THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

SEP 2 3 2020

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Represenative McCarthy:

I am writing to certify, under section 804(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(l)), that I have determined that implementation of section 804(b)-(h) through the final rule Importation of Prescription Drugs, which I will sign immediately after this certification, poses no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer. The final rule (Regulation Identifier Number (RIN) 0910-AI45) includes conditions under which certain prescription drugs can be imported from Canada to the United States under section 804 of the FD&C Act. This certification is limited to implementation of section 804(b)-(h) through the final rule and does not authorize any other method of implementing section 804.

The final rule implementing section 804(b)-(h) of the FD&C Act includes requirements that provide control over and transparency into the supply chain. The final rule allows States, the District of Columbia, territories, and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, to submit "Section 804 Importation Program" (SIP) proposals to the Food & Drug Administration (FDA) for review and authorization. An importation program could be co-sponsored by a pharmacist, a wholesaler, a State, the District of Columbia, a territory, or an Indian Tribe. These programs, authorized by FDA for renewable 2-year periods, will manage the importation of certain prescription drugs that are approved in Canada and, but for the products' labeling when marketed in Canada, meet the conditions in an FDA-approved new drug application or abbreviated new drug application. Under these importation programs, a "foreign seller" that is licensed to wholesale drugs in Canada and registered with FDA will purchase eligible prescription drugs directly from the manufacturer. An importer that is a wholesale distributor or pharmacist licensed in the United States will buy the drugs directly from the foreign seller. Both the foreign seller and the importer are subject to certain requirements under the rule, including serialization and recordkeeping requirements. In addition, eligible prescription drugs must undergo statutorily prescribed testing to ensure that the drugs are authentic, are not degraded, and meet established specifications and standards. If FDA accepts the testing results, then the drugs must be re-labeled with the FDA-approved labeling. Biological products, controlled substances, and certain other categories of drug products, such as drugs subject to Risk Evaluation and Mitigation Strategies (REMS), will not be eligible for importation under the final rule. The final rule also includes post-importation requirements, including safety reporting and recall requirements. Importation programs must also demonstrate a significant cost reduction to the American consumer. An importation program may be terminated by FDA at any time for the reasons outlined in this final rule.

The personal importation provisions of section 804(j) of the FD&C Act are not being implemented through this rulemaking, and thus section 804(j) is not currently in effect. Any implementation of section 804(j) and any other implementation of section 804 outside the scope of the Importation of Prescription Drugs rulemaking would occur through a separate certification.

I look forward to continuing our work together to help American patients access safe, effective, and high-quality prescription drugs. A copy of this letter is also being sent to President of the Senate Pence, Speaker Pelosi, Majority Leader McConnell, Minority Leader Schumer, Chairmen Alexander and Pallone, Senator Murray, and Representative Walden.

Sincerely,

Alex M. Azar II