Association for Accessible Medicines

Your Generics & Biosimilars Industry

March 9, 2020

SUBMITTED ELECTRONICALLY

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-5711; Importation of Prescription Drugs; Comments of the Association for Accessible Medicines

Dear Sir or Madam:

The Association for Accessible Medicines ("AAM") appreciates the opportunity to submit these comments to the Food and Drug Administration ("FDA") on its proposed rule to allow importation of certain prescription drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). 84 Fed. Reg. 70796 (Dec. 23, 2019) (Docket No. FDA-2019-N-5711). AAM and its member companies have a significant interest in the proposed importation plan because, if finalized, it would apply directly to certain generic drugs approved and marketed in Canada. Moreover, importation of brand prescription drugs originally intended for the Canadian marketplace could have a significant, negative effect on the health of the marketplace for generic drugs in the United States ("U.S.").

AAM represents the manufacturers and distributors of finished generic pharmaceuticals and biosimilars, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar industry. Our members manufacture more than 90% of all generic pharmaceuticals dispensed in the U.S., and their products are used in more than three billion prescriptions every year. Generics represent greater than 90% of all prescriptions dispensed in the U.S., but only 22% of expenditures on prescription drugs. AAM is the sole association representing America's generic drug sector.

AAM applauds FDA's commitment to use its existing statutory and regulatory authority to increase access to lower-cost, safe, and effective drugs for American patients. AAM believes that regulatory policies designed to facilitate generic drug competition in the U.S. will have the greatest impact on lowering drug costs and increasing access to safe and effective medicines that Americans can afford. AAM thus requests that FDA prioritize the implementation of policies that foster access to *FDA-approved* generic drugs, rather than drugs that are intended for foreign markets, such as Canada, and then re-purposed for U.S. patients. At a minimum, FDA should ensure that its importation policies do not reduce incentives for the development of generic drugs or otherwise impede access to these lower-cost, safe and effective medicines.

AAM is concerned that FDA's proposed rule to allow commercial-scale importation of Canadian drugs under Section 804 Importation Programs ("SIPs") is unauthorized, unworkable, will not result in significant cost savings to American patients, and may actually impair generic drug competition in the U.S., thereby resulting in increased prescription drug costs.

- First, AAM is concerned that the proposed rule, if finalized, will further weaken the incentives for the development of safe and effective generic drugs at a time when the generic drug industry is especially fragile and subject to increasing financial and competitive pressures. If the proposed rule impairs generic drug competition in the U.S., it could have the perverse effect of actually *increasing* prescription drug costs for American patients.

- Second, there is no evidence that the Secretary of Health and Human Services ("HHS") can accurately certify to Congress that implementation of section 804: (a) will pose no additional risk to the public's health and safety, and (b) will result in a significant reduction in the cost of covered prescription drugs to the American consumer. To the contrary, the proposed rule indicates clearly and unequivocally that the Secretary *cannot* make this certification. Because this certification is a prerequisite to section 804 becoming effective, the proposed rule, if finalized, would be unauthorized and *ultra vires*.

- Third, the proposed rule raises significant legal and Constitutional issues, particularly with respect to the forced disclosure and use of trade secrets and confidential commercial information. These legal issues undoubtedly will spark waves of litigation that AAM believes will hamstring the program for years and, worse, divert FDA resources from implementing regulatory policies that could foster generic competition in the U.S. and thus actually lower drug costs for American patients.

- Finally, the proposed rule poses several implementation issues that need to be modified or clarified before FDA finalizes the proposed importation program (assuming the above issues can be resolved). These include, among other things, explaining how SIP sponsors can identify eligible Canadian drug products for importation; deciding who will be responsible for conducting required testing; and clarifying a manufacturer's ability to charge for required information and services.

For all of these reasons, FDA should refrain from finalizing the proposed importation plan in its current form. Instead, FDA should devote its limited resources toward implementing regulatory policies that lower prescription drug prices through enhanced generic drug competition, which has a proven track record of lowering drug costs for American patients. AAM's detailed comments are set forth below.

I. Generic Drug Competition has a Proven Track Record of Reducing Prescription Drug Costs for American Patients and Thus Should be Prioritized and Protected

The generic drug industry currently provides massive cost savings to American consumers and the U.S. healthcare system as a whole. In 2018, more than 4 billion generic prescriptions were filled

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across the U.S., representing more than 90% of all dispensed prescriptions.[1] Yet generics account for only 22% of expenditures on prescription drugs.[2] Indeed, traditional generic drugs saved the U.S. healthcare system approximately $293 billion in 2018 – *and nearly two trillion dollars over the past ten years.*[3] As a result, the future affordability of medicines for patients is inextricably linked to the success of the generic drug industry.

Although these savings are impressive – and help ensure that patients do not need to make decisions between paying their rent and paying for their medicine – AAM believes there is significant room for improvement, particularly with respect to "specialty drugs." Specialty drugs, which include biologics and other complex medicines, account for only 2% of prescriptions but already represent almost half of drug spending.[4] As AAM has pointed out in prior comments to FDA,[5] there are numerous policy opportunities for FDA, HHS and other government agencies to encourage increased generic and biosimilar competition, particularly with respect to specialty drugs, and thereby provide patients and taxpayers with even greater savings. Some areas for improvement include patent abuses; regulatory abuses (*e.g.*, REMS) that slow or prevent generic and biosimilar approval; market imbalances that prevent competition even when generic and biosimilar products receive approval; and formulary issues.

AAM believes that regulatory policies that directly address these competition issues with respect to generic drugs and biosimilars will have a greater impact on lowering the costs of prescription drugs and biologics than the proposal to allow importation of certain prescription drugs from Canada. This was also the conclusion of the HHS Task Force on Importation ("HHS Task Force") in its 2004 Report on Prescription Drug Importation, which concluded that American consumers could realize more cost savings by "switching from more expensive brand-name products to exclusive use of FDA-approved generic products already on U.S. pharmacy shelves."[6]

AAM thus respectfully requests that FDA prioritize the implementation of regulatory policies that remove existing barriers to full and free competition from FDA-approved generic and biosimilar products. AAM has already identified and explained these policies in detail in prior comments and will not repeat them here. In AAM's view, FDA should devote its time and resources toward implementing policy initiatives that have a direct effect on generic drug and biosimilar competition

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[1] AAM, *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, p. 4 (2019) ("AAM Savings Report").

[2] AAM Savings Report, p. 4.

[3] AAM Savings Report, p. 4.

[4] AAM Savings Report, p. 4.

[5] *See, e.g.*, Comment from Association for Accessible Medicines, Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access, Docket No. FDA-2017-N-3615 (Nov. 17, 2017); Comment from Association for Accessible Medicines and the Biosimilars Council, Facilitating Competition and Innovation in the Biological Products Marketplace, Docket No. FDA-2018-N-2689 (Sept. 21, 2018).

[6] HHS Task Force on Drug Importation, Report on Prescription Drug Importation, p. 67 (Dec. 2004) ("HHS Task Force Report"), *available at* https://www.regulations.gov/document?D=FDA-2019-N-5711-0008.

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before undertaking a massive effort to import a highly circumscribed set of prescription drugs from Canada.

At a minimum, FDA should ensure that any importation rule it adopts does not reduce incentives for the development of generic drugs and biosimilar products or otherwise impede access to these lower-cost, safe, and effective medicines. AAM is concerned that several aspects of the proposed rule could do just that. First, the proposed rule appears to permit the importation of lower-cost Canadian drugs into the United States during relevant periods of patent and/or exclusivity protection covering the brand name product. [7] Moreover, the prior entry of a Canadian import likely will reduce the incentives for generic applicants to undertake patent litigation in the first place.

Second, the proposed rule appears to permit importation prior to and during a "first applicant's" 180-day exclusivity period, significantly undermining the value of 180-day exclusivity. If generic companies face competition during the 180-day exclusivity period not just from the brand and (possibly) an authorized generic – but also from Canadian imports – the incentives for challenging patents on brand-name drugs will be meaningfully eroded. AAM believes this is likely to result in less generic competition in the U.S. and higher prices for American patients.

Third, the proposed rule appears to provide an undeserved competitive advantage to Canadian imports over lower-priced generic drugs by permitting labeling statements highlighting cost reductions. Specifically, FDA is proposing to require the labeling of drugs imported from Canada to contain the following statement: "This drug was imported from Canada under the [Name of State or Other Governmental Entity and of Its Co-Sponsors, If Any] Section 804 Importation Program *to reduce its costs to the American consumer*." 84 Fed. Reg. at 70833 (proposed 21 C.F.R. § 251.13(b)(6)(i)) (emphasis added).

Since generic drugs typically are not permitted to be labeled with comparative cost information, this required labeling statement could mislead physicians, pharmacists, and patients into believing that a drug product imported from Canada under a SIP is less costly than an FDA-approved generic version of the reference listed drug ("RLD"). AAM believes this would provide an unfair competitive advantage to Canadian imports that could further damage the fragile marketplace for FDA-approved generic drugs. Moreover, this labeling requirement, perversely, could result in *increased* drug costs for American patients by inappropriately diverting sales to a Canadian import that otherwise would have gone to an even lower-priced generic.

Accordingly, before finalizing the proposed rule, FDA should carefully assess the likely effects of Canadian importation on generic drug competition generally and on overall drugs costs in the United States. This is especially critical given the importance of the generic drug marketplace for driving savings for American patients. Because of the magnitude of savings generated by generic drug competition (as described above), even minor disruptions to that marketplace could have major effects on competition and, concomitantly, drug costs. AAM thus requests that FDA conduct or commission a study to assess the likely effects of FDA's proposed importation plan on generic drug competition. Unless FDA's proposed importation plan achieves savings that clearly and significantly

[7] *See Impression Prods. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523 (2017) (holding that an authorized sale outside the United States exhausts all rights under the Patent Act).

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outweigh any potential disruptions to the generic drug marketplace, FDA should reconsider its proposal.

II. There is No Basis for the Secretary of HHS to Make the Required Certification Under Section 804(l)(1)

As a matter of law, Section 804 can become effective only if the Secretary of HHS certifies to Congress that the implementation of the entire section (*i.e.*, "this section") will: (1) "pose no additional risk to the public's health and safety;" and (2) "result in a significant reduction in the cost of covered products to the American consumer." 21 U.S.C. § 384(l)(1). Since 2000, no HHS Secretary has been able or willing to certify that importation of foreign drugs would pose no additional safety risks or result in significant cost savings to American patients. 84 Fed. Reg. at 70799. On the contrary, FDA and HHS consistently have raised concerns that:

- FDA cannot ensure the safety and effectiveness of drugs imported via such a program;
- A section 804 importation program would open up the "closed" U.S. distribution system, thereby increasing the opportunity for counterfeit and substandard drugs to enter the distribution system; and
- A section 804 importation program would not result in significant cost savings to American patients.

84 Fed. Reg. at 70799. In this case, each of the reasons that previously precluded a certification applies with equal (if not greater) force to FDA's proposed importation rule. Because the Secretary cannot make an accurate certification under section 804(l)(1) of the FFDCA, 21 U.S.C. § 384(l)(1), section 804 as a whole cannot become effective, and FDA's regulations, if finalized, thus would be *ultra vires*.

A. The Proposed Rule Will Not Result in Significant Cost Savings to American Patients

There is no evidence that the proposed rule, if finalized, will result in significant cost savings to American patients.

The category of drugs subject to importation is likely to be circumscribed because an "eligible prescription drug" must comply with approval requirements in both Canada and the U.S. 84 Fed. Reg. at 70827 (proposed 21 C.F.R. § 251.2). In other words, the Canadian version of the drug must meet all conditions (other than labeling) set forth in the approved New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") for the U.S. version of the drug, including specifications, manufacturing facilities, and manufacturing lines. This requirement is critical to assure the safety and effectiveness of drugs imported from Canada. The HHS Task Force explained:

> [F]oreign versions of FDA-approved drugs may not be the same as their U.S. counterparts due to differences in formulation, source of ingredients or manufacturing processes. These differences may occur

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> even when the FDA-approved medicine and a foreign version are made in the same facility. In these cases, each drug is made on a different line and subject to different standards and controls to meet the requirements of the respective country.[8]

AAM believes that only a fraction of the drugs approved in Canada meet this rigorous "FDA approval" requirement because of differences, both large and subtle, between FDA's and Health Canada's approval requirements (*e.g.*, different specifications).[9] In 2004, the HHS Task Force concluded that "[m]ost drugs imported into the U.S. from Canada now are not approved under section 355 [of the FFDCA]."[10] Because the "FDA approval" requirement "strictly limits the universe of drugs that are eligible to be imported from Canada," the HHS Task Force determined that, under section 804, "very few drugs would be eligible for importation, specifically, a small subset of drugs that have approved NDAs and ANDAs."[11] There is no reason to believe this situation has changed materially since the HHS Task Force made this finding.

Third, the "FDA approval" requirement gives brand manufacturers unprecedented control over whether a particular drug is eligible for importation under section 804. For example, if a manufacturer wanted to protect a particularly expensive and highly profitable brand-name drug product from importation, it could do so by making minor formulation changes to the Canadian version or moving production of the Canadian version to a manufacturing facility or line that is not inspected or approved by FDA. As a result, only the least expensive and least profitable drugs are likely to remain eligible for importation under section 804.

Fourth, brand name manufacturers may seek to protect their most expensive and profitable drugs in other ways. "They may restrict shipments to foreign wholesalers, to other entities involved in exports to the U.S., or to an exporting country as a whole."[12] They may impose contractual limits on the ability of Canadian wholesalers to import their drugs into the U.S. They may delay product launches in Canada to reduce the period when importation would undercut U.S. sales. Or they may seek to increase the costs of importation to Foreign Sellers and/or Importers participating in a SIP.

For example, even though section 804 requires manufacturers to provide written authorization for an Importer to use the approved labeling "at no cost," 21 U.S.C. § 384(h), the statute does not impose any similar "no cost" requirement on other information and services that manufacturers must provide to Importers to facilitate importation. Accordingly, AAM believes it is highly likely that manufacturers will charge Importers high fees for, *inter alia*, conducting required testing at a

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[8] HHS Task Force Report, pp. 14-15.

[9] Even slight differences in approval requirements, such as minor specification changes or use of a different manufacturing line, would disqualify a Canadian-sourced drug from importation under section 804. "If a drug imported from Canada is not actually an FDA-approved product, FDA cannot assure that an imported drug product is readily substitutable for the FDA-approved version without a showing of bioequivalence." HHS Task Force Report, p. 27.

[10] HHS Task Force Report, p. 26.

[11] HHS Task Force Report, p. 26.

[12] HHS Task Force Report, p. 77.

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qualified laboratory or supplying the information that Importers would need to conduct the required testing themselves (*e.g.*, specifications, proprietary testing methods). *See id.* § 384(e). By increasing the costs associated with importing drugs from Canada, brand manufacturers can reduce any cost savings that could be passed on to American consumers. While FDA might seek to prohibit this type of charging by manufacturers, such a prohibition is likely inconsistent with the statute and would raise significant Takings Clause issues.

AAM believes that the above-described restrictions will severely limit any cost savings from FDA's proposed rule. The HHS Task Force has explained that the existence of lower prices abroad is not sufficient to ensure significant cost savings; rather, "[t]he volume and type of foreign drugs that may be imported is also critical in determining total savings …."[13] For the reasons described above, FDA's proposed rule is likely to apply only to an extremely small subset of the *least* expensive drugs available in Canada. As such, savings to the American consumer from a legalized importation scheme are likely to be small.

For many of the same reasons, the HHS Task Force determined in 2004 that "total savings to drug buyers from legalized commercial importation would be one to two percent of total drug spending and much less than international price comparison might suggest."[14] The HHS Task Force further found that "[m]ost of the savings would likely go to third party payers, such as insurance companies and HMOs[,]" and thus that "savings going directly to individuals would be less than one percent of total spending."[15] To put this in perspective, the HHS Task Force concluded that American consumers could realize more cost savings by "switching from more expensive brand-name products to exclusive use of FDA-approved generic products already on U.S. pharmacy shelves."[16] The HHS Task Force considered the potential savings from importation to be "small," *i.e.*, non-significant.[17]

There is no evidence that circumstances have materially changed since 2004 or that the HHS Task Force's analysis of potential savings from legalized importation is no longer accurate. To the contrary, in the preamble to its proposed rule, FDA explicitly acknowledges that the concerns about the ability to achieve cost savings raised in past analyses "remain valid." 84 Fed. Reg. at 70800. This should be the end of the matter.

Nevertheless, FDA contends that its proposal to implement section 804 through a SIP program sidesteps the prior cost savings analyses because it would require proposed SIPs, individually, to "demonstrate significant cost reductions to the American consumer." *Id*. Given the factors described above, however, this showing should be impossible to make for any individual SIP because each SIP will operate on a much more limited scale and scope than the nationwide program analyzed by the HHS Task Force. FDA attempts to address this problem by proposing to assess "significant cost

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[13] HHS Task Force Report, p. 67.

[14] HHS Task Force Report, p. 65.

[15] HHS Task Force Report, p. 65.

[16] HHS Task Force Report, p. 67.

[17] HHS Task Force Report, p. 67.

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savings" in the context of each specific SIP proposal. *Id*. at 70807. In other words, cost savings would be assessed only with respect to the specific consumers covered by the SIP (*e.g.*, residents of a particular state). AAM believes that this limitation conflicts with the clear language of the statute, which requires cost savings to be assessed in relation to "the American consumer," not individual subsets of American consumers defined by specific SIPs.

Finally, FDA itself has admitted that it does not currently have enough information to certify that its proposal will result in "significant" cost savings to American patients – or even to patients covered by any particular SIP. According to FDA, "[W]e are unable to estimate the cost savings from this proposed rule, as we lack information about the likely size and scope of SIP programs and about 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 United States, and which SIP eligible products are produced by U.S. drug manufacturers." *Id*. at 70823. In its Preliminary Regulatory Impact Analysis, FDA's Economics Staff even concedes that "there is a question as to whether this proposed rule could yield non-zero benefits."[18]

Given FDA's admission that it lacks any information regarding potential cost savings, there is no reasonable basis for the HHS Secretary to make the certification required by section 804(l)(1) that implementation of section 804 "will" result in "significant" cost savings to the "American consumer." Moreover, FDA has no authority to issue a conditional certification establishing what is essentially a pilot program – *i.e.*, time-limited SIPs – to gather more data regarding whether it can accurately make the required certification. If FDA currently lacks the necessary data, its certification will be, as a legal matter, invalid.

B. The Proposed Rule, if Finalized, Would Pose Additional Risks to the Public Health and Safety

There likewise is no evidence that the proposed rule, if finalized, will pose no additional risk to the public's health and safety as required by the section 804 certification. On the contrary, by creating cracks in America's closed distribution system, FDA's proposed importation scheme will entail unavoidable additional risks to the health and safety of American patients from counterfeit, adulterated, and substandard prescription drugs.

First, FDA does not have adequate resources to effectively monitor the safety and integrity of drugs imported from Canada, including conducting inspections of Foreign Sellers, Importers, and Qualified Laboratories. In 2004, the HHS Task Force identified resource constraints as one of the main issues preventing the Secretary of HHS from making a safety certification.[19] In the years since, these resource constraints have not abated. On the contrary, FDA concedes in the preamble to the proposed regulations that "resource constraints … limit FDA's ability to provide effective safety oversight" of the proposed importation plan. 84 Fed. Reg. at 70802. AAM believes that this

[18] FDA, Importation of Prescription Drugs: Preliminary Regulatory Impact Analysis, Docket No. FDA-2019-N-5711, p. 9, *available at* https://www.regulations.gov/document?D=FDA-2019-N-5711-0002.

[19] HHS Task Force Report, p. 23 ("a commercial importation program could be feasible but would require … substantial additional resources ….").

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concession precludes the Secretary of HHS from certifying that the proposed importation plan would pose no additional risks to patients.

FDA's proposal to compensate for this resource shortfall by relying upon SIP sponsors, Foreign Sellers, Importers and others to police compliance is not an adequate substitute for direct and rigorous FDA oversight. Although FDA expects to limit SIP sponsorship (at least initially) to state and other non-federal government entities, there is no evidence that these governmental entities have the resources or expertise to monitor and ensure compliance with *federal* regulatory requirements. For example, SIP sponsors will be responsible for ensuring that all participants in the SIP – including entities located in Canada (*i.e.*, Foreign Sellers) and other foreign countries (*i.e.*, manufacturers) – comply with the requirements of section 804. 84 Fed. Reg. at 70830 (proposed 21 C.F.R. § 251.3(d)(10)). Likewise, SIP sponsors will be responsible for ensuring that Importers comply with adverse event and field alert reporting requirements. AAM notes that most SIP sponsors and Importers will have no prior experience or existing systems for complying with these requirements. Thus, the risk of non-compliance is high.

Nor is Health Canada likely to fill the gap. Although FDA notes that regulatory harmonization between Canada and the U.S. has increased since 2004, there is no indication that Health Canada has the resources or interest in monitoring the safety, effectiveness or authenticity of drugs intended for the U.S. market. On the contrary, in 2004, Health Canada informed the HHS Task Force that it "does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and *does not intend to do so in the future*."[20] The proposed rule does not provide any information that would contradict this conclusion.

Second, although FDA asserts that pharmaceutical supply chains have matured and strengthened since 2004 with implementation of the Drug Supply Chain Security Act ("DSCSA")[21] and technological advancements to detect counterfeit drugs, 84 Fed. Reg. at 70801, the importation proposal could weaken these new and developing supply chain protections and potentially introduce new risks for all American patients. For example, the importer would not be required to obtain DSCSA track and trace information from the foreign seller when supplying product to importers that are wholesalers or distributors. For such products typically distributed in U.S. interstate commerce, the wholesaler or distributor would *be unable to accept ownership* without the DSCSA-required transaction information, statement and history. Furthermore, drugs initially obtained by a Canadian Foreign Seller may not have a product identifier as required by the DSCSA, but instead would be required to affix or imprint one, which could introduce (at the very least) confusion by the assignment of a new serial number. Moreover, under FDA's proposal, Foreign Sellers are tasked with determining whether drugs they receive from manufacturers are counterfeit, diverted, stolen, or otherwise adulterated. AAM believes this proposal places an inordinate amount of trust in a foreign entity that is likely to be subject to only light oversight by Health Canada, the SIP sponsor, and, most notably, FDA. This, in turn, will open up a significant hole in the otherwise hard-earned, closed

[20] HHS Task Force Report, pp. 60-61 (emphasis added).

[21] Pub. L. No. 113-54, Title II (2013).

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American distribution system that is likely to be exploited by counterfeiters or other foreign criminal organizations.[22]

Although FDA attempts to plug this regulatory gap by, *inter alia*, limiting the size of the distribution chain, requiring Foreign Sellers to apply a Section 804 Serial Identifier ("SSI") to foreign goods, requiring detailed information sharing between manufacturers, Foreign Sellers and Importers, and imposing rigorous testing requirements on imported drugs, the complexity of these additional requirements is itself a liability that could be exploited by unscrupulous criminal organizations. For this reason, the HHS Task Force stated that although new technologies, such as track and trace, are "promising, [but] until they are *fully adopted internationally* they cannot be adequately relied upon to secure the safety, efficacy, and integrity of the global market to safely import prescription drugs in the U.S."[23] The HHS Task Force also observed that safety and quality "cannot be tested into a product."[24] Because the DSCSA requirements have not been fully adopted internationally and do not apply to drugs intended for the Canadian market, FDA's importation plan necessarily poses additional risks to the health and safety of American patients from counterfeit, substandard and otherwise adulterated imported drugs.

Finally, any safety certification must account for personal importation. FDA seeks to avoid consideration of the significant safety risks posed by personal importation by stating that it is "not proposing to implement the personal importation provisions in section 804(j) through this rulemaking." 84 Fed. Reg. at 70800. But if the Secretary of HHS makes a certification pursuant to section 804(l)(1), the entire section becomes effective, including subsection (j) governing personal importation. 21 U.S.C. § 384(l)(1) ("This section shall become effective …"). There is no statutory option for making a partial certification or triggering the effectiveness of only a subset of section 804's provisions.

For example, if section 804 becomes effective as a result of the Secretary's certification, FDA would be required to grant individuals a waiver, by regulation, to import prescription drugs from Canada if certain criteria specified in the statute are met (*e.g.*, not to exceed a 90-day supply; valid prescription). *Id*. § 384(j)(3). Accordingly, FDA cannot ignore the safety ramifications of personal importation simply by stating that its currently proposed regulations do not cover it.

When personal importation is considered, it becomes even more evident that there is no reasonable basis for the Secretary of HHS to certify that implementation of section 804 would pose no additional risks to the public's health and safety. On the contrary, in the preamble to the proposed rule, FDA catalogues the myriad, major risks posed by personal importation, including the dangers of purchasing drugs through online pharmacies, the involvement of sophisticated criminal enterprises, and the inability to identify the source of drugs ordered from Canadian online pharmacies. 84 Fed. Reg. at 70800. Because these risks are significant, they categorically preclude the Secretary from issuing a valid certification under section 804(l)(1).

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[22] HHS Task Force Report, p. x. ("Legalized importation of drugs in such a way that creates an opening in the 'closed' system will likely result in some increase in risk, as the evidence shows that weakness in the oversight of drug regulation and the distribution system have been exploited.").

[23] HHS Task Force Report, p. x (emphasis added).

[24] HHS Task Force Report, p. 21.

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C. FDA is Not Authorized to Implement Section 804 as a Demonstration Project Based on a Conditional Certification

Finally, AAM is concerned that FDA's proposal seeks to establish a demonstration project – based upon a *conditional* certification – designed to explore whether commercial-scale importation from Canada can be accomplished safely and in a manner that provides significant cost savings to patients. As noted above, FDA has no grounds for certifying that its proposed importation plan will result in any cost savings at all to American patients – much less *significant* cost savings. FDA thus explains that the Secretary's certification "will be conditioned on each authorized SIP meeting the relevant requirements of section 804 of the FD&C Act and this rule, including the use of time-limited importation programs as described in this document." 84 Fed. Reg. at 70803. In other words, the Secretary's certification is conditional and depends on a series of subsequent determinations that individual SIPs do not pose additional safety risks and will result in significant cost savings.

The proposed certification, however, is conditional in an even stronger sense because those individualized SIP assessments, of necessity, will be made on a conditional basis too. Specifically, FDA is proposing that SIPs terminate automatically after two years (unless reauthorized). 84 Fed. Reg. at 70810. FDA explains that this two-year termination period is necessary to allow SIP sponsors to "demonstrate that they can in fact import drugs from Canada with no additional risk to the public's health and safety and that such importation in fact results in a significant reduction in the cost of covered products to the American consumer." *Id.* Moreover, FDA explains that "[a]fter 2 years, we will have the data necessary to evaluate a SIP's success," *i.e.*, whether the safeguards established by section 804 "are working." *Id*. In other words, FDA and HHS will not know whether any particular SIP is safe or results in lower costs to American patients, or whether the proposed section 804 importation program as a whole is "working," until at least two years after implementation of the program. FDA thus clearly is establishing the SIP program as a demonstration project.

Although AAM does not dispute the wisdom of initiating a Canadian importation program as a demonstration project, AAM does not believe that section 804 permits this option. Rather, the clear and unambiguous language of the statute requires that, before section 804 becomes operative, the Secretary of HHS must certify that implementation "will" pose no additional risks and "will" result in significant cost savings. 21 U.S.C. § 384(l)(1). The statute does not permit the Secretary to certify that implementation "may" accomplish these goals. Nor does it permit the Secretary to implement section 804 as a two-year demonstration project to enable a future assessment as to whether the requirements of the certification have been or can be met. Rather, when the Secretary makes the required certification, he or she must have confidence that the proposed importation program actually satisfies the safety and cost savings requirements. AAM believes that FDA would need additional statutory authority to implement section 804 as a demonstration project, based on a conditional certification, as currently proposed.

III. The Proposed Rule Violates Numerous Statutes and the U.S. Constitution

In addition to being unauthorized because of the inability to provide an accurate section 804 certification, AAM is concerned that the proposed rule, if finalized, will be subject to judicial

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challenge because it appears to violate several statutes, including the FFDCA and the TSA, as well as the Fifth Amendment to the U.S. Constitution. AAM is particularly concerned that the proposed rule: (1) authorizes the importation of unapproved drugs; (2) authorizes FDA to disclose trade secrets and confidential commercial information ("CCI") to third parties; and (3) takes sponsors' property without just compensation. These legal issues undoubtedly will spark waves of litigation that likely will hamstring and delay the importation program for years. Worse, AAM is concerned that the implementation problems will divert FDA resources from implementing regulatory policies that could foster generic competition in the U.S.

A. The Proposal Authorizes the Importation of Unapproved Drugs

AAM believes the proposed regulation authorizes the importation of unapproved drugs in violation of sections 505 and 804 of the FFDCA. 21 U.S.C. §§ 355, 384. Specifically, the proposed regulation permits Importers to commercially distribute drug products with labeling that differs from the approved labeling in significant ways. For example, in addition to identifying the name and place of business of the Importer, the labeling must differ from the FDA-approved labeling by including the Importer's NDC number and a conspicuous statement identifying the drug as a Canadian import under an approved SIP. 84 Fed. Reg. at 70833 (proposed 21 C.F.R. § 251.13(b)(4), (5), (6)). In addition, if the SIP sponsor maintains a website, the labeling may include the website address. *Id.*

Because approval of an NDA or ANDA includes the specific content of the labeling, a drug distributed with labeling that differs from the FDA-approved labeling is an unapproved drug. 21 U.S.C. § 355(a). Although FDA and the courts have created certain exceptions from this requirement, none of those exceptions apply here. For example, minor labeling changes may be made without FDA approval if the sponsor notifies FDA of those changes in an annual report. *See* 21 C.F.R. § 314.70(d). The required disclosure statement and voluntary SIP website address, however, are not the types of minor labeling changes that could be implemented without FDA approval. On the contrary, in a highly analogous situation regarding imports under section 801(d)(1)(B), FDA has taken the position that a similar disclosure statement "would not be appropriately submitted in an annual report" and instead would require a labeling supplement. FDA, *Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act* [Draft], pp. 3-4 (Dec. 2019). Moreover, FDA is not even requiring SIP sponsors or Importers to submit the above-described labeling changes in an annual report (presumably since they do not own an approved NDA or ANDA).[25]

FDA and the federal courts also have carved out an exception from the FDA approval requirement for the repacking and relabeling of solid oral dosage form drugs by a third party.[26] This exception, however, only applies if "the labeling used for the repacked product is identical to that of the approved drug except for labeling changes necessary for compliance with section 502(b) of the Act."[27] Section 502(b) of the FFDCA, of course, requires identification of the "manufacturer, packer,

[25] AAM notes that FDA has no authority to require the sponsor of the NDA or ANDA to submit a supplement or annual report for the labeling changes made to drugs imported from Canada under a SIP.
[26] FDA, Compliance Policy Guide ("CPG") 446.100 (Jan. 1991); *U.S. v. Kaybel*, 430 F.2d 1346 (3d Cir. 1970).
[27] CPG 446.100.

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or distributor" and an "accurate statement of quantity." 21 U.S.C. § 352(b). Because the labeling statements required or permitted by the proposed rule go well beyond what is necessary to identify the "manufacturer, packer, or distributor" or "an accurate statement of quantity," they are not exempted from the requirement to obtain FDA approval.

Section 804 clearly and unequivocally prohibits FDA from issuing regulations that permit the importation of unapproved drugs. 21 U.S.C. § 384(c)(1). Because FDA's proposed regulations do just that, they violate both section 505 and 804 of the FFDCA and are *ultra vires*.

B. The Proposal Authorizes the Unlawful Disclosure of Trade Secrets and CCI

AAM is also extremely concerned that the proposed importation scheme authorizes FDA to disclose trade secrets and CCI to Importers in violation of the FFDCA, the Defend Trade Secrets Act ("TSA")[28], and FDA's disclosure regulations. Specifically, FDA warns that it will disclose to an Importer a wide range of the manufacturer's trade secret information and CCI – including specifications, manufacturing processes, testing protocols, and batch records – if the manufacturer fails to provide such information voluntarily "in a timely fashion." For example, FDA explains:

> In the event that a manufacturer fails to provide information required by this proposed rule in a timely fashion, including information necessary for the Importer to conduct the Statutory Testing, authenticate the drug being tested, or confirm that the labeling is in compliance with the FD&C Act, *FDA may provide such information to an Importer if the information is contained in the manufacturer's approved NDA or ANDA.*

84 Fed. Reg. at 70818 (emphasis added). There is no question that much, if not all, of the information FDA proposes to disclose would be considered trade secrets[29] and/or CCI.[30]

Although FDA's ability to disclose any particular piece of information must be based on an individualized assessment of its status, if FDA or a court determines that such information constitutes a trade secret or confidential commercial information, FDA is prohibited from disclosing it. Since 1938, the FFDCA has included an express prohibition against the public disclosure of any

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[28] Pub.L. 114–153

[29] FDA's regulations define a "trade secret" as "any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial efforts. There must be a direct relationship between the trade secret and the productive process." 21 C.F.R. § 20.61(a). Manufacturing processes are typically considered to be trade secrets.

[30] FDA's regulations define CCI as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." 21 C.F.R. § 20.61(b). Information submitted in an NDA or ANDA, other than manufacturing information, typically is considered to be CCI. *See Pub. Cit. Health Res. Group v. FDA*, 704 F.2d 1280, 1290 (D.C. Cir. 1983) (defining safety and effectiveness data as "confidential commercial information" rather than trade secrets); *Pub. Cit. Health Res. Group v. FDA*, 997 F. Supp. 56 (D.D.C. 1998) (applying "confidential commercial information" test to safety and effectiveness data).

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information submitted to FDA in an NDA or ANDA "concerning any method or process which as a trade secret is entitled to protection . . .."[31] FDA's longstanding interpretation of this provision is that it applies to, and prevents disclosure of, among other things, manufacturing information and animal and human data submitted in a new drug application.[32]

The TSA provides an independent legal basis for protecting trade secrets and CCI submitted to FDA in an NDA or ANDA.[33] The TSA imposes criminal liability against any government official who discloses, in any manner not authorized by law, any submitted information which "concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity [or] confidential statistical data . . . of any person, firm, partnership, corporation or association . . .."[34]

Moreover, although the Freedom of Information Act ("FOIA") contains a general presumption in favor of disclosure,[35] it also includes specific exemptions, one of which exempts trade secrets and confidential commercial information from the otherwise applicable disclosure requirements (hereinafter referred to as "Exemption 4"). In particular, Exemption 4 of the FOIA provides that "trade secrets and commercial or financial information obtained from a person and privileged or confidential" are exempt from disclosure under FOIA.[36] The federal courts have held that the TSA is at least coextensive with Exemption 4 of FOIA.[37] FDA likewise has taken the position that Exemption 4 is at least as broad as the confidentiality provisions contained in both the FFDCA and the TSA.[38] Accordingly, when information is exempt from disclosure under Exemption 4, "the government is precluded from releasing it under the Trade Secrets Act."[39] As FDA has explained,

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[31] 21 U.S.C. §331(j).

[32] 39 Fed. Reg. 44602, 44,634 (Dec. 24, 1979). Since passage of the FFDCA in 1938, FDA's longstanding and consistent position has been that research data submitted in an NDA "ordinarily represent valuable commercial property and trade secrets that must be retained as confidential and may not be disclosed to the public." 37 Fed. Reg. 9128, 9130 (May 5, 1972); *see also* 39 Fed. Reg. 44,602, 44,637 ("The Food and Drug Administration has since 1938 pledged that all trade secret information contained in a new drug application will be held in confidence, and has stated that animal and human tests can fall within that section.").

[33] 18 U.S.C. §1905.

[34] *Id*.

[35] 5 U.S.C. §552(a).

[36] 5 U.S.C. §552(b)(4).

[37] *McDonnell Douglas Corp. v. NASA*, 180 F.3d 303, 305 (D.C. Cir. 1999); *CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1151 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 977 (1988).

[38] 39 Fed. Reg. 44602, 44612 (when the FFDCA and TSA prohibitions apply, "disclosure of trade secrets and confidential commercial or financial information by the Food and Drug Administration is wholly prohibited by Federal law.").

[39] *McDonnell Douglas*, 180 F.3d at 305.

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"even if the Commissioner wishes as a matter of discretion to release [trade secrets or confidential commercial information], such disclosure cannot lawfully be undertaken."[40]

Both FDA and HHS have promulgated regulations that implement the protections against disclosure for trade secrets and confidential commercial information embodied in Exemption 4 of the FOIA.[41] FDA's regulations state that "[d]ata and information submitted or divulged to the Food and Drug Administration which fall within the definition of a trade secret or confidential commercial or financial information are not available for public disclosure."[42] FDA's confidentiality regulations are consistent with Exemption 4 of the FOIA, the TSA, and 21 U.S.C. §331(j), all of which require the Agency to assiduously protect trade secrets and CCI from premature public disclosure.

Although FDA is permitted to *use* trade secrets and CCI under some circumstances, such as to make certain regulatory decisions, the FFDCA,[43] TSA,[44] and FDA's disclosure regulations[45] clearly and unambiguously prohibit the *disclosure* of such information to third parties without the owner's consent. The Supreme Court and other courts have held that this distinction between disclosure and use is significant.

For example, in *Ruckelshaus v. Monsanto Co.*,[46] the United States Supreme Court permitted the federal government to *use* trade secrets and CCI contained in one application to support approval of a different sponsor's application, but it distinguished this from *disclosure* of such information to the subsequent sponsor. Specifically, the Supreme Court observed that the TSA explicitly prohibits a Government employee from "publish[ing], divulg[ing], disclos[ing], or mak[ing] known"[47] confidential information received in his or her official capacity.[48] Other courts have followed this

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[40] 39 Fed. Reg. at 44,612; *see also id.* at 44,619 ("The Commissioner advises, for the reasons set out elsewhere in this preamble, that he has no discretion to release trade secret information.").

[41] HHS has promulgated FOIA regulations that are similar to FDA's and which exempt CCI from the FOIA disclosure requirements. *See* 45 C.F.R. §5.65. Since FDA is a component of HHS, these HHS regulations also apply to FDA. *Id.* §5.3 (HHS regulations apply to "all components of the Department").

[42] 21 C.F.R. §20.61(c).

[43] 21 U.S.C. § 331(j) (prohibiting the "using by any person to his own advantage, or revealing … any information [acquired under the FDC Act] concerning any method or process which as a trade secret is entitled to protection").

[44] 18 U.S.C. § 1905 (makes it a crime if a governmental employee or agency publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties …").

[45] 21 C.F.R. § 20.61 (exempting trade secrets and CCI from disclosure under FOIA).

[46] 467 U.S. 986, 1002 (1984).

[47] The current version of the Trade Secrets Act contains the same elements as described by the Court. *See* Subsection(c) of our discussion of FDA's disclosure laws in this memorandum for additional information.

[48] *Monsanto*, 467 U.S. at 1009 n.13.

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reasoning, distinguishing between agency use of trade secrets and CCI, which may be permitted, and agency disclosure of trade secrets and CCI, which is not.[49]

Here, because FDA has indicated it will *disclose* trade secrets and CCI to Importers, the proposed rule violates the clear and unambiguous statutory and regulatory provisions set forth in the FFDCA, the TSA, and FDA's regulations prohibiting such disclosures. Accordingly, AAM respectfully requests FDA to reverse this position and state that it will not disclose any trade secret or CCI contained in a manufacturer's NDA or ANDA without the express written consent of the manufacturer.

C. The Proposal Violates the Takings Clause of the U.S. Constitution

AAM believes that the proposed rule also will expose the federal government to significant liability under the Takings Clause of the Fifth Amendment to the U.S. Constitution. The Fifth Amendment explicitly prohibits the government from taking private property for public use without just compensation.[50] Here, the proposed rule would effect a "taking" by requiring manufacturers to disclose to third parties, and to allow such third parties to use, their trade secrets, confidential commercial, trademarks and copyrights, all of which constitute "property" for purposes of the Takings Clause. Indeed, the proposed widespread public disclosure of such information likely would destroy the status of such property as trade secret and/or CCI. AAM notes that there are no limitations on the number of parties to whom disclosure may be required, so it is possible that disclosure could be required to be made to scores of Importers and Qualifying Laboratories. This would destroy the value of the property itself.

Moreover, neither the statute nor FDA's proposed regulations provides "just compensation" for such takings. Both, in fact, are silent as to whether manufacturers can charge Importers for providing required information and/or testing services (as discussed further below). Moreover, both the statute and regulations explicitly state that manufacturers must provide Importers with authorization to use the approved labeling "at no cost."

AAM believes that the value of the property involved – trade secrets and CCI regarding approved brand and generic drugs – will be immense and that, if implemented, FDA's proposed regulation could give rise to astronomical liability against the federal government under the Takings Clause. This liability, in fact, is likely to outweigh any potential savings from the importation proposal itself. Moreover, litigation over these Takings Clause issues likely will be time-consuming and expensive, diverting FDA's limited resources from implementing regulatory policies that could foster generic competition in the U.S. Accordingly, AAM believes that FDA should focus its limited resources on facilitating generic drug competition in the U.S., which will have a larger and more immediate impact on drug costs than the proposed importation program.

This is particularly important because, unlike drugs intended for foreign markets that are re-purposed for American patients, FDA-approved generic drugs operate wholly within the closed U.S.

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[49] *See, e.g.*, *Tri-Bio Laboratories, Inc. v. U.S.*, 836 F.2d 135, 141 n. 7 (1987) ("Because the Trade Secrets Act, 18 U.S.C. § 1905, prohibits only public *disclosure* of application data, it does not bar internal agency use of submitted data.").

[50] U.S. CONST. amend. V ("[N]or shall private property be taken for public use, without just compensation.").

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distribution system and thus do not pose any increased risks of substandard, adulterated, or counterfeit drugs for American patients. Although AAM believes FDA's importation proposal includes important safeguards to help address these safety and quality concerns for drugs originally intended and labeled for the Canadian marketplace (*e.g.*, limiting the length of the foreign supply chain), as discussed in more detail above, these stopgap measures cannot assure the same level of safety and quality as maintaining a closed distribution system, particularly given FDA's limited resources to ensure compliance by foreign actors.

IV. Implementation Issues

If FDA moves forward with finalizing the proposed regulation despite the issues identified above, AAM believes that there are several implementation issues that need to be changed or clarified by FDA.

First, FDA should explain in more detail how it envisions SIP sponsors will identify drugs that are eligible for importation. As explained above, a Canadian drug is eligible for importation only if it satisfies all requirements set forth in an NDA or ANDA, including specifications, manufacturing locations, and manufacturing lines. Because this information is proprietary, and because there is no requirement for a manufacturer to disclose such information prior to approval of a SIP, a SIP sponsor likely will not have access to this information while it is preparing its SIP proposal.[51] As a result, SIP proposals may contain numerous proposed drugs that are later determined to be ineligible for importation. FDA review of such proposals, in turn, will waste valuable agency resources. AAM does not believe FDA can or should require manufacturers to disclose this highly proprietary manufacturing information prior to SIP approval. Further explanation of the process envisioned by FDA thus would be helpful.

Second, FDA should provide more clarity about the process for requesting and providing a manufacturer attestation pursuant to proposed § 251.5. As an initial matter, the regulations do not appear to require FDA to officially notify a manufacturer that the Agency has approved a SIP proposal covering the manufacturer's product(s). Because of the sensitivity of the formulation and manufacturing information contained in the attestation, FDA should clarify in the regulations that a manufacturer is not required to provide an attestation unless it has received formal notification from FDA that an applicable SIP has been approved.

Moreover, the regulations fail to address situations where the manufacturer determines it cannot provide the requested attestation because the Canadian version of the drug differs in one or more respects from the approved U.S version. FDA should clarify that a manufacturer may decline to provide an attestation if, in the manufacturer's opinion, the Canadian version of the drug fails to meet any of the conditions in the FDA-approved NDA or ANDA, including process-related and manufacturing specifications. FDA should further clarify that the refusal or failure to provide an attestation under such circumstances is not a violation of the regulations or section 804 of the FFDCA. Finally, FDA should specify that a manufacturer's notice that it cannot or will not make an attestation constitutes confidential information that may not be disseminated or used by the Importer,

[51] FDA's regulations appear to confirm this, requiring SIP sponsors to provide information about the manufacturing location only if available. See 84 Fed. Reg. at 70829 (proposed 21 C.F.R. § 251.3(c)(4), (5)).

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since even a declination provides valuable information about the specifications and/or manufacturing processes used for the Canadian and U.S. versions of the drug.

Third, FDA should provide more clarity regarding who will be responsible for conducting required testing under a SIP. Both the statute and proposed regulations provide that the required testing can be conducted by either the importer or the manufacturer but do not address what happens if there is a dispute about who should conduct the testing (*e.g.*, both parties want to conduct it). Because such testing requires the disclosure of highly sensitive trade secret and CCI, AAM requests FDA to clarify that the manufacturer has the initial option to conduct such testing and that the importer may conduct it only if the manufacturer declines.

Fourth, FDA should clarify that manufacturers may charge reasonable, market-based prices for any information, documentation, or testing required under the statute or FDA's regulations, other than written authorization for the importer to use the approved labeling for the prescription drug. As noted above, the statute explicitly provides that written authorization to use the approved labeling must be provided "at no cost," 21 U.S.C. § 384(h), but it does not include similar language elsewhere in section 804. It is a well-recognized canon of statutory interpretation that "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."[52] Thus, the statute must be interpreted to permit manufacturers to charge importers for information (*e.g.*, attestation, testing standards, executed batch records) or services (*e.g.*, laboratory testing) that they are required to provide under the statute (other than authorization to use the approved labeling). Moreover, this interpretation is necessary to avoid significant Takings Clause issues under the U.S. Constitution.[53]

The regulations also should clarify that a manufacturer is not required to provide any information or service specified in the regulations without reasonable, market-based compensation from the Importer or SIP sponsor (other than written authorization to use the approved labeling). The regulations should further clarify that such failure is not a violation of the regulation or section 804 of the FFDCA, if the parties fail to agree on a reasonable, market-base price for such information or services.

Fifth, AAM requests FDA to amend the regulations to allow identification of the manufacturer on the labeling of a drug imported and distributed via a SIP only if the manufacturer consents to such identification. A manufacturer may not be willing or able to vouch for the safety, effectiveness or authenticity of a drug imported via a SIP. In such cases, the manufacturer should be not forced to make even a tacit endorsement of the product by having its name identified on the associated labeling. Identifying only the Importer is consistent with the FFDCA and FDA's labeling regulations, which permit labeling to identify the manufacturer, packer, **or** distributor. 21 U.S.C. §

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[52] *Russello v. United States*, 464 U.S. 16, 23 (1983); *see also Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirements manifest."); *Stat-Trade, Inc. v. FDA*, 869 F. Supp. 2d 95, 105 (D.D.C. 2012).

[53] *See United States v. Caronia*, 703 F. 3d 149 (2d Cir. 2012) (applying the principle of constitutional avoidance in interpreting the FFDCA to avoid potential constitutional issues under the First Amendment).

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352(b); 21 C.F.R. § 201.1(a). In this case, the Importer is functioning as a distributor and thus can be the sole entity identified on the labeling.

Finally, AAM believes it would be helpful for FDA to add a definition of "significant reduction in the cost to the American consumer" that describes with specificity how SIP sponsors can and should make this showing. AAM believes that FDA should identify a threshold for determining whether a reduction is significant (*e.g.*, 50%). For the reasons discussed above, AAM also believes that the population considered should be broader than the specific patient population participating in the SIP. Finally, the definition should require SIP sponsors to account for all costs associated with implementing the SIP, including testing, relabeling, and obtaining required information from manufacturers.

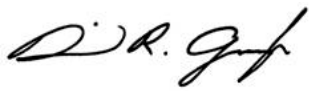
V. Conclusion

For the reasons discussed above, AAM is concerned that FDA's proposed rule to allow commercial-scale importation of Canadian drugs under SIPs is unauthorized, unworkable, will not result in significant cost savings to American patients. Rather, it may actually *impair* generic competition in the U.S., thereby resulting in increased prescription drug costs.

AAM believes that regulatory policies designed to facilitate generic drug competition in the U.S. will have greater impact on lowering drug costs and increasing access to safe and effective medicines that Americans can afford. AAM thus requests that FDA prioritize the implementation of policies that foster access to *FDA-approved* generic drugs, rather than drugs that are intended for foreign markets, such as Canada, and then re-purposed for U.S. patients.

We thank you for your consideration of these comments. If you have any questions, please do not hesitate to contact the undersigned directly.

Sincerely,



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