COLORADO
Department of Health Care Policy & Financing
303 E. 17th Ave. Suite 1100
Denver, CO 80203

Date May 5, 2025

BY ELECTRONIC FILING (via www.regulations.gov)
Kelsi Feltz
Office of Information and Regulatory Affairs
725 18th Street NW
Washington D.C., 20503

Re: Request for Information: Deregulation, Docket No. OMB-2025-0003-0001

Dear Ms. Feltz,

On behalf of the Colorado Department of Health Care Policy & Financing (HCPF), we appreciate the opportunity to provide comments in response to the Office of Management and Budget's (OMB) Request for Information: Deregulation (OMB-2025-0003-0001). We appreciate OMB's efforts to identify federal rules that may be outdated, unduly burdensome, or in need of amendment. In particular, we submit these comments in connection with the Final Rule on Importation of Prescription Drugs, codified at 21 CFR Parts 1 and 251, which we believe contains numerous provisions that significantly impede our ability to implement a successful Section 804 Importation Program (SIP). The rule is unduly burdensome, and, in some cases, we feel unnecessary for successfully importing prescription drugs from Canada in a safe, cost-effective, and administratively workable manner.

HCPF appreciates the continued communication and partnership with FDA regarding the status of Colorado's pending SIP Proposal and appreciates the Final Rule's foundational framework for the importation of prescription drugs from Canada. However, we are concerned about requirements that rely extensively on manufacturer cooperation, restrict supply chain flexibility, and impose unnecessary program shipping costs, and the ability for importation programs to be paused or ended.

1. **Manufacturer Cooperation:**
    a. The Final Rule is silent on the practical necessity for direct negotiation with manufacturers, even though Canadian wholesalers typically operate under contracts barring export to the United States. Because the rule does not anticipate this scenario, states are left with no clear regulatory path for incorporating negotiations into their SIPs. We have raised this issue with FDA since 2023[1] and continue to urge our federal partners to issue supplementary

[1] Colorado SIP Application Appendix H, FDA Correspondence (Pages 16-34)

guidance or amend the rule to clarify how a SIP might proceed in compliance with labeling, attestation, and other requirements when direct manufacturer negotiations are required to secure product supply. As reflected in public petitions and in direct outreach to companies,[2] manufacturers have repeatedly indicated a reluctance to participate in any initiative that introduces competition or price reductions into U.S. markets. This dynamic has the potential to completely sabotage our ability to implement a Section 804 importation program. Colorado has already devoted significant time and resources trying to navigate this legal gray area, which has already impeded progress toward implementation and discouraged potential partners. Allowing the FDA to impose reasonable manufacturer incentives or other means to encourage participation would further safeguard the viability of state-led SIPs, thereby generating much needed savings for Coloradans. Without such measures, manufacturer intransigence is likely to create a significant barrier to the success of any state importation effort.

b. We also call attention to provisions at 21 CFR 251.16 that place substantial responsibilities on drug manufacturers, including the need to provide timely attestations and disclosures to U.S. Importers or other SIP participants. In practice, we have found that manufacturers will likely resist these requirements, which will lead to delays or complete nonparticipation. We therefore urge the FDA to restore or incorporate language similar to what was proposed in 21 CFR 251.16(i) of the Notice of Proposed Rulemaking (NPRM),[3] under which the FDA could provide the necessary information to the Importer if a manufacturer fails to do so. We believe that adopting such authority in the event of manufacturer noncompliance would mitigate this risk and help avoid the frequent stalemates that arise when manufacturers simply decline to cooperate with a SIP. Reducing direct reliance on manufacturers for operational data or confirmations and supporting FDA's responsibility in these actions would foster more predictable, streamlined compliance and reduce the risk that a manufacturer can unilaterally derail an entire importation program in direct opposition to Congress' and FDA's clear intentions.

2. **Lack of supply chain flexibility:** The language at 21 CFR 251.3(b) restricts an initially authorized SIP to a single designated Foreign Seller.[4] Consequently, a state must rely on a singular Canadian Foreign Seller as the program becomes established.[5] This creates undue burden and unnecessary risk to the Foreign Seller, and the SIP Sponsor, by allowing drug manufacturers to punish that single Foreign Seller by curtailing or refusing product sales. This limitation hinders robust competition and jeopardizes Colorado's ability to import prescription drugs under the program in a manner that reliably delivers cost savings to Coloradans. We respectfully recommend that the Final Rule be revised to permit supply chain

[2] Colorado SIP Application Appendix H, FDA Correspondence (Pages 28-29)

[3] NPRM - Importation of Prescription Drugs 12.18.19

[4] Colorado's pending SIP with FDA has one singular foreign seller as per regulatory requirements.

[5] Drug Importation Final Rule (page 23-24)

flexibility so Colorado can protect our contracted partners, including Colorado's Foreign Seller, i.e.: flexibility permitting multiple Foreign Sellers or unique contracting relationships to procure imported drugs to support importation programs. This simple change will not overly burden the FDA's oversight because all Foreign Sellers and their compliance programs will be laid bare for the agency's review. It also will limit manufacturers' (and even large distributors') abilities to punish participants. Like any free market, more suppliers increase competition and thus reduce costs.

3. **Overly complex supply chain steps for testing, labeling, relabeling, and distributing prescription drugs:** Currently, imported drugs must undergo multiple, often redundant, transitions within the supply chain after importation for sampling and testing, relabeling, and the admissibility decision before they can be made available for distribution. Though well intentioned, this approach is unnecessarily cumbersome, adds significant costs, and reduces savings. There are multiple ways the process could be simplified. For example, FDA could allow sampling for statutory testing[6] to take place in Canada. This one step would speed up the testing process and avoid duplicative shipping while minimizing administrative burdens and related costs. In addition, after testing is approved and drugs are relabeled, a small sample of relabeled drugs could be submitted to FDA's local port for a final admissibility decision. Alternatively, FDA could inspect relabeled drugs for admissibility at the relabeler's facility. Shipping complete pallets of drugs multiple times throughout the US[7] is burdensome and expensive, cutting into the potential savings for Coloradans to enjoy.

4. **Automatic Termination of Authorized SIPS after 2 years:** 21 CFR 251.6(a), mandates automatic termination of an authorized SIP after two years unless proactively extended by FDA. This approach is a direct disincentive. States already are taking financial risks in investing to establish a SIP and proposing it to FDA. But in this provision, the Rule's own terms forecast that the savings that might be achieved will be short lived and therefore, unnecessarily, stunted. There should be little doubt that the first years of a SIP would include the lowest importation volume and therefore be the least efficient. We also note there are no clearly stated criteria for continuing a SIP after the two-year mark, creating substantial uncertainty for states and private-sector participants. Section 804 already equips FDA with sufficient authority to suspend or terminate a SIP that compromises public health or violates regulatory standards. An automatic two-year cutoff is therefore unnecessary. It further undermines sponsor and partner confidence, particularly when implementing new and complicated programs that require substantial start-up investments. Allowing SIPs to continue, unless specifically found noncompliant, alleviates unnecessary risk and enables long-term planning, learnings and improvements from prior years' experiences, the addition of new Foreign Sellers and supply chains to increase competition and reduce costs, and greater efficiency

[6] HCPF is aware that statutory testing must take place in the United States as defined by 21 USC 384, Importation of Prescription Drugs (a)(4) and (e).

[7] In Colorado's case, imported medications would travel from the C.B.P. Port of Entry in Detroit, MI, to the importer/relabeler in Boise, ID, back to C.B.P. Port of Entry in Detroit, MI, for the admissibility decision by FDA, and then back to Boise, ID, for distribution as referenced on page 2.

in the outyears. HCPF would gladly work with FDA to provide for keeping SIPs current with regular reporting.

5. **Preventing the termination of all importation**: HCPF would like to request FDA specify the areas of a SIP where noncompliance would lead to a SIP sponsor ceasing all importations under 21 CFR 251.18. As drafted, the provision grants FDA authority to halt a SIP Sponsor's importations if "any aspect of the SIP does not meet applicable requirements of the FDCA, FDA regulations, or the authorized SIP." This provision is extraordinarily broad. It could mean that a single instance of drug degradation or a minor labeling oversight, either of which could happen in any ordinary imported drug supply chain operated by the manufacturer itself, would nonetheless require halting every import under the entire program, regardless of its scope. We urge FDA to adopt a more tailored approach, whereby complete cessation of all import activities would be reserved for the most serious of situations – e.g., circumstances where counterfeits are found by FDA which were missed by the SIP sponsor and SIP market participants. Further, the agency should limit this recourse to the affected drug(s) - and not to the entire SIP. Further, FDA could replace cessation with a prompt notification requirement to FDA. These proposed revisions ensure protection of public health in real time without unnecessarily completely halting a SIP that is otherwise fully compliant.

Thank you for the opportunity to submit these comments. We believe these proposed changes would significantly reduce regulatory burdens and enhance the feasibility of Colorado's Section 804 Importation Program without compromising the safety or authenticity of imported prescription drugs. We look forward to continued engagement with federal partners to refine the Final Rule, reduce unnecessary barriers to importation, and provide significant savings to consumers while preserving public health.

Sincerely,

Kim Bimestefer
Executive Director
Department of Health Care Policy & Financing

cc:
Office of Drug Security, Integrity and Response, Office of Compliance, & Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Karen Meister, Senior Policy Advisor, U.S. Food and Drug Administration