COLORADO
Department of Health Care Policy & Financing

303 E 17th Avenue
Denver, CO 80203

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Division of Docket Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comment to Docket No. FDA-2023-P-1773-004, Response to Citizen Petition

The Colorado Department of Health Care Policy and Financing ("the Department" or "HCPF") respectfully submits this response to the Pharmaceutical Research and Manufacturers of America ("PhRMA") Supplement to Citizen Petition ("Petition"), assigned Docket No. FDA-2023-P-1773-0004. In the Petition, PhRMA requested that the U.S. Food and Drug Administration ("FDA") refrain from authorizing Colorado's Section 804 Importation Program ("SIP") Proposal to import prescription drugs from Canada ("Amended Proposal"). The Department respectfully objects to the Petition and urges FDA to deny the Petition. In summary, the Petition misuses the citizen petition process for the purpose of delaying FDA's review of the Amended Proposal, demands inappropriate review of confidential and proprietary information, misrepresents the supporters of the Petition, and publicly spreads disinformation about Colorado's proposed prescription drug importation program ("Program").

The proper purpose of a citizen petition is to provide an avenue for an interested person to petition FDA "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action."[1] In this case, PhRMA is attempting to delay any FDA action on the Department's Amended Proposal to prevent competition against brand-name drug companies who have been extracting excessive profits from Coloradans year over year by charging far higher prices to US residents, companies, municipalities and other government organizations than the prices that they charge to other countries for the same drug.

Brand-name drug companies have abused the citizen petition process before, engaging in anti-competitive behavior by seeking to delay FDA's approval of generic drugs.[2] In 2019, FDA released final agency guidance to curb citizen petition abuse with regard to Abbreviated New Drug Application holder applications. Even more recently, FDA denied a citizen petition that was submitted by the same stakeholders as this Petition and made nearly identical complaints against Florida's importation program.[3]

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[1] 21 C.F.R. §§ 10.25(a) and 10.30

[2] https://www.fda.gov/media/172538/download?attachment; https://www.regulations.gov/comment/FDA-2009-D-0008-0030

[3] https://www.regulations.gov/document/FDA-2021-P-0034-0008

FDA should deny the Petition as an attempt merely to delay FDA action on HCPF's Amended Proposal, which would extend the time during which PhRMA's members can continue to operate without meaningful market competition. Congress intended that any SIP should reduce drug costs to consumers. Competition by drug importation is the method Congress chose to accomplish that intent. PhRMA should not be able to abuse the citizen petition as an anticompetitive tool to delay FDA's implementation of congressional intent.

PhRMA also complains that it is unable to review and evaluate details in HCPF's Amended Proposal that are obviously confidential and proprietary. The same kind of information is similarly protected from public inquiry when drug companies submit their data to FDA in conjunction with new drug applications. FDA's refusal to disclose confidential commercial and proprietary information in the Department's Amended Proposal does not give PhRMA a basis to petition FDA to deny the Amended Proposal.

In addition, PhRMA's petitioning co-parties, namely the Council for Affordable Health Coverage ("CAHC") and the Partnership for Safe Medicines ("PSM"), claim to represent business and advocacy groups broadly. However, they are largely driven by PhRMA's own agenda. Both CAHC[4] and PSM[5] receive substantial funding from PhRMA and its drug industry constituents and partners. This facade is designed to give the appearance that CAHC and PSM are independent in their opposition to state importation programs, whereas their financial ties demonstrate the contrary.

Finally, HCPF firmly believes PhRMA's Petition is being used to spread disinformation about the Department's Amended Proposal. HCPF has effectively demonstrated that the Program can save Coloradans up to $51 million in the first three years, without posing additional risk to public health and safety.

We respectfully request that FDA deny the Petition. The Amended Proposal is responsive to FDA's March 2, 2023, Request for Information, and Coloradans look forward to a speedy approval. HCPF appreciates its partnership with FDA on the Program and looks forward to continuing this important work together to achieve drug cost savings for Coloradans.

Respectfully Submitted,

Kim Bimestefer
Executive Director
Colorado Department of Health Care Policy & Financing

[4] https://apps.irs.gov/pub/epostcard/cor/530241211_202112_990O_2023050921182993.pdf

[5] https://www.bloomberg.com/news/features/2019-10-23/big-pharma-helped-fund-sheriffs-ad-blitz-against-drug-imports; https://kffhealthnews.org/news/non-profit-linked-to-phrma-rolls-out-campaign-to-block-drug-imports/