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Additional Guidance From FDA on Importing Drugs From Canada

In a follow-up to its final rule on the importation of prescription drugs from Canada, which became effective on November 30, 2020, the U.S. Food and Drug Administration (FDA) published additional final guidance on May 25 in the form of 12 questions and answers (the Guidance) regarding the legal requirements for small entities to import prescription drugs from Canada. As explained by the FDA, "This guidance is intended to help small entities better understand the final rule, 'Importation of Prescription Drugs,' published October 1, 2020 (85 FR 62094). The Secretary of Health and Human Services issued the final rule to implement [S]ection[s] 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(b) through (h)) to allow importation of certain prescription drugs from Canada. The purpose of the final rule is to achieve a significant reduction in the cost of covered products to the American consumer while posing no additional risk to the public's health and safety." The Guidance expands the groups previously identified as authorized Section 804 Importation Program (SIP) sponsors that were allowed to import certain prescription medications (i.e., states and Indian tribes) to now include pharmacists and wholesale distributors meeting certain conditions. The Guidance spells out how importers can obtain eligible drugs through an authorized SIP sponsor and addresses testing along with labeling requirements. Under the Guidance, SIP sponsors must also show they can provide significant cost reductions for American consumers through importation. The Guidance does not change the types of drug products that are eligible for importation and continues to exclude certain classes of drugs such as controlled substances, biological products, infused drugs, drugs that are injected, and drugs that are subject to a risk evaluation and mitigation strategy under FDA requirements. For any drug product not excluded by the rule, the FDA will determine whether the product can be imported safely in the context of a specific SIP proposal on a product-by-product basis. While consumers and employer-sponsored health plans welcome the changes in the Guidance to help effectuate cost savings, there are two significant issues to note:

1. The Guidance does not implement the personal importation provisions in Section 804(j) of the FD&C Act.
2. The Guidance applies only to importation from Canada—not any other countries.

Pharmacies, self-insured employers or others with questions regarding the importation of prescription medications from Canada should contact one of our Life Sciences attorneys.

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