and timely market competition. The Agency takes seriously its responsibility to ensure that the medicines Americans use are safe and effective.

II. DISCUSSION

Your Petition and Supplement request that FDA "refrain from authorizing [Florida's SIP] Proposal and disclose the identities of Foreign Sellers for public comment" (Petition at 1). You state that interested parties have been unable to engage with FDA, in particular through the citizen petition process, prior to the Agency making a determination on Florida's SIP Proposal. The Petition and Supplement also state that Florida's SIP Proposal did not satisfy statutory and regulatory requirements. The Supplement summarizes several deficiencies identified in previous letters from FDA to Florida and further notes concerns regarding potential storage, handling, and distribution of imported drugs; screening for evidence that imported drugs are adulterated, counterfeit, damaged, tampered with, or expired; and details regarding potential cost savings. The Petition and Supplement also assert that Florida's SIP Proposal cannot be authorized because it was submitted pursuant to an invalid certification and unlawful final rule. Finally, the Petition requests that FDA publicly disclose Foreign Sellers as soon as they are identified.

We note that both Pharmaceutical Research and Manufacturers of America and the Partnership for Safe Medicines submitted comments on the proposed rule on Importation of Prescription Drugs (84 FR 70796, December 23, 2019) (section 804 proposed rule) and FDA responded to those comments in the preamble to the final rule. The arguments that you make in your Petition and Supplement overlap substantially with the arguments made in those comments on the section 804 proposed rule.

For the reasons below, we are denying your requests.

A. Procedural Issues

The Petition and Supplement raise a procedural concern that interested parties have been unable to engage effectively with FDA prior to the Agency making a decision on Florida's SIP Proposal. The Supplement states that you have not had access to Florida's SIP Proposal and that has been "obfuscating a comprehensive assessment whether the proposed importation scheme meets statutory and regulatory requirements" (Supplement at 6).

As a preliminary matter, section 804 of the FD&C Act provides for importation of certain prescription drugs from Canada without a manufacturer's authorization. In contrast, section 801 of the FD&C Act states that, with certain exceptions, including for importation pursuant to section 804, no drug may be imported into the United States for commercial use if such drug is

manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States. Therefore, it is reasonable for FDA to limit the SIP Proposal review process – which involves importation pursuant to section 804 – to FDA, the subject matter experts FDA consulted at HHS/ASPE (the Office of the Assistant Secretary for Planning and Evaluation), and the SIP Sponsor.

Moreover, it is typical for regulatory submissions to FDA not to be made public or otherwise shared with external parties while they are pending with the Agency. For example, generally FDA does not make public the existence or content of a pending NDA or ANDA. See 21 CFR 312.130(a); 21 CFR 314.430(c). As discussed in the preamble to the final rule, we disagree that all potentially interested parties, including manufacturers that hold the NDAs or ANDAs of the FDA-approved counterparts of the eligible prescription drugs that a SIP seeks to import, are entitled to participate in FDA's review of a SIP Proposal. While all interested persons are afforded the right to participate in rulemaking through the submission of written data, views, or arguments (see 5 U.S.C. 553(c)), the same is not true for Agency decisions on regulatory submissions while they are pending with the Agency. The Administrative Procedure Act gives agencies wide discretion to determine the appropriate level of public participation in such agency decisions. See 5 U.S.C. 555(b) ("So far as the orderly conduct of public business permits, an interested person may appear before an agency. . . for the . . . determination of an issue").

Consistent with the above, manufacturers had the opportunity to participate in the notice-and-comment rulemaking that led to the promulgation of the final rule and they can provide input on individual SIPs through the citizen petition process. FDA's citizen petition process "preserve[s] the participation opportunities of interested persons." *Nichols* v. *Bd. of Trs. Asbestos Workers Local 24 Pension Plan*, 835 F.2d 881, 897 (D.C. Cir. 1987). This established process permits anyone to request that FDA take (or refrain from taking) any form of action regarding a SIP. See 21 CFR 10.25(a), and 85 FR 62094 at 62121–22). The Supplement alleges that this citizen petition process is inadequate because FDA has not made public Florida's SIP proposal amendments and therefore petitioners cannot provide comment (Supplement at 6). Again, analogously, interested parties often use citizen petitions to present their views regarding NDAs or ANDAs under review. *See, e.g., ViroPharma, Inc.* v. *Hamburg*, 898 F. Supp. 2d 1, 12 n.11 (D.D.C. 2012) ("When the FDA is considering an ANDA, those with rights to or scientific knowledge of the innovator drug may provide technical information relating to the generic drug's bioequivalence by filing a 'citizen petition'"). Interested parties can also seek judicial review and, if the court permits, have access to appropriate documents in the administrative record during the course of litigation. We note that manufacturers will be involved after a SIP has been authorized, and that interested persons are permitted to file a citizen petition at any time, including after a SIP has been authorized. In particular, an eligible prescription drug may not be imported or offered for import under a SIP unless the Importer has filed a Pre-Import Request for that drug in accordance with FDA's regulations and FDA has granted the Pre-Import Request. See § 251.5(a). The Pre-Import Request must include, among other things, an attestation and information statement that the Importer will request from the manufacturer which will establish that the drug proposed for import, but for the fact that it bears the HPFB-approved labeling, meets the conditions in the FDA-approved NDA or ANDA, including any process-related or other requirements for which compliance cannot be established through laboratory testing. See §§ 251.5(c)(4)(xii) and (d).

B. FDA's Review of Florida's SIP Proposal

With regard to the merits of Florida's SIP Proposal, your original Petition asserted that FDA could not authorize Florida's original November 2020 SIP Proposal unless and until a Foreign Seller was identified that met the statutory and regulatory requirements (Petition at 9). Florida identified its Foreign Seller in its submission dated April 19, 2021. We reviewed the information Florida provided about the Foreign Seller and found that the SIP Proposal provided sufficient information to meet the requirements for authorization. The SIP Proposal adequately explained the Foreign Seller's responsibilities and procedures and the State's plan for oversight of the Foreign Seller. Additionally, the SIP Proposal includes documentation that the Foreign Seller is FDA-registered, and includes procedures that demonstrate how the Foreign Seller will meet the supply chain security obligations set forth at § 251.14(c).

Your Petition also identified a number of aspects of Florida's original November 2020 SIP Proposal that you asserted diverged from the requirements in the FD&C Act and the final rule in ways that undermine public health and safety (Petition at 10). Specifically, your Petition claimed that Florida's SIP Proposal "impermissibly delegates significant State and Importer responsibilities to" a wholesale distributor, LifeScience Logistics, "without providing a justification" (Petition at 10). With regard to the Petition's assertions that the Proposal impermissibly delegated State and Importer responsibilities to LifeScience Logistics, FDA's review of Florida's Proposal, including subsequent revisions, found that LifeScience Logistics is in fact proposed to be the Importer, and that the proposed responsibilities of LifeScience Logistics described in the Proposal accorded with those requirements imposed on the Importer in FDA's final rule. Furthermore, the State proposed to engage in oversight necessary to ensure that the specific responsibilities placed in the rule on the SIP Sponsor are met. For example, the Proposal includes explanations of how Florida will ensure that all SIP participants comply with section 804 of the FD&C Act, such as through routine submission of detailed reports to Florida and conduct of on-site visits; and it explains that Florida will regularly solicit information from the Importer and Foreign Seller to develop and submit reports required of the SIP Sponsor under § 251.19, through which it will confirm, among other things, that the Importer purchased the drugs it imported directly from the Foreign Seller.

Your Petition further argued that Florida's November 2020 SIP Proposal "fails to provide assurances that imported drugs will be transported, stored, repackaged, and relabeled in compliance with CGMP requirements" (Petition at 13). Based on our review of Florida's SIP Proposal, as amended, it contains such assurances, including in detailed standard operating procedures (SOPs) provided by the Foreign Seller and Importer to the state. Specifically, the Proposal explains that Florida will monitor performance and "ensure adherence to state and federal regulations"—which include CGMP requirements—by all the entities participating in the SIP.

Your Petition further argued that the November 2020 SIP Proposal did not satisfy requirements related to statutory testing, supply chain security, and post-importation pharmacovigilance (Petition at 14). Regarding statutory testing, the Petition notes that in its November 2020 submission the State proposed to omit drugs planned for import under its program from statutory testing. FDA found that in subsequent revisions, Florida assured that drugs offered for import would undergo testing for authenticity, testing for degradation, and testing to ensure that the

eligible prescription drugs are in compliance with established specifications and standards, in accordance with section 804(e)(1) of the FD&C Act and FDA's regulations. FDA's January 5, 2024, authorization letter explained that unless the manufacturer has notified the Importer that it intends to conduct the required testing under § 251.16(e), the Importer's detailed statutory testing plan must be provided in the Pre-Import Request following authorization (§ 251.5(c)(4)(xi)).

Regarding the supply chain security concerns raised in the Petition, those concerns focused on uncertainty in the November 2020 Proposal on how drugs would be handled on foreign soil, given that foreign entities involved in the importation may lack a nexus with the United States, and on how the Proposal would ensure that participating entities comply with the relevant security chain security requirements in the final rule and in the Drug Supply Chain Security Act (DSCSA). Based on its review of Florida's SIP Proposal, as amended, FDA has determined that the procedures set forth in the Proposal, if followed, adequately showed that the SIP Sponsor, the Importer, and the Foreign Seller would meet the specific supply chain security requirements in § 251.14, along with applicable DSCSA requirements; see also our discussion below of similar issues raised in your September 2021 Supplement. Additionally, while the November 2020 Proposal did not identify the specific foreign entities involved, in subsequent revisions Florida identified a Foreign Seller and, as noted above, FDA found that the SIP Proposal, as amended, adequately explained the Foreign Seller's responsibilities and procedures and the State's plan for oversight. FDA retains authority to oversee Foreign Sellers and other SIP participants on an ongoing basis after authorization, such as through inspections or audits. See § 251.7(b).

Regarding post-importation pharmacovigilance, your Petition asserts that responsibilities such as submitting adverse event reports and field alert reports are improperly delegated to LifeScience Logistics rather than to the Importer, upon whom FDA's regulations place such requirements. See § 251.18. However, as noted above, in subsequent revisions Florida clarified that LifeScience Logistics is in fact proposed to be the Importer and will take on the required responsibilities. The Petition also states that entities such as LifeScience Logistics or the Florida Department of Health do not have the necessary expertise to conduct pharmacovigilance activities, asserting as examples that the Proposal conflates terms such as adverse event reporting and field alert reporting, and that Florida proposes only to submit field alert reports for a subset of microbiological contamination situations. FDA's review of Florida's SIP Proposal, as amended, determined that the Proposal adequately describes how, if properly implemented and executed, the SIP Sponsor will ensure the Importer fulfills its responsibilities for post-importation reporting required in § 251.18. Florida's SIP Proposal as amended, indicates that field alerts will be issued for any of the following: labeling problems that can cause the prescription drug to be identified as another product; biological contamination; changes in the chemical or physical composition of the prescription drug that leads to deterioration, degradation, or toxicity; and any failure of a shipment or batch of prescription drugs to meet the specifications in its NDA or ANDA.

Your Petition additionally argued that the recall, return, and compliance plans outlined in Florida's November 2020 SIP Proposal lack elements required under FDA's regulations (Petition at 19). With regard to the recall plan, the Petition argues that the division of duties is not clear, that the plan does not specify how information will be provided to FDA and to the Foreign Seller, and that the plan does not explain how the decision that a recall is necessary will be made. The Petition states that the return plan suffers from "similar flaws" (Petition at 19-20). FDA's

review of Florida's SIP Proposal, as amended, determined that it includes recall and return plans that meet the requirements of FDA's regulations and that the plans were sufficient to ensure that dangerous products would be taken out of distribution. As amended, Florida's SIP proposal indicates that either the State or the Importer may identify an issue requiring issuance of a recall and specifies scenarios in which a recall is necessary while also giving broad latitude to allow either the Importer or the State to recall products. With regard to the compliance plan, the Petition states that it is "missing . . . a set of objective criteria for the SIP Sponsor to utilize to ensure that all requirements are met," that the division of compliance responsibilities among supply chain entities is unclear, that the "division of labor among parties that will operationalize the SIP" is unclear, and that the SIP Proposal lacks "specific forward-looking written compliance policies, procedures and protocols" (Petition at 21). FDA has determined that Florida's SIP Proposal, as amended, contains a compliance plan that specifies in detail the criteria that the State will utilize to ensure that requirements are met. This compliance plan includes specific written compliance policies, procedures, and protocols that demonstrate that the compliance program meets the requirements of FDA's regulations and describes which parties will be responsible for those policies, procedures, and protocols.

Your Petition also asserted that Florida's November 2020 SIP Proposal "does not demonstrate that the SIP entities have the fiscal resources and capacity necessary to ensure that drugs imported under the SIP would be safe" (Petition at 22). Based on its review of the Florida SIP Proposal, as amended, FDA has determined that Florida provided adequate information regarding its plan for oversight to help ensure that drugs imported under the SIP will be safe. For example, Florida's proposal included an explanation of how it will ensure that all of the participants in the SIP comply with the requirements of section 804 and FDA's regulations. Florida's proposal also included its compliance plan, which includes, among other things, a plan for timely communication of any compliance issues to Florida.

Your Petition also stated that Florida's SIP Proposal failed to demonstrate how the SIP will result in a significant reduction in the cost of covered products to the American consumers as required by the statute and FDA's regulations (Petition at 23). Your Petition asserted that Florida's SIP Proposal "focuses on purported savings to the State, without demonstrating that consumers would see a benefit" (Petition at 23), "lacks factual support to justify its wide-ranging cost savings estimates" (Petition at 24), and "ignores significant costs associated with establishing and administering an importation program" (Petition at 24). After careful review of Florida's SIP Proposal, ASPE determined that the SIP Proposal provides adequate support that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the state seeks to import. Florida's SIP Proposal explained that consumers would see a benefit because the aggregate reduced cost of the drugs imported under the SIP would benefit taxpayers of the State of Florida whose tax dollars are used by the State to purchase drugs for covered beneficiaries.

Your Petition further asserted that Florida's SIP Proposal "lacks strong protection of trade secrets and CCI" (Petition at 25), that its "[f]ailure to adequately incorporate SIP-specific language in the labeling could lead to reputational harm for manufacturers" (Petition at 25), and that Florida's SIP Proposal lacks information about the NDA/ANDA holders and manufacturers of the eligible drugs and the commercial availability of their FDA-approved counterparts required for FDA to evaluate the SIP (Petition at 26). We disagree. Florida's SIP proposal, as

amended, adequately explained how it will protect the confidentiality of trade secrets and confidential commercial information. With respect to the Petition's claim about SIP-specific language in labeling, Florida revised its original proposed labeling to include the SIP-specific language. Finally, with regard to your assertion that the SIP Proposal lacks requisite information about the NDA/ANDA holders and manufacturers of the eligible drugs and the commercial availability of FDA-approved counterparts, Florida amended its proposal to include this information.

Your Supplement addressed Florida's April 2023 SIP Proposal and acknowledged that in the time since Florida's original submission, the State had amended its proposal numerous times, and FDA had identified deficiencies and sent Requests for Information (RFI), including an RFI in November 2022 that "highlighted numerous deficiencies in the November 2021 Amended Proposal, many of which were emphasized in [y]our Original Citizen Petition."

Additionally, your Supplement references deficiencies described in FDA's August 2023 RFI, in particular about how Florida will assure drug supply chain security for imported drugs and how Florida will ensure that the SIP will result in a significant reduction in cost to American consumers (Supplement at 7–8).

FDA reviewed the information Florida provided in response to FDA's RFI letters and found that the State adequately addressed the deficiencies FDA identified in those RFIs. The supply chain security deficiencies identified in FDA's RFIs pertained, generally, to the Foreign Seller's obligations under § 251.4(c); the Importer's obligations under § 251.4(d); and requirements in § 251.4(e) on the return and disposition of non-saleable drugs. FDA found that the revised SIP Proposal Florida submitted on October 20, 2023, contained adequate revisions regarding these supply chain security requirements. However, FDA sought clarification on a few areas where those revisions were not consistently reflected in the accompanying revised SOPs. Based on a careful review of the November 16, 2023, revisions provided by Florida in response to FDA's RFI and requests for clarification, FDA determined that Florida had provided adequate information to conclude that, if all the SIP Proposal's proposed procedures were followed, the requirements in § 251.4(c)-(e) would be met. The cost reduction deficiencies identified in FDA's August 2023 RFI pertained, generally, to information HHS needed about Florida's expenditure, price, and quantity projections for each drug in order to adequately assess the proposal. As noted above, after careful review of Florida's revised SIP Proposal, ASPE determined that the SIP proposal provides adequate support that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the State seeks to import.

The August 2023 RFI also identified deficiencies related to the proposed labeling, including drug-specific edits that FDA requested that Florida make to ensure, apart from the certain exceptions provided for in the final rule, the labeling of each imported drug will be the same as the FDA-approved labeling under the applicable NDA or ANDA. After careful review of Florida's revisions, FDA concluded that the proposed labeling was sufficient to meet the requirements of 21 CFR part 251, with certain specific corrections identified. Accordingly, in FDA's authorization letter to Florida dated January 5, 2024, FDA clarified that importation may not proceed until the corrections are made and requested that Florida submit the corrected labeling for FDA's review prior to the submission of a Pre-Import Request, in order to facilitate the importation process and ensure that the requirements of the FD&C Act and 21 CFR part 251

are met. FDA also found that Florida's revised proposal adequately addressed the remaining deficiencies identified in the August 2023 RFI; for example, Florida clarified that the Importer, LifeScience Logistics, would store and maintain the shipment of drugs offered for import entry review, at a secured warehouse within 30 miles of the authorized Port of Entry identified by FDA, in accordance with 251.17(b), while the shipment is awaiting FDA's admissibility decision. At this time, the only authorized port of entry is Detroit, Michigan. See U.S. Customs and Border Protection Cargo Systems Messaging Service bulletin, Nov. 9, 2020, at https://content.govdelivery.com/accounts/USDHSCBP/bulletins/2aabc2f. See also FDA Supplemental Guide for the Automated Commercial Environment/International Trade Data System (ACE/ITDS), https://www.cbp.gov/document/guidance/fda-supplemental-guide.

Your Supplement also notes that Florida's April 2023 SIP Proposal does not explain certain changes, such as changes to the list of drugs to be imported (Supplement at 8). The Supplement speculates that certain drugs may have been removed from the list due to concerns raised in a letter from FDA that the drugs could not be relabeled without breaching their container/closure systems (Supplement at 9). However, FDA's regulations afford significant flexibility to SIPs to choose which eligible prescription drugs to import and in what quantities; thus, the changes Florida has made to its list of drugs (as compared to the list in its original SIP Proposal) are not a reason not to authorize its SIP.

Finally, the Supplement claims that there are additional reasons that Florida's SIP Proposal does not demonstrate that the proposed importation will result in a significant reduction in the cost to the American consumer without additional risk to public health and safety (Supplement at 8–9). Specifically, the Supplement asserts that the SIP Proposal:

- Contains only vague assurances that drugs will be stored, handled, and distributed in a compliant manner outside Florida state lines, as required by 21 C.F.R. § 251.3(e)(11)(i), including at the importer's facility in Whitestown, Indiana and abroad;

- Provides no guidelines for ensuring that each supply chain participant complies with storage instructions included in each drug's labeling, as required by 21 C.F.R. § 251.3(e)(11)(i);

- Purports to rely on the Drug Supply Chain Security Act (DSCSA) to ensure a secure supply chain to satisfy 21 C.F.R. § 251.3(e)(11)(ii), even though (1) Canada lacks a track and trace system, as [LifeScience Logistics] itself acknowledges in an email obtained via a [Freedom of Information Act (FOIA)] request; (2) products imported under the final rule are exempt from key provisions of the DSCSA; and (3) Florida's proposal to require a lot-specific machine-readable bar code in the product identifier violates the DSCSA, which requires package specific bar codes.

- Does not indicate how Florida plans to ensure that drug supply chain participants screen the eligible prescription drugs for evidence that they are adulterated, counterfeit, damaged, tampered with, or expired, as required by 21 C.F.R. § 251.3(e)(11)(iii), beyond a vague assurance that [the Importer, LifeScience

> Logistics] will "physically inspect each drug shipment received from [the Foreign Seller] Methapharm Inc. against shipping paperwork and a set of specifications developed for each drug imported" [(Florida's April 2023 Amended Proposal)].

We disagree.

Regarding the arguments in the first two bullets above, the SIP Proposal describes procedures the State will use to ensure storage, handling, and distribution practices of supply chain participants, including transportation providers, meet the requirements of 21 CFR 205 and do not affect quality or impinge on security of the eligible prescription drugs, as required by § 251.3(e)(11)(i). The Importer and re-labeler identified in the SIP Proposal are facilities that are both owned and operated by LifeScience Logistics, and are licensed as wholesale distributors in accordance with 21 CFR part 205 and the state laws of Florida and Indiana, respectively, and the re-labeler is FDA-registered. Additionally, the SIP Proposal contains descriptions, detailed in attached SOPs, explaining how supply chain participants, including transportation providers, will engage in storage, handling, and distribution practices that, as specifically required by § 251.3(e)(11)(i), meet the requirements of 21 CFR part 205 and do not affect quality or impinge on security of the eligible drugs. For example, among other things, the Proposal explains that LifeScience Logistics' facilities must be equipped with environmental controls to monitor temperature and have cold storage units available for prescription drugs requiring refrigeration. The Proposal also includes adequate information regarding quality assurance functions to ensure that specific storage conditions are followed.

Regarding the arguments in the third bullet above, FDA found that the procedures in Florida's SIP Proposal describe steps that the State will take to ensure that the supply chain is secure, as required by § 251.3(e)(11)(ii). Specifically, FDA found that Florida's SIP Proposal relies on the DSCSA only to the extent that such requirements apply to drugs imported under this program, and that the State proposes that the Foreign Seller and Importer will undertake processes to achieve additional safeguards necessary to maintain supply chain security, as envisioned by 21 CFR 251. Additionally, Florida's revised SIP Proposal does in fact require package-specific product identifiers that would comply with the DSCSA. Specifically, FDA found that the revised Proposal and SOPs in Florida's final submission described a system for package-level product identification and tracing, in which LifeScience Logistics would facilitate the affixation of an appropriate product identifier, as that term is defined in section 581(14) of the FD&C Act, and would maintain electronic files and data needed to associate the product identifier with the package-level serial identifier assigned by the Foreign Seller.

Regarding the arguments in the fourth bullet above, FDA found that the procedures in Florida's SIP Proposal describe steps the State will take to ensure that the Importer screens eligible prescription drugs it imports for evidence that they are adulterated, counterfeit, damaged, tampered with, expired, suspect foreign product, or illegitimate foreign product, as required by § 251.3(e)(11)(iii). The SIP Proposal explains the Importer's plan to compare, upon receipt of eligible prescription drug and records from the Foreign Seller, such information with information the Importer received from the manufacturer, including relevant information about the transaction that the manufacturer provided to the Foreign Seller upon its transfer of ownership of the product for the Canadian market. The SIP Proposal also explains the Importer's plan to physically inspect drug shipments against shipping paperwork and a set of specifications,

including damage, tamper seal intact, lot number, and DIN, and determine whether expiration dating on packaged units aligns with shipping paperwork and if there is no presence of counterfeit or illegitimate products. The SIP Proposal further explains the Importer's plan to evaluate product for authenticity, including using visual inspections and laboratory testing, and addresses screening procedures.

Your Supplement also lists two purported deficiencies in Florida's April 2023 SIP Proposal related to the requirement to demonstrate a significant cost reduction for consumers (Supplement at 9). Specifically, you assert that Florida's SIP Proposal:

- Purports to rely on an actuarial analysis that "d[id] not include prescription drug rebates under the Medicaid Drug Rebate Program (MDRP)" and that expressly acknowledges "that the impact of those rebates could fully offset the projected 'savings' attributable to this program," [(Florida's April 2023 Amended Proposal)] while redacting all rebate information that the State supposedly incorporated into the analysis; and

- Does not provide any detail on "administrative costs" that likely will be borne by the State, does not address potential markups by the foreign seller or the burden on law enforcement, and does not justify the 75% uptake estimate, making it impossible to rely on the projected total savings provided.

We disagree.

Regarding the arguments in the first bullet above, the SIP Proposal accounts for prescription drug rebates, in the aggregate, when reporting projected cost savings. With regard to rebates for specific drugs, which as the Petition notes were redacted, the SIP Proposal used a break-even analysis to address the uncertainty in future rebates. Under this approach, the break-even percentage is calculated, which is the highest that rebates could rise before importation from Canada no longer generated cost-savings for Florida. The break-even percentages Florida calculated are higher than the percentage rebates implicit in Florida's projected cost savings estimates.

Regarding the arguments in the second bullet, Florida's analysis accounts for both fixed and variable administrative costs and for price markups. With regard to potential markups by the Foreign Seller, Florida's proposal accounts for an importation fee that the Importer charges Florida that will cover the total cost of importation, which would include any expenses above the Foreign Seller's prices. Turning to Florida's "75% uptake estimate," it is provided as part of the sensitivity analysis that the State conducted to account for uncertainty that exists about the level of uptake. Regarding "the burden on law enforcement," the Petition does not explain what is meant by that or how the SIP Proposal should address it. In any event, we believe Florida's SIP Proposal addresses the key factors that are potentially relevant to cost savings. We do not currently have information to suggest that Florida's SIP Proposal, if authorized and implemented, would impose a significant burden on law enforcement.

In sum, notwithstanding your arguments, ASPE, and in turn FDA, determined that the SIP proposal provides adequate support that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the State seeks to import.

C. Validity of the Secretary's Certification and the Final Rule

For the reasons below, we disagree with the claims in the Petition and Supplement that the Secretary has yet to make a valid certification and that FDA and HHS have not promulgated a valid rule pursuant to section 804 of the FD&C Act. Many of these issues were discussed in detail in the preamble to the final rule, and we incorporate those responses by reference here.

1. Certification

The Petition asserts that the Secretary's certification violated section 804(l)(1), and was thus invalid, because it was "conditioned on assumptions that States will submit SIPs in the future that will meet the safety and cost criteria"; because the final rule provides too much flexibility in demonstrating that cost savings are passed on to consumers; because the certification provision is broader than "discrete SIPs sponsored by individual states or tribes"; and because the certification was for "only commercial importation under subsections (b) through (h) [of section 804 of the FD&C Act]" (Petition at 7).

The Petition further asserts that the certification "does not satisfy the [Administrative Procedure Act's] APA's requirement of reasoned decisionmaking" because the Secretary did not adequately consider potential health risks and consumer savings, "important aspects of the problem before him," and "long-held prior positions and factual findings related to importation," and because the Secretary's rationale "is internally inconsistent and fails to support his decision to authorize commercial importation under the Final Rule" (Petition at 7–8). The Petition also asserts that the certification was procedurally improper because "HHS lacked authority to promulgate the [notice of proposed rulemaking] NPRM before the Certification was issued," and that HHS and FDA should have disclosed facts and analyses supporting the certification during the notice and comment rulemaking process (Petition at 8).

We disagree. First, the Secretary's certification was consistent with the FD&C Act. As discussed in the rulemaking (85 FR 62094 at 62111–12), for section 804 to become effective, subsection (l) requires the Secretary to certify that the implementation of this section will pose no additional risk to the public's health and safety, and result in a significant reduction in the cost of covered products to the American consumer. In conjunction with the final rule, the Secretary certified that implementation of section 804(b)–(h) will pose no additional risk to the public's health and safety, and will result in a significant reduction in the cost of covered products to the American consumer. The Secretary's certification was based on the requirements and safeguards in FDA's regulations implementing section 804, which were designed to ensure that FDA and other components of HHS receive the necessary information to ensure this certification applies to a particular SIP. Although the certification provision in section 804(l) does not expressly address the review of sponsored plans for importation, there is nothing in the provision that precludes the Secretary from basing the certification on an implementing regulation that ensures any importation made under section 804 meets appropriate standards, including a requirement that importation plans be sponsored by certain entities and reviewed and authorized by the Secretary. In fact, the statute's certification provision contemplates that the Secretary will base his decision on certain requirements or other policies established by him because the provision asks whether *implementation* of section 804 will lead to the findings necessary to make the certification.

Regarding cost savings, under the final rule, implementation of section 804(b) through (h) will result in a significant reduction in the cost of covered products to the American consumer. Section 251.3(e)(9) requires the SIP Sponsor's importation plan to explain, in a manner sufficiently detailed to allow for a meaningful evaluation, how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer. The information needed to demonstrate anticipated cost savings to the American consumer will be dependent on the specific mechanisms which a SIP Proposal uses to reduce costs for American consumers. Moreover, § 251.7(c) provides that FDA may revoke the authorization of a SIP if, among other reasons, the Agency determines that continued implementation of the SIP will not result in a significant reduction in the cost of drugs covered by the SIP to the American consumer. Together, these provisions ensure that there is a meaningful assessment of whether drugs imported under a particular SIP will result, and are resulting, in a significant reduction in the cost of covered products to the American consumer, which, in turn, allowed the Secretary to make the cost-related finding for the certification under section 804(l).

Nor do we agree that the statute's reference to the American consumer means that before a certification can be made, there must be a finding that *all* American consumers will benefit from a significant reduction in the cost of covered products. In any case, the Secretary's certification does not limit the number of American consumers who could benefit from importation of drugs under section 804. A SIP or combination of SIPs could be broad in scope and provide significant cost savings to numerous Americans.

We also disagree that a certification under section 804(l) must cover all of section 804 of the FD&C Act. In general, section 804 contains two importation pathways: (1) Commercial importation of drugs from Canada under subsections (b)–(h), and (2) personal importation under subsection (j). Each importation pathway must be certified by the Secretary under section 804(l) to be effective. However, section 804 does not explicitly require a certification to cover both pathways. In stating that this section only becomes effective if the implementation of the section meets the certification criteria, section 804(l) accomplishes two objectives: (1) Ensuring that any provision in section 804 does not take effect unless the Secretary certifies that implementation of the provision would meet the certification criteria; and (2) providing for the possibility that implementation could take different forms, including implementing section 804 in a way that only pertains to the commercial importation pathway or the personal importation pathway. At this time, the Secretary has not certified to Congress that the implementation of section 804(j) would pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer. Unlike commercial importation under FDA's regulations, medications that are purchased online and imported through international mail, express couriers, and other means for personal use pose significant challenges for FDA and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers. While there are pharmacy websites that operate legally and offer convenience, privacy, and safeguards for purchasing medicines, there are many rogue online pharmacies that sell medicines directly to consumers at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by pharmacies licensed by a State in the United States. Further, drugs promoted online as being from Canada or approved in Canada in many instances are not actually from Canada and not approved in Canada. Instead,

these drugs are often obtained from ever-evolving illicit sources of supply. Additionally, the provisions in section 804(j) on personal importation do not provide the same safeguards as the provisions on commercial importation in sections 804(b)-(h), such as those at section 804(e)(2) pertaining to statutory testing of eligible prescription drugs.

We also disagree with the Petition's APA and procedural arguments regarding the Secretary's certification. As discussed above, the Secretary adequately explained his rationale for the certification under section 804(l), including his rationale for limiting the certification to commercial importation. With regard to issuing the NPRM before the certification, the section 804 proposed rule did not have legal effect at the time it was issued. Therefore, the proposed rule's cited legal authorities did not necessarily need to be in effect at that time. The Secretary made the required certification under section 804(l) concurrent with the final rule. Therefore, section 804 was in effect as a legal authority for the final rule. Furthermore, the certification requirement was included in section 804 so that the section would not be implemented before a certification is made. We do not believe that Congress intended for the provision to preclude the issuance of a proposed rule proposing how the section could be implemented in a manner that meets the basis for a certification, once that certification is made (see 85 FR 62094 at 62113).

With regard to consideration and disclosure of facts and analyses supporting the certification, we do not agree that the certification under section 804(l) of the FD&C Act is a rule that must undergo notice and comment rulemaking in accordance with the APA. A rule, as defined in the APA (5 U.S.C. 551(4)), is the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing. 5 U.S.C. 553, which governs notice and comment rulemaking, only applies to "substantive, legislative rules." *Clarian Health W., LLC* v. *Hargan*, 878 F.3d 346, 356 (D.C. Cir. 2017). Legislative rules "purport[] to impose legally binding obligations or prohibitions on regulated parties," "would be the basis for an enforcement action for violations of those obligations or requirements," or "set[] forth legally binding requirements for a private party to obtain a permit or license." *Nat'l Min. Ass'n* v. *McCarthy*, 758 F.3d 243, 251–52 (D.C. Cir. 2014). The certification is not such a rule. In accordance with section 804(l), the certification is made to Congress. While the certification made by the Secretary leads to section 804(b)–(h) becoming effective, the only consequence of making section 804(b)–(h) effective is that, per section 804(b), the Agency can issue a regulation that was subject to the very process requested by the commenter (notice and comment rulemaking). Thus, the certification has no independent effect on outside parties that warrants notice and comment under section 553 of the APA. We also note that, even if the certification were an agency action under the APA, it is more in the nature of a declaratory order that clarifies the Agency's position on the matters presented in section 804. See 5 U.S.C. 554(e) ("the agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty"); *Wilson* v. *A.H. Belo Corp.*, 87 F.3d 393, 397 (9th Cir. 1996) (upholding a declaratory order that was issued sua sponte, in the absence of any parties before the Agency); *Time Warner Entm't Co., L.P.* v. *FCC*, 240 F.3d 1126, 1141 (2001) (an agency has "very broad discretion whether to proceed by way of adjudication or rulemaking"). Also, a rulemaking "generally involve[s] broad applications of

more general principles." *Neustar, Inc.* v. *FCC*, 857 F.3d 886, 893 (D.C. Cir. 2017). But the certification was a one-time, particularized "finding" by the Secretary that led to section 804(b)–(h) becoming effective. 85 FR 62094 at 62114 (the "certification is a finding that functions as a procedural step" that permits the agency to engage in rulemaking and "has no independent effect on outside parties"); see 21 U.S.C. § 384(l). In this way, it was more of a "case-specific individual determination[]." *Neustar*, 857 F.3d at 893. Finally, unlike other provisions of section 804 of the FD&C Act, section 804(l) does not direct the Secretary to implement the provision by issuing a regulation. A comparison between the statutory provisions for issuance and revocation of the certification further confirms that the former is not subject to 5 U.S.C. § 553. Congress provided a process for revoking the certification "after a hearing on the record" under 5 U.S.C. §§ 556–57. Section 804(l)(2)(B). In contrast, it specified no procedural requirements—and certainly not those under 5 U.S.C. § 553—for issuing the certification. Section 804(l)(1). The lack of such direction indicates that Congress did not intend for the notice and comment requirements to apply.

In any case, we do not agree that the public did not have an opportunity to meaningfully comment on the Secretary's certification. Because the *Importation of Prescription Drugs* rulemaking constituted the basis for the certification, the certification effectively underwent notice and comment in the context of the rulemaking, and any additional notice and comment process for the certification would have been duplicative. Section 804(l) states that section 804 of the FD&C Act will become effective only if the Secretary certifies to Congress that the implementation of this section will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer. As discussed above, the Secretary made this certification on the basis of the final rule, which contained provisions and safeguards to ensure that any SIP that is authorized by FDA will be consistent with the certification. Implementation of section 804(b)–(h) through FDA's regulations will result in a significant reduction in the cost of covered products to the American consumer because the regulations require, among other things, that the SIP Sponsor's importation plan explain how the SIP Sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer. Other provisions of the final rule ensure that a SIP will not pose an additional risk to the public's health and safety. The Agency sought and received comments on the proposed rule and issued the final rule after considering those comments. Because the certification relies on the final rule, the public had an opportunity to meaningfully comment on the certification (see 85 FR 62094 at 62113–14).

2. Final rule

a. Consistency with the FD&C Act

The Petition also asserts that drugs imported under FDA's regulations would "necessarily be unapproved new drugs and misbranded drugs, neither of which can legally be imported into the U.S." (Petition at 8). The Petition also states that "the labeling mandated by regulation would mislead consumers that the drugs have been approved by FDA (which they have not) and have the assurances associated with FDA-approved drugs (which they do not)" (Petition at 8).

We agree that section 804 drugs will not themselves be the subject of an approved NDA or ANDA. They will, however, meet the requirement in section 804(c)(1) of the FD&C Act that

they comply with section 505 of the FD&C Act (21 U.S.C. 355) (including with respect to being safe and effective for the intended use of the prescription drug). Specifically, for purposes of a section 804 drug, FDA interprets compliance with section 505 to mean that the HPFB-approved drug meets the conditions in an FDA-approved NDA or ANDA. Before a section 804 drug is imported pursuant to section 804 and FDA's regulations, FDA must make a determination, on the basis of the statutory testing and information provided by the drug's manufacturer, that the drug meets the conditions in an approved NDA or ANDA. See § 251.17.

Requiring approval of an application under section 505 of the FD&C Act for drugs imported under section 804 of the FD&C Act would render section 804 superfluous. If an Importer sought and obtained FDA approval of a drug that was previously only approved for sale in Canada, it would not need to import the drug under section 804. Instead, it could simply import the drug under section 801 of the FD&C Act without meeting any of the additional safeguards imposed under section 804. Thus, it is reasonable for FDA to interpret "complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug)" to mean that the HPFB-approved drug meets the conditions in an FDA-approved NDA or ANDA, without itself having an approved NDA or ANDA.

Section 804 drugs generally will bear the labeling of their FDA-approved counterparts, with certain exceptions set forth in FDA's regulations. Specifically, the labeling of a section 804 drug may differ from the approved labeling to the extent that it includes: (1) The section 804 drug's NDC number, which will help with supply chain management and security, among other things, (2) the name of the Importer, which will ensure that the persons responsible for the product can be identified, (3) the labeling statement required by § 251.13(b)(4)(iv), which will help avoid confusion between products with the same name, help pharmacists distinguish a section 804 product when selecting the product on the pharmacy shelf, and, potentially, help with pharmacovigilance, and (4) the SIP's website address, which will also help avoid confusion by educating pharmacists, healthcare providers, pharmacy benefit managers, health insurance issuers and plans, as appropriate, and patients.

We disagree with the Petition's assertions that section 804 drugs will be misbranded or that their labeling will be misleading in any particular. Section 804(h) of the FD&C Act requires that the manufacturer of a section 804 drug authorize the Importer to use the approved labeling for the drug, while section 804(c)(3) provides that the regulations implementing section 804 must require that safeguards be in place to ensure that section 804 drugs comply with section 502 of the FD&C Act (21 U.S.C. 352), among other provisions. Section 804 would not require that Importers be authorized to use the approved labeling if introducing a drug with that labeling into interstate commerce would violate section 502. In addition, the labeling will not mislead consumers about the manufacturer's role in the importation of a section 804 drug because of the labeling statement required by § 251.13(b)(4)(iv), which will make clear that the drug was imported under a SIP without the manufacturer's authorization. Likewise, as noted below, there is not an increased likelihood that section 804 drugs will be adulterated in violation of section 501 of the FD&C Act (21 U.S.C. 351), because of the supply chain security, statutory testing, and other protections in section 804 and FDA's regulations (see 85 FR 62094 at 62115).

For these reasons, we disagree with the Petition that FDA will be required to refuse admission to section 804 drugs under section 801(a)(3) of the FD&C Act, which provides that articles shall be

refused admission if, among other things, they are "adulterated, misbranded, or in violation of section 505."

b. FDA Authority

The Petition also argues that FDA's regulations are invalid because FDA lacks statutory authority to: "(1) require a manufacturer to attest that a drug meets the conditions in an approved NDA or ANDA but for the fact that the drug bears Canadian labeling, or to notify FDA and explain with specificity why it cannot provide that attestation; (2) disclose the trade secret and confidential information that the U.S.-approved product and foreign-approved product are the same; and (3) require manufacturers to disclose trade secrets and other confidential information and provide samples of analytical reference standards and the FDA-approved drug to Importers for free" (Petition at 8). As discussed below, the Petition also states that these provisions also "raise serious constitutional questions under the Fifth Amendment to the U.S. Constitution, which prohibits the Government from taking property without providing just compensation" (Petition at 8).

The Petition further claims that FDA's regulations are arbitrary and capricious. The Petition asserts that HHS and FDA did not explain why the Agencies "deviat[ed] from . . . longstanding policy that "Canadian versions" of FDA-approved drugs are unapproved and misbranded drugs that are not eligible for importation, and . . . prior repeated determinations that section 804 importation would not significantly reduce consumer drug costs" (Petition at 8). The Petition also asserts that, "the Final Rule fails to adequately consider how commercial importation under SIPs will necessarily increase the likelihood that U.S. patients will receive adulterated drugs and otherwise compromise U.S. public health and safety" (Petition at 8–9). In addition, the Petition argues that the final rule inappropriately provided that States will be able to protect public health and safety because FDA will approve a SIP Proposal only upon a demonstration that the public health and safety will be protected (Petition at 9). The Petition also states that the final rule did not "offer a reasoned explanation for why manufacturers cannot charge Importers reasonable, market-based prices for the costs of conducting the statutory testing or provision of trade secrets and [confidential commercial information], analytical reference standards, and FDA-approved drugs" (Petition at 9).

As discussed in the rulemaking (85 FR 62094 at 62120–21), FDA has authority under section 804 to promulgate regulations regarding manufacturers' information and manufacturers' participation in the importation of their drugs by SIPs. With regard to the manufacturer's attestation and information statement described in § 251.5(c)(4)(xii), section 804(c)(1) of the FD&C Act specifies that the regulations must require that safeguards be in place to ensure that each drug imported under the regulations complies with the FD&C Act, including sections 501, 502 and 505. It would not be possible to ensure that each drug imported under the regulations complies with sections 501, 502, and 505, as required by section 804(c)(1), without the information from the manufacturer that is captured in the attestation and information statement. Only the manufacturer knows whether a drug that was originally intended for the Canadian market was manufactured "in conformity with current good manufacturing practice," as required by section 501. In addition, section 804(c)(3) authorizes the Secretary to include regulatory provisions that the Secretary determines to be appropriate as a safeguard to protect the public health or as a means to facilitate importation of prescription drugs (see 85 FR 62094 at 62120).

With regard to § 251.14(b), which requires the manufacturer to provide to the Importer a copy of any transaction documents that were provided from the manufacturer to the Foreign Seller, FDA's authority to require this derives from section 804(c)(3) and (e) of the FD&C Act. Under section 804(e)(2)(A)(i), if the Importer does the statutory testing, the manufacturer has to provide certain information, including "information needed to . . . authenticate the prescription drug being tested." The information needed to authenticate a section 804 drug includes the transaction documents that the manufacturer provides to the Importer under § 251.14(b). These documents enable the Importer and FDA to conduct a cross check of the transaction documents that the Foreign Seller provides to the Importer under § 251.14(c)(6). This cross check is valuable supporting evidence of the authenticity of the drug, helping to ensure that importation under section 804 poses no additional risk to the public's health and safety. Under § 251.14(b), manufacturers must provide the transaction documents needed for the cross check regardless of whether the Importer or the manufacturer conducts the statutory testing. FDA's authority to require this when the manufacturer conducts the testing derives from section 804(c)(3) of the FD&C Act, which provides that the regulations "shall contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs." As noted earlier, the cross check of the transaction documents from the sale of the drug by the manufacturer to the Foreign Seller is a valuable safeguard that protects the public health by providing evidence of the drug's authenticity.

With regard to requirements in §§ 251.16(b) and (d) that the manufacturer provide the Importer with the information that the Importer needs to conduct the statutory testing, section 804(b) requires that the Secretary issue regulations permitting the importation of certain drugs under section 804 and section 804(e) specifies that these regulations shall require the manufacturer to provide the Importer with the "information needed to authenticate the prescription drug being tested." Sections 804(d)(1)(J)(i)(III) and 804(d)(1)(L) specify that the regulations shall require the Importer to submit to FDA documentation demonstrating that section 804 drugs were tested "for authenticity and degradation" and that the Importer submit to FDA laboratory records including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards. While sections 804(d)(1)(J)(i)(III) and 804(d)(1)(L) do not state that the regulations must require manufacturers to provide the information needed to conduct these tests, FDA has the authority to require this under section 804(c)(1), which directs the Secretary to issue regulations that require that safeguards be in place to ensure that section 804 drugs comply with section 501, 502, and 505 of the FD&C Act, and under section 804(c)(3), which directs the Secretary to issue regulations that contain any additional provisions determined by the Secretary to be a means to facilitate the importation of prescription drugs.

The Petition also asserts that the section 804 certification and final rule are invalid because there was not an adequate explanation for "HHS and FDA's departure from long-held prior positions and factual findings related to importation" (Petition at 7-8). We disagree. As HHS explained in the section 804 rulemaking, HHS's previous analyses regarding the feasibility of implementing section 804 did not consider the possibility of implementing section 804(b) through (h) of the FD&C Act solely through programs that are proposed by States (or certain other non-federal governmental entities and their co-sponsors, if any) and authorized by FDA. HHS and FDA reviewed those past analyses and concluded that while the concerns about public health and

safety and the ability to achieve cost savings remain valid, section 804 of the FD&C Act can be implemented in a manner consistent with the certification criteria through programs, overseen by States or certain other non-federal governmental entities and their co-sponsors, if any, that require authorization by and reporting to FDA. These programs would be required to demonstrate to FDA that they could import drugs from Canada at no additional risk to the public's health and safety consistent with the requirements in section 804 of the FD&C Act and the section 804 final rule. These include, among other requirements, requirements relating to the types of drugs eligible for importation, the distribution channels and methods used for product traceability, and the testing of eligible prescription drugs for authenticity and degradation. In addition, in accordance with section 804, the final rule requires that drugs imported under section 804 meet the conditions in an FDA-approved NDA or ANDA except for deviations from the required U.S. labeling. SIPs authorized by FDA will also demonstrate significant cost reductions to the American consumer.

As discussed above, we also disagree with the Petition's assertion that there is an increased likelihood that section 804 drugs will be adulterated in violation of section 501 of the FD&C Act, because of the supply chain security, statutory testing, and other protections in section 804 and the final rule.

Regarding the Petition's mention of oversight by States and Indian Tribes, under the final rule, a Section 804 Importation Program Sponsor ("SIP Sponsor") means a State or Indian Tribe that regulates wholesale drug distribution and the practice of pharmacy that submits a proposal to FDA that describes a program to facilitate the importation of prescription drugs from Canada under section 804 of the FD&C Act and is responsible for oversight of the implementation of the program (85 FR 62094 at 62127). We believe oversight by a State or Indian Tribe is an important safeguard because these entities, which oversee pharmacies and wholesale distribution and have tools to protect public health, are uniquely positioned to provide independent oversight of importation activities (see 85 FR 62094 at 62098). However, in certain future circumstances described in the final rule, a pharmacist or wholesale distributor may be a SIP Sponsor.

The preamble to the final rule (85 FR 62094 at 62119) explained that we do not agree that section 804 of the FD&C Act is best interpreted to permit manufacturers to charge Importers for information (such as the attestation and information statement, the executed batch records, and the statutory testing information) or services (such as conducting statutory testing) that section 804 and FDA's regulations require them to provide. Section 804(h) explicitly requires manufacturers to authorize Importers to use a drug's approved labeling at no cost. This does not mean that manufacturers can charge for information or services that they are required to provide. If manufacturers were permitted to charge it would directly undermine section 804's cost-reducing goal. Moreover, interpreting section 804 to permit manufacturers to charge Importers is not necessary to avoid a Fifth Amendment Takings Clause issue because, as explained below, neither section 804 nor FDA's regulations effects a taking under the Fifth Amendment.

c. First Amendment

The Petition states that the final rule "compromises manufacturers' constitutional speech rights" (Petition at 9). The Petition asserts that the final rule "compels manufacturers to allow Importers to use, at no cost, the manufacturers' FDA-approved labeling, which includes the manufacturers'

speech" (Petition at 9). The Petition states that "[t]his compelled use of manufacturers' labels, which often include the manufacturer's name and other trademarks, would imply that the manufacturers vouch for the quality of the imported drugs and the accuracy of their labeling and are associated with the Importer and the SIP, notwithstanding the statement that drugs were being imported without manufacturers' authorization" (Petition at 9). The Petition states that "[t]he compelled attestation, use-of-labeling, and testing provisions also amount to a compelled subsidy of Importers," noting that there are penalties for a knowing failure to comply with the testing provisions (Petition at 9). The Petition also asserts that the final rule deprived manufacturers of "the opportunity to add to the labels any disclaimers or other language to indicate, for instance, that they do not stand behind such products" (Petition at 9). The Petition also notes that the final rule did not "establish a process for solving disputes over attestations," and therefore "manufacturers may feel compelled to make attestations with which they disagree, in violation of the First Amendment" (Petition at 9).

As discussed in the preamble to the final rule (85 FR 62094 at 62115–16), we disagree with the premise in the Petition that these provisions should be understood as speech regulations that implicate the First Amendment. The final rule requires manufacturers to engage in the authentication and quality assurance process for drugs imported under a SIP. Manufacturers can participate directly, by conducting the statutory testing themselves, or they can facilitate the process by providing the necessary testing information to the Importer. Manufacturers must also provide the attestation and information statement and the executed batch records required by § 251.5(c)(4)(xii), to establish that a section 804 drug meets the conditions in the FDA-approved NDA or ANDA, including any process-related or other requirements for which compliance cannot be established through laboratory testing. Participating in and facilitating authentication and quality assurance are not fundamentally expressive activities, even though there is necessarily information exchanged. Similarly, authorizing the use of FDA-approved labeling neither restricts a manufacturer's speech nor compels it to express ideas with which it disagrees (85 FR 62094 at 62115).

The referenced provisions of the final rule are needed to ensure that drugs imported under a SIP comply with sections 501, 502, and 505 of the FD&C Act, as required by section 804, in addition to other provisions, such as section 804(e) of the FD&C Act. The testing results, attestation and information statement, and executed batch records are needed to ensure that the drugs are authentic, not degraded, and are in compliance with established specifications and standards, and to confirm compliance with any process-related or other requirements that cannot be established through laboratory testing. The FDA-approved labeling is necessary to ensure that prescribers, pharmacists, and patients have the information they need to prescribe, dispense, and use the drugs appropriately. Without these provisions, it would not be possible to ensure that drugs imported under section 804 meet U.S. legal and regulatory requirements and thus pose no additional risk to the public's health and safety (85 FR 62094 at 62115). Manufacturers are being called upon to help with the process of product authentication, quality control, and product identification, not compelled to speak a message.

While the requirement that a drug's manufacturer authorize an Importer to use the drug's FDA-approved labeling does not equate to a requirement that the manufacturer convey or subsidize the conveyance of an idea, the Petition argues that consumers could mistakenly conclude from the inclusion of a manufacturer's name and trademarks on the labeling that, among other things, the

manufacturer vouches for the safety, efficacy, and quality of its drug when imported by a SIP. The Petition also argues that consumers could mistakenly assume that a manufacturer authorized the importation of its drug by the SIP. To address the concern that the use of the FDA-approved labeling might create the misleading impression that the manufacturer is conveying or subsidizing the conveyance of ideas through the labeling of a section 804 drug, in the final rule FDA revised § 251.13(b)(4)(iv) to require the following disclosure: "[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." FDA determined that it is not necessary to require the addition of the manufacturer's name and place of business if they do not already appear on the FDA-approved labeling.

Even if the First Amendment were implicated, any minimal burdens on speech are more than adequately justified by the purposes served by this program. The Government may require factual and uncontroversial disclosures that are justified by a governmental interest and do not unduly burden protected speech. The provisions at issue here—attesting that a product meets the conditions in its approved NDA or ANDA and supplying related information, supplying testing protocols and executed batch records, and authorizing the use of labeling—all relate to the conveyance of factual and uncontroversial information. The Government interest is clear. Prescription drug spending in the United States has increased dramatically in recent years and is projected to account for an increasing share of the country's health care spending. This program is designed to address that problem by allowing for the importation of lower cost prescription drugs from Canada into the United States. And there is no burden on protected speech—nothing in any of these provisions limits manufacturers' ability to speak freely about their products.

The Petition implies that the regulations would compel the manufacturer to provide a false or misleading attestation. We disagree. FDA's regulations do not require a manufacturer to attest to anything that the manufacturer does not know or cannot attest to truthfully. If, for example, the drug that the manufacturer manufactures for sale in Canada does not meet the conditions in the FDA-approved NDA or ANDA, a manufacturer could not and should not attest that "but for the fact that [a drug] bears the HPFB-labeling," the drug "meets the conditions in the FDA-approved NDA or ANDA." This is clarified in the final rule in § 251.5(d), which states that if the manufacturer cannot provide the attestation and information statement, it must notify FDA and the Importer of its inability and articulate with specificity the reason or reasons for it. In addition, a manufacturer's attestation and information statement would be as of the date that the drug in question left the manufacturer's control. A manufacturer could not and should not attest, for example, that the Foreign Seller held the manufacturer's drug in compliance with CGMP.

Moreover, the Government's interest in the goals of this program is substantial and the regulation is no more extensive than necessary to directly advance that interest. The increasing cost of prescription drugs is causing hardship to American consumers. The regulation would directly address this by providing for the importation of lower cost prescription drugs from Canada to significantly reduce the cost of covered products to the American consumer, while posing no additional risk to the public's health and safety. The information that the manufacturer is required to supply is no more extensive than necessary to ensure that section 804 drugs are authentic, not degraded, and meet the conditions in an FDA-approved NDA or ANDA, all of which serves to ensure that the drugs are safe and effective. Likewise, the FDA-approved labeling is necessary to ensure that prescribers, pharmacists, and patients have the information

they need to prescribe, dispense, and use the drugs appropriately. As noted earlier, the required labeling statement will help avoid potential confusion between products with the same name and help pharmacists distinguish a section 804 product when selecting the product on the pharmacy shelf. The labeling statement may also aid in pharmacovigilance. Finally, the addition of the disclosure that the drug was imported from Canada without the manufacturer's authorization will prevent prescribers, pharmacists, or patients from mistakenly concluding that the manufacturer is conveying an idea or subsidizing the conveyance of an idea.

d. Fifth Amendment Takings

The Petition also raises Fifth Amendment Takings claims. As noted above, the Petition asserts that "provisions of the Final Rule raise serious constitutional questions under the Fifth Amendment to the U.S. Constitution, which prohibits the Government from taking property without providing just compensation" (Petition at 8). The Petition references provisions in the final rule that "(1) require a manufacturer to attest that a drug meets the conditions in an approved NDA or ANDA but for the fact that the drug bears Canadian labeling, or to notify FDA and explain with specificity why it cannot provide that attestation; (2) disclose the trade secret and confidential information that the U.S.-approved product and foreign-approved product are the same; and (3) require manufacturers to disclose trade secrets and other confidential information and provide samples of analytical reference standards and the FDA-approved drug to Importers for free" (Petition at 8). The Petition further asserts that the final rule may violate the Fifth Amendment's Takings Clause "by expropriating manufacturers' intellectual property in their drug labeling, testing protocols (or testing services), and in the similarity (or lack thereof) of U.S. and Canadian drugs, and giving it to Importers without providing any compensation" (Petition at 9).

While the Petition does not clearly articulate what property interest has been "expropriate[ed]" without compensation in violation of the Fifth Amendment, or cite any legal authority, we disagree with the suggestion that there has been a taking. As discussed in the preamble to the final rule, the government is not required to pay for the incidental effects of its laws and regulations. In this case, the pharmaceutical industry operating in the United States has benefited from Federal laws and regulations that allow manufacturers to recoup the costs of pharmaceutical research and development and to be rewarded for their investments in it. As explained in the rulemaking, however, the increasing cost of prescription drugs is placing a heavy burden on American consumers (85 FR 62094 at 62117). Section 804 and FDA's regulations require manufacturers of certain drugs—those imported under SIPs—to provide limited information to Importers or qualified laboratories under limited circumstances. That Congress chose to place an incidental burden on the pharmaceutical industry to reduce the cost of prescription drugs does not offend any principle of fundamental fairness.

The U.S. Supreme Court has held that "when a regulation impedes the use of property without depriving the owner of all economically beneficial use, a taking still may be found based on 'a complex of factors,' including: (1) The economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action." (*Murr* v. *Wisconsin*, 137 S. Ct. 1933, 1943 (2017) (citing *Palazzolo* v. *Rhode Island*, 533 U.S. 606, 617 (2001)).) The U.S. Supreme Court has held that two categories of regulatory action are generally per se takings:

(1) When the government "requires an owner to suffer a permanent physical invasion of her property;" and (2) when regulations "completely deprive an owner of 'all economically beneficial us[e]' of her property" (*Lingle* v. *Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005) (quoting *Lucas* v. *S.C. Coastal Council*, 505 U.S. 1003, 1019 (1992))). Neither of those circumstances is present here.

With regard to the economic impact of section 804 of the FD&C Act and the final rule on manufacturers, we note that the Government action here is limited. Courts have rejected regulatory takings claims even where the government's action "impose considerable costs on private actors in the regulated industry." *Mobile Relay Assocs.* v. *FCC*, 457 F.3d 1, 12 (D.C. Cir. 2006). Instead, in evaluating the economic impact of a regulation, courts have explained that the "touchstone" is "proportionality": "the size of a liability only weighs in favor of finding a taking insofar as it is out of proportion to the legitimate obligations society may impose on individual entities." *B&G Constr. Co.* v. *Dir., OWCP*, 662 F.3d 233, 260 (3d Cir. 2011) (cleaned up). Because manufacturers will retain the right to exclude everyone except Importers and qualifying laboratories from the use of their trade secrets and commercial or financial information that is privileged or confidential, their trade secrets and commercial or financial information that is privileged or confidential will retain significant value. An Importer or qualifying laboratory's use of a manufacturer's trade secrets or commercial or financial information that is privileged or confidential will be limited to conducting the statutory testing and establishing that an eligible prescription drug meets the requirements of the FD&C Act and FDA's regulations. Consistent with section 804 of the FD&C Act, FDA's regulations mandate that the trade secrets and commercial or financial information that is privileged or confidential that the manufacturer provides be used only for purposes of testing or otherwise complying with the FD&C Act and FDA's regulations. Moreover, the government action here may be further constrained by the fact that there will be a limited number of SIPs working with a limited number of Importers and qualifying laboratories, and by the fact that the SIPs will be time limited. The economic impact of FDA's regulations is also constrained by the fact that manufacturers will retain their right to protect their trade secrets against disclosure. As required by section 804(e)(2) of the FD&C Act, the final rule mandates in § 251.16(g) that the Importer keep any information that the manufacturer provides 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 in strict confidence. The final rule also requires that 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 be kept in strict confidence. Moreover, manufacturers have the option of conducting the statutory testing themselves, which would obviate the need to disclose the statutory testing information to the Importer. While the manufacturer would still need to disclose the statutory testing information and results to FDA, FDA would ensure that any trade secrets or confidential commercial information remain confidential consistent with the law. In addition, as discussed earlier, the labeling statement will make it clear that the section 804 drug was imported without the manufacturer's authorization (see 85 FR 62094 at 62118).

With regard to potential interference with distinct investment-backed expectations, regulated industry has been on notice since at least October 28, 2000, when the predecessor to the current section 804 of the FD&C Act was signed into law as part of the Medicine Equity and Drug Safety (MEDS) Act of 2000, that manufacturers could be required to disclose information

needed for safe importation. Thus, sponsors of NDAs or ANDAs submitted after that date could not have a reasonable investment-backed expectation that is inconsistent with section 804. With regard to drugs marketed under applications submitted before October 28, 2000, it would be reasonable for manufacturers to expect that a provision like section 804 would be enacted. Those that do business in highly regulated fields, such as the prescription drug industry, are on notice that changes are possible.

With regard to the "character of the governmental action," section 804 of the FD&C Act and the final rule do not amount to a physical invasion and they have a legitimate public purpose, to significantly reduce the cost of covered products to the American consumer without any additional risk to the public's health and safety. For these reasons, neither section 804 nor the final rule amounts to a taking of manufacturers' property that requires compensation under the Fifth Amendment.

D. Identification of Foreign Seller

The Petition notes, correctly, that FDA cannot approve a SIP Proposal "unless and until a Foreign Seller is identified that meets the statutory and regulatory requirements" (Petition at 9). However, we disagree with the Petition's request "that FDA disclose the name of Foreign Sellers in SIPs, and in particular, the name of the Foreign Seller added to Florida's Proposal as soon as the State provides the relevant information to FDA" (Petition at 27). The Petition states that disclosure of this information is important for transparency and due process, to allow a petitioner to comment on a SIP Proposal, and to promote international harmonization (Petition at 27). The Petition also argues that, in the case of Florida's SIP Proposal, the state might not consider the identity of its Foreign Seller to be confidential business information to be protected from disclosure (Petition at 27–28).

With regard to disclosure of potential Foreign Sellers, as discussed in the preamble to the final rule, we do not intend to publicly disclose information from the SIP Proposal or authorization that is confidential business information where such disclosure is restricted by law, potentially including information about Foreign Sellers or the eligible prescription drugs that might be imported. Generally, information about suppliers and proposed business plans is confidential business information unless that information is made public by the information owner. However, as noted in the Petition, this information might become public in other ways, such as through State open records laws. In this case, Florida has publicly identified the name and address of the Foreign Seller for its SIP Proposal.

III. CONCLUSION

For the reasons set forth above, your Petition is denied.

Sincerely,

Douglas C. Throckmorton -S

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Patrizia Cavazzoni, MD
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