DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Importation of Prescription Drugs

Docket No. FDA-2019-N-5711

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Table of Contents

Executive Summary

The proposed rule, if finalized, would allow commercial importation of certain prescription drugs from Canada through time-limited programs, Section 804 Importation Programs or SIPs, sponsored by at least one non-federal government entity with possible co-sponsorship by a wholesaler or pharmacist. As we lack information about the expected scale or scope of such programs, we are unable to estimate how they may affect U.S. markets for prescription drugs. In particular, we are unable to estimate the volume or value of drugs that may be imported under the SIPs or the savings to U.S. consumers who may participate in such programs.

Costs of the proposed rule may fall on the federal government, importation program sponsors, importers, and manufacturers of imported drugs. The federal government would incur costs to implement the proposed rule and conduct oversight of authorized programs. Sponsors would face costs to prepare proposals, implement approved programs, and produce program reports and records. If their drugs are imported into the U.S. from Canada, drug manufacturers may have to provide importers with certain information. These costs depend on the number and type of participating importation programs. We lack information to estimate these costs.

Finally, U.S. patients, as well as wholesale drug distributors, pharmacies, hospitals, and third-party payers may all experience savings, but we lack information necessary to estimate such savings. As drug distributors realize savings in acquiring imported drugs and pass some of these savings to consumers, it is possible that U.S. drug manufacturers may experience a transfer in U.S. sales revenues to these parties.

I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We cannot anticipate if sponsors will contract with small entities to implement their authorized SIP proposals and request comment on the impact the proposed rule may have on small entities. We also lack information to quantify the total impacts of the proposed rule. Therefore, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule, if finalized, would allow commercial importation of certain prescription drugs from Canada through time-limited programs, Section 804 Importation Programs (SIPs), sponsored by at least one non-federal government entity with possible co-sponsorship by a wholesaler or pharmacist. If such programs allow importers to leverage drug price differences between the U.S. and Canada, they may result in cost savings for U.S. consumers.

Costs of the proposed rule may accrue to the federal government, SIP sponsors, importers, and manufacturers of imported drugs. The federal government would incur costs to implement the proposed rule and conduct oversight of authorized programs. Program sponsors would face costs to prepare proposals, implement approved programs, and produce program reports and records. Drug manufacturers will have to provide certain information to importers if their drugs are imported into the U.S. from Canada.

SIPs may offer cost savings to patients, as well as participating wholesale drug distributors, pharmacies, hospitals, and third-party payers. As drug distributors realize savings in acquiring imported drugs and pass some of these savings to consumers, it is possible that U.S. drug manufacturers may experience a transfer in U.S. sales revenues to these parties.

We are unable to estimate the cost savings from this proposed rule, as we lack information about the likely size and scope of SIP programs, the specific drug products that may become eligible for importation, the degree to which imported drugs would be less expensive than non-imported drugs available in the U.S., and which SIP eligible products are produced by U.S. drug manufacturers.

Summary of Benefits, Costs, and Distributional Effects of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential cost savings to consumers and third-party payers or entities						
Costs	Annualized Monetized $millions/year					7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential costs to federal government, SIP sponsors, importers, and manufacturers of imported drugs						
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From: U.S. drug manufacturers			To: Importers and U.S. consumers			Not Quantified
Effects	State, Local or Tribal Government: Potential costs and cost savings to state, tribal, and territorial government entities from sponsoring SIPs Small Business: Wages: Growth:							

We lack information about the likely size and scope of SIP programs, the specific drug products that may become eligible for importation and which SIP eligible products are produced by U.S. drug manufacturers, and the degree to which imported drugs would be less expensive than non-imported drugs available in the U.S. to estimate the present

and annualized values of the costs and cost savings of the proposed rule over an infinite time horizon. The designation under Executive Order 13771 of any final rule resulting from this proposal will be informed by comments received. Thus, we exclude the Executive Order 13771 summary table from this analysis.

II. Preliminary Economic Analysis of Impacts

A. Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended section 804 of the Federal Food, Drug, and Cosmetic Act to allow for drug importation from Canada. Section 804 directs the Secretary of the Department of Health and Human Services (DHHS), after consultation with the United States Trade Representative and the Commissioner of Customs, to promulgate regulations permitting pharmacists and wholesalers to import Canadian prescription drugs into the United States. However, implementation of section 804 requires the Secretary to certify, first, that any importation program must "pose no additional risk to the public's health and safety," and, second, that importation must "result in a significant reduction in the cost of covered products to the American consumer." Since section 804 was enacted, no Secretary has certified that these criteria can be met.

Several state governments are considering or developing commercial drug importation programs to expand access to Canadian drugs. According to the National Academy for State Health Policy, 30 states have pursued some form of legislative action related to wholesale drug importation.[1] Colorado, Florida, and Vermont passed laws to allow importation of prescription drugs from Canada.

B. Need for the Rule

Some prescription drug products are priced much higher in the U.S. than abroad, raising questions about the adequacy of competition in U.S. markets for these drugs and whether new policy approaches, such as importation under section 804, might effectively limit prices in those markets and protect consumers from unreasonable price increases. As described in section III of the preamble of this proposed rule, FDA has revisited the question of whether section 804 could be implemented in a manner consistent with the requirements for the Secretary's certification. FDA has determined that a narrow implementation of section 804 through time-limited programs, overseen by states or certain other government entities (with possible co-sponsorship by a wholesaler or pharmacist), could enable importation to occur in a manner consistent with the certification criteria. This implementation could potentially provide relief to some American consumers from the burden of rising prescription drug prices.

[1] The National Academy for State Health Policy's legislation tracker reports this information: https://nashp.org/rx-legislative-tracker-2019/. Accessed August 29, 2019.

C. Purpose of the Proposed Rule

This rule proposes to allow importation of certain prescription drugs from Canada.[2] It proposes detailed procedures for safe, time-limited commercial drug importation programs by state, tribal, or territorial government entities.

First, the proposed rule describes necessary procedures and precautions for the safe implementation of these time-limited SIPs. The proposed rule would help to ensure drug safety and efficacy through pre- and post-importation requirements, including: the provision of detailed proposals, pre-importation requests, supply chain security requirements, statutorily-prescribed testing, re-labeling with FDA-approved labels, recordkeeping, recall action plans, and adverse event reporting. Import entry would be restricted to the port of entry specified in an approved SIP so the FDA can ensure that it has adequate resources at the port to process admissibility determinations and perform sampling of any shipment containing eligible prescription drugs, if necessary.

Second, for acceptance under the Secretary's conditional certification, the proposed rule would require SIP sponsors to show that a program will provide cost savings to the American consumer. SIP sponsors would provide such information as part of their initial proposal, ongoing reporting, and requests for extension. As a result, any SIPs implemented under the proposed rule, if finalized, would be expected to produce significant cost savings for affected consumers.

When the proposed rule, if finalized, becomes effective, state, tribal, or territorial governmental entities could submit SIP proposals to the Secretary of DHHS.

D. Baseline Conditions

We adopt a baseline that reflects our best forecast of the world without the proposed rule. As described above, the Secretary would allow the importation of prescription drugs by certifying that importation poses no additional risk to the public's health and safety and achieves significant cost savings for the American consumer.

Currently, these conditions have not been certified, and U.S.-authorized commercial importation of Canadian drugs does not occur. Though some states have pursued such importation legislation, there is no federal program to accept proposals for importation projects. No federal government resources are allocated to consider or approve such proposals or to monitor adherence to any requirements that such proposals must follow. Moreover, no resources are allocated to facilitate, enforce, and monitor potentially approved importation programs in a way that ensures both safety and cost savings.

As described above, some states have developed or are developing legislation and proposals for the wholesale importation of prescription drugs, but implementation of such

[2] This proposed rule would establish a new part 251 of Title 21 of the Code of Federal Regulations to implement section 804(b)-(h) (21 (USC 384(b)-(h)).

plans is not permitted in the absence of this rule. We therefore use a baseline in which no states or government entities implement plans to import prescription drugs.

The regulatory baseline is subject to uncertainty, as there is a Center for Medicare and Medicaid Services (CMS) proposed rule currently undergoing interagency review that may, if its proposed pilot program is similar to that discussed in an associated advance notice of proposed rulemaking, reduce drug producers' ability to price-discriminate between the U.S. and Canada. If the CMS proposed rule is finalized first, it could substantially reduce the scope of the potential impacts of this proposed rule, depending on the overlap between the sets of drugs eligible under the two policies.[3]

E. Benefits of the Proposed Rule

We do not have information to allow us to estimate quantitatively the benefits of this proposed rule, if finalized. Benefits of the proposed rule, if any, would be in the form of significant cost savings to patients and to third-party payers or entities such as retail pharmacies and hospitals. Developing estimates of such benefits from SIPs would require, among other information, about the likely scale and scope of approvable SIPs and the specific drugs these SIPs would import.

FDA is aware of several studies estimating the potential savings from commercial drug importation [1] [2] [3]. However, these studies consider importation at a much broader scope than the current rule proposes, analyzing national aggregates for prescription drugs in general as opposed to state-specific programs involving specific drugs and distribution channels. In addition, savings from specific programs will be highly sensitive to the set of included drug products as well as the prices of those products, which can fluctuate substantially over short time periods. Therefore, earlier studies would not likely yield reasonable projections of savings from this proposed rule. We note that in 2017 the Congressional Budget Office issued a one-page report with preliminary estimates of S.469, the Affordable and Safe Prescription Drug Importation Act[4] [4]. S.469 is generally much broader in scope than this proposed rule, including importation of prescription drugs from other high-income countries in addition to Canada. The estimates thus consider a much larger quantity of potential drug imports than would be possible under this proposed rule. Because of these issues, we do not consider results outlined in these studies applicable to this proposed rule.

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[3] The CMS advance notice of proposed rulemaking (https://www.federalregister.gov/documents/2018/10/30/2018-23688/medicare-program-international-pricing-index-model-for-medicare-part-b-drugs) targets certain Medicare Part B drugs administered in physician offices or hospital outpatient departments and defines the set of eligible drugs as single source drugs, biologicals, biosimilars, and multiple source drugs with a single manufacturer. In contrast, Section 804(a)(3), and thus FDA's proposed rule, excludes from the definition of "eligible prescription drug" biological products, as well as controlled substances, infused drugs, intravenously injected drugs, and drugs that are inhaled during surgery. FDA's proposed rule would also exclude additional categories of drugs, including intraocularly and intrathecally injected drugs, drugs that are subject to Risk Evaluation and Mitigation Strategies (REMS), and drugs that do not meet the definition of a "product" for purposes of section 582 of the FD&C Act.

[4] The full text of the bill is available at https://www.congress.gov/bill/115th-congress/senate-bill/469/text.

In this section, we note the factors influencing potential benefits.

- U.S.-Canada drug price differences:
  Existing price differences for some drugs can be large. Several studies indicate relatively large differences in prices between the U.S. and other countries, including Canada [5] [6] [7]. These studies note, however, that the magnitude of international price differences typically varies with the specific set of drugs studied and that many drugs are not available in the same dosage form and strength in different pairs of countries. Estimated price differences can also vary according to how comparable products are identified (e.g. the definition of a drug) and how prices are measured (e.g. per milligram, dose, or package). The point of sale at which prices are captured (e.g. manufacturer, wholesale, retail) may also mask likely markups, discounts, and rebates. Finally, the most appropriate price measure for forecasting savings may vary according to the intended beneficiaries in each SIP.

- SIP costs and mark-ups:
  By contracting with SIP sponsors, importers and private intermediaries would face costs to implement SIPs and use markups to cover these costs and profit. Existing prices may provide a limited basis for forecasting savings to consumers without information on the likely markups applied at each stage in the supply chain. These markups depend on the management of individual SIPs and the drugs chosen for import.

- Canadian drug supply and potential regulatory response:
  Increases in competition in U.S. prescription drug markets may be limited. The Canadian drug supply is smaller than the U.S. drug supply[5] [8] [9], and the Canadian supply of eligible prescription drugs for import is controlled by the same manufacturer as controls the U.S. supply. In addition, Canadian regulatory agencies and/or manufacturers may also limit supply to be exported to the U.S. For all these reasons, there is question as to whether this proposed rule could yield non-zero benefits.

- Affected drug manufacturers:
  We lack data on whether imported drugs will be predominantly produced by domestic or foreign manufacturers and thus cannot estimate potential reductions in revenue to domestic drug manufacturers that may occur with importation. Cost savings to U.S. intermediaries and consumers through lower prices on imported drugs produced by a domestic manufacturer may come at the expense of the domestic manufacturer. We cannot estimate potential reductions in revenue to U.S. drug manufacturers. Cost savings from imported drugs produced by a foreign manufacturer benefit U.S. intermediaries and consumers by reducing what the U.S. spends on drugs from abroad.

[5] In 2018, roughly 700 million prescriptions were dispensed from Canadian retail pharmacies, compared to 5.8 billion in the U.S.

There are many payors in the U.S market, but this framework does not consider the potential implications of private and government insurance as well as other purchasers in the supply chain including hospitals and physicians. Moreover, the prices paid by multiple payors may be different, unobservable, or both. Finally, this framework does not consider the response of the manufacturer with regard to supplying the Canadian market.

F. Costs of the Proposed Rule

We do not have information to allow us to estimate quantitatively the costs of this proposed rule, if finalized. Costs of the proposed rule may accrue to the federal government, SIP sponsors, importers, and the manufacturers of imported drugs. Developing estimates of such costs from SIPs would require information about the likely number, scale, and scope of approvable SIPs and the specific drugs these SIPs would import, including whether the manufacturers of these imported drugs are domestic or foreign.

Though we note that 30 states have pursued some form of legislative action related to wholesale drug importation,[6] we cannot predict how many non-federal government entities might submit approvable SIP proposals. We also lack information to predict the potential timing of proposal submissions, implementation, and extensions. Moreover, we note that the proposed rule is designed to give flexibility to sponsors in how to develop their programs. Not only will the number and timing of proposals vary, but the scope and scale of proposals may be subject to significant variability. Due to these information constraints, we discuss costs qualitatively.

1. Costs to Federal Government

To implement the rule, if finalized, FDA would incur costs related to set-up prior to importation, proposal review and management, and compliance, monitoring, and enforcement. Because the proposed rule is designed to give flexibility to sponsors in how to develop their programs, we expect significant variation in proposal scale and scope and, thus, significant variability in potential resource needs.

- Pre-importation set-up:
  To prepare for importation by approved SIPs, FDA would incur costs to alter existing import computer systems and educate importers on procedures for filing entry of SIP drugs. FDA would also face costs to establish necessary monitoring and compliance resources at the specified ports of entry.

- Proposal management and review:
  All SIP sponsors would go through a review process to ensure that SIPs pose no additional risk to public health and safety and result in significant cost savings to the American consumer. This assessment would include corresponding with SIP sponsors and importers as well as reviewing SIP proposals, Pre-Import Requests,

[6] The National Academy for State Health Policy's legislation tracker reports this information: https://nashp.org/rx-legislative-tracker-2019/. Accessed August 29, 2019.

quarterly reports, SIP proposal and/or Pre-Import Request updates, and extension requests. Review costs could be incurred even if no SIP is ultimately approved.

- Import compliance, monitoring, and enforcement:
  Upon finalization of the proposed rule and authorization of a SIP, FDA would face costs associated with the compliance, monitoring, and enforcement of importation programs. FDA staff would perform review and testing activities during the pre-importation and importation stages. Such responsibilities include reviewing the importer's testing plan in the Pre-Import Request, reviewing testing results including complete laboratory records, and performing testing of SIP drug samples collected by FDA. Staff at the port of entry would perform admissibility review and make admissibility determinations of entries containing SIP drugs. FDA would also undertake a variety of monitoring and compliance activities, including label review and post-marketing surveillance, audits of SIP sponsors, potential appeals processes, recall review and effectiveness, and monitoring of adverse event reporting. As part of its ongoing compliance efforts, FDA would conduct inspections of foreign sellers, qualifying laboratories, and relabelers. FDA will be able to draw on all of this information about individual SIPs and individual imported drugs to monitor and evaluate the overall impacts of importation under Section 804. Finally, FDA would provide surveillance of entries falsely submitted as entries of compliant prescription drugs under a SIP, as well as monitor for any potential unintended consequences related to implementation of the proposed rule.

2. Costs to Section 804 Importation Program Sponsors

SIP sponsors would face set-up costs such as reading the final rule, SIP proposal development and submission, and contracting with importers and foreign sellers. Once a program begins, sponsors would face possible costs of extension and an annual reporting burden for each year the SIP operates. SIP sponsors would also incur costs of educating affected consumers and other parties in the drug supply chain about the SIP and developing a system for reporting adverse events and effectuating recalls. Some government entities may face a cost of developing and passing legislation before developing a SIP proposal. However, we recognize that some sponsors may choose to contract the development of proposals to a third party and thus incur only the costs related to contracting. Alternatively, some government entities may sponsor a proposal with a wholesaler, a pharmacist, or other government entities. Because we lack information to predict how each SIP might operate, we cannot quantify these costs to sponsors. Some of these impacts—such as costs of SIP proposal development and submission by early adopters—would be incurred even if no SIP is ultimately approved.

We note that the net financial impact on sponsors may be positive or negative. As undertaking a SIP is a voluntary activity, sponsors interested in reducing their own expenditures on prescription drugs would likely undertake SIPs only if they anticipate ultimately recovering all program costs directly from the resulting cost savings. Hence, the rule would likely leave such sponsors with net financial benefits. However, a non-

federal government entity might also choose to develop a SIP as a public service to reduce the prescription drug expenditures of its residents. In this case, the sponsor may deliberately incur costs of developing and implementing the program that it does not plan to recover, thus operating at a net financial loss.

3. Costs to Drug Manufacturers

As U.S. drug distributors realize savings in acquiring imported drugs and pass some of these savings to consumers and other parties in the drug supply chain, it is possible that U.S. drug manufacturers may experience declines in U.S. sales revenues. It is also possible that U.S. manufacturers of imported drugs may incur certain compliance costs if their drugs are imported into the U.S. from Canada.[7] Because we lack information on the type and quantity of drugs that would be imported through SIPs, we cannot predict which manufacturers, domestic or foreign, might face these costs.[8]

To ensure the authenticity of SIP drugs, the proposed rule would require the U.S. manufacturer to provide importers with certain information regarding testing methodology to authenticate the SIP drug as well as attestations and/or other evidence to establish that such a drug meets all conditions in the FDA-approved new drug or abbreviated new drug application. Alternatively, the manufacturer could choose to conduct this testing itself and may incur costs for this additional testing. Manufacturers would also have to provide additional attestations (authenticity testing is required for each shipment offered for import) that the SIP drug continues to meet the conditions in the FDA-approved drug application throughout the course of the program. It is possible that manufacturers may incur costs to provide these attestations to the importer. However, the magnitude of these costs may depend on the drugs imported in each SIP.

The manufacturer of a drug that is imported would also need to provide the importer with written authorization for the importer to use, at no cost, the FDA-approved labeling of the prescription drug. Manufacturers might face a cost to transmit this information as well as possibly an unquantifiable loss related to the proprietary value of this property, if any. In other words, it is possible that this labeling could help the importer capture a larger portion of the market currently held by the manufacturer and/or any other authorized user of the proprietary name and labeling.

[7] We note that foreign drug manufacturers face the same costs, but we do not consider foreign manufacturers in our account of costs to U.S. society.

[8] SIPs that significantly reduce the profits of drug manufacturers globally may disincentivize investment in research and development of new drug products. Any benefits of such investment (e.g., patients whose lives are extended or improved by new therapies) would be lost to society as a cost of the proposed rule. Because SIPs will be limited both in scope and duration, we believe the potential for effects on research and development will also be limited. We request comment on the potential for research literature on optimal patent length to be matched with an analysis of which pharmaceuticals have the most import potential. We further request feedback on whether the results of such a matching exercise could be used to assess whether the drug products affected by this proposal are likely to be currently over- or under-incentivized.

4. Costs to Importers and Other Intermediaries

Private intermediaries, such as wholesaler drug distributors or pharmacists, that contract with a SIP sponsor to implement a SIP would face business expenses, including but not limited to the purchase of drugs from Canadian foreign sellers, relabeling (including affixing the product identifier), compliance with proposal, pre-importation, and importation requirements, and testing by third-party laboratories. Importers' annual reporting burdens would include submission of pre-importation requests and fulfilling importation requirements. Importers would also face recordkeeping burdens to demonstrate compliance with secure supply chain and post-importation requirements.

However, importers will only undertake these costs if they ultimately expect to profit from the sale of imported drugs. An importer's expenses reduce the portion of cost savings passed on to the American consumer. However, this net transfer should be positive because the importer recovers its expenses and earns some profit by selling the drug down the supply chain.

We lack information about the potential number of participating importers, given that a single importer could contract with multiple SIPs, as well as the potential costs and profits importers might face. We describe these considerations in the benefits section. While we thus cannot include estimated importer costs quantitatively, we note that incurring these costs should always result in a net positive impact to the importer.

G. Distributional Effects

To the extent that this proposed rule is effective at leading to importation of prescription drugs that would be sold at less than current U.S. prices, it may provide benefits to American consumers unable and/or unwilling to pay for their prescribed medications.

We lack data on whether imported drugs will be predominantly produced by U.S. or foreign manufacturers and thus cannot estimate reductions in revenue to U.S. drug manufacturers. Cost savings on imported drugs produced by a domestic manufacturer would be a transfer from the domestic manufacturer to U.S. intermediaries and consumers through lower prices. Cost savings from imported drugs produced by a foreign manufacturer benefit U.S. intermediaries and consumers by reducing what the U.S. spends on drugs from abroad.

As noted earlier, we are not able to estimate the scale and scope of importation under approved SIPs, and thus we are unable to assess distributional effects quantitatively.

H. International Effects

The proposed rule, if finalized, would have potentially adverse effects on manufacturers selling drugs in Canada and on Canadian consumers.

As with other members of the supply chain, we assume that a Canadian foreign seller would not enter into an agreement with an importer unless it was profitable to do so.[9] The Canadian foreign seller will thus capture some portion of the manufacturer's initial U.S. sales revenues. The foreign seller's additional profit is a cost of the proposed rule if imported drugs are produced by a U.S. manufacturer.

Any SIPs resulting from the proposed rule may risk creating or exacerbating drug shortages in Canada.[10] If the Canadian government responds to shortages by relaxing price controls, Canadian consumers may face higher drug prices. Due to lack of information regarding the types and volumes of eligible prescription drugs that potential future SIPs might successfully import into the U.S., as well as the scope of possible responses by the government of Canada (e.g., a ban on wholesale prescription drug exports[11]), we cannot quantify potential impacts on Canadian consumers. In general, any costs imposed on Canadian consumers may be larger on an individual basis than corresponding benefits received by U.S. consumers, due to the comparative magnitudes of U.S. demand and Canadian supply with respect to most, if not all, drugs.

III. Initial Small Entity Analysis

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. If a rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any adverse impact of the rule on small entities.

Under the current (2017) Small Business Size Standards published by the U.S. Small Business Administration, pharmaceutical preparation manufacturing firms (NAICS code 325412) qualify as small businesses if they employ fewer than 1,250 employees. According to the most recent (2016) Statistics of U.S. Businesses, at least 939 of 1,017 firms classified in the pharmaceutical preparation manufacturing industry employed fewer than 1,250 workers. We observe that at least 92% of firms in this sector qualify as small businesses, which is understated due to data limitations. Similarly, at least 95% of

[9] Each foreign seller must register its name and place of business with the Secretary. It must provide the name of the SIP sponsor with which it works and relevant contact information. It must also register the name of its United States agent and follow all specified requirements for wholesalers. Additionally, the foreign seller would have to ensure that a section 804 serial identifier ("SSI"), which is a unique alphanumeric serial number of up to 20 characters, is affixed or imprinted to each package and homogenous case of drugs for import. Foreign sellers would also incur costs from FDA inspections.

[10] In 2019, for example, the Canadian Pharmacists Association discussed the current issue of drug shortages in Canada: https://www.pharmacists.ca/news-events/news/drug-shortages-have-greatly-increased-over-the-past-3-5-years-say-canadian-pharmacists/?lang=en. Moreover, the Health Canada Minister held a roundtable with healthcare industry stakeholders in August 2019, at which there was consensus that the proposed rule would exacerbate drug shortages in Canada.

[11] In 2007, following a proposal in Congress to import prescription drugs from Canada, the Canadian government introduced a bill to restrict exportation of drugs marketed in Canada. While neither the American nor Canadian bills were passed, the Canadian government could respond similarly to the proposed rule. Other possible responses include creating a licensing and permitting process or collecting fees from SIPs, which would increase the costs of participating in a SIP.

drug wholesalers (NAICS code 424210), or 6,542 out of 6,833 firms, fall under the threshold of 250 employees to qualify as small businesses. According to data from the 2012 SUSB survey, the most recent to include revenue information, at least 98% of pharmacies and drug stores (NAICS code 446110), or 18,490 out of 18,852 firms, fall under the revenue threshold of $27.5 million dollars and thus qualify as small businesses.

The proposed rule, if finalized, would commence agency review of SIP proposals submitted for authorization by states and government entities. According to the most recent (2017) Census of Governments, among "general-purpose local governments" there are 3,031 county governments, 19,495 municipalities, and 16,253 townships. We do not expect entities other than state governments to prepare proposals, and hence to incur any direct costs from the submission of proposals.

If any SIP proposals are submitted and authorized, resultant programs may possibly affect wholesalers and pharmacies to the extent that these parties either profit from access to lower-cost, imported drugs or are undercut by others with such access. Any authorized SIP that successfully introduces lower-cost, imported drugs may also decrease the profits of pharmaceutical manufacturers.

We cannot anticipate if sponsors will contract with small entities to implement their authorized SIP proposals and request comment on the impact the proposed rule may have on small entities. We also lack information to quantify the total impacts of the proposed rule. Therefore, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

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