March 6, 2020

Submitted electronically to Regulations.gov

Lyndsay Hennessey
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: Proposed Rule: Importation of Prescription Drugs, Docket No. FDA-2019-D-5711, [84 Fed. Reg. 70796 (Dec. 23, 2019)]

Dear Ms. Hennessey:

AmerisourceBergen Corporation (AmerisourceBergen) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) December 23, 2019, proposed rule, titled "Importation of Prescription Drugs." We appreciate FDA's ongoing commitment to ensure the U.S. pharmaceutical supply chain remains and safe and secure.

AmerisourceBergen, headquartered in Valley Forge, PA, and employing approximately 21,000 associates, is one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care. We provide logistical, inventory and other service support which manufacturers and pharmacies would otherwise have to perform themselves. The services provided by the primary pharmaceutical distribution industry underpins the U.S. pharmaceutical supply chain and allows patients to get medicines timely, safely and efficiently.

AmerisourceBergen shares FDA's commitment to expanding Americans' access to high quality, safe and effective, affordable medicines. As a long-standing member of the Healthcare Distribution Alliance (HDA), we supported enactment of the Drug Supply Chain Security Act (DSCSA) and continue to work with our primary pharmaceutical supply chain partners to implement the law to improve the ability of the FDA and industry to prevent and remove dangerous products from the supply chain.

As the administration considers policy changes to expand Americans' access to affordable medicines, we believe it is essential, first and foremost, to maintain the integrity of the supply chain and to avoid any regulatory changes that would undermine the law's security protections. To this end, AmerisourceBergen has significant safety and operational concerns about commercial importation of

pharmaceuticals as outlined in the proposed rule. We summarize our primary concerns below and refer you to HDA's public comment for substantive perspective on our industry's concerns about the proposed rule's potential for weakening DSCSA protections.

Despite FDA's efforts to design a rule that would allow for safe, secure importation, while simultaneously allowing consumers to experience significant cost savings, we are concerned that by opening up the closed U.S. system of distribution to new trading partners, the U.S. may inadvertently introduce new risks and vulnerabilities to the supply chain. We also note the length and complexity of the different steps that must be followed for importation to occur may pose new opportunities for diversion and wrongdoing.

Moreover, while the proposed rule provides assurances of a safe, secure importation program because of the extra protections that the DSCSA institutes, it concurrently excludes certain participating entities and products from those same security requirements. We do not agree with the proposal to exempt dispensers acting as U.S. Importers from affixing product identifiers to imported products in any circumstance; we believe all drugs imported under this rule should be serialized, regardless of the U.S. Importer's business status or dispensing intentions. Allowing pharmaceuticals to be transacted, sold, dispensed or otherwise change ownership without a product identifier could potentially make the supply chain vulnerable to suspect and illegitimate products. Thus, should the rulemaking proceed, we urge FDA to align the requirements for imported unapproved drugs with the requirements specified in the DSCSA for U.S. drugs and supply chain members.

We appreciate your consideration of our comments and continue to stand ready to serve as a resource as we operate within the regulatory framework that ensures safe, accessible and affordable medicines are available to all Americans.

Sincerely,

Robert Mauch, Ph.D.
EVP & Group President
AmerisourceBergen Corporation

cc: Connie T. Jung, R.Ph., PhD
Office of Compliance, Center for Drug Evaluation and Research