AMCP Regulatory NewsBREAK

FDA Authorizes Florida's Drug Importation Program

- On January 5, 2024, the Food and Drug Administration (FDA) issued a letter authorizing the state of Florida's Section 804 Importation Programs (SIP) proposal (Authorization Letter).
- The Authorization Letter states that Florida's SIP proposal meets the statutory and regulatory requirements and that the state demonstrated that importation would reduce the cost of covered products without posing additional health and safety risk. Florida will be responsible for ensuring supply chain integrity, monitoring and submitting adverse event reports, complying with drug recall procedures and reporting quarterly to the FDA.
- The Authorization Letter outlines the requirements that must be met for the imported prescription drugs. The following are just a few of these requirements:
    - An importer must submit a Pre-Import Request to FDA. Once FDA grants such a request, the importer may ship the product through the authorized port of entry for examination by the government.
    - The manufacturer or the importer must conduct testing to ensure that the eligible prescription drugs comply with established specifications and standards (Statutory Testing). The Pre-Import Request must contain a Statutory Testing plan with:
        - (A) a description of how the samples will be selected;
        - (B) the name and location of the qualifying United States laboratory that will conduct the Statutory Testing; and
        - (C) a description of the testing method(s).
- The FDA will continue to exercise oversight to ensure the proposal is followed and that Florida's program meets ongoing statutory and regulatory requirements.

More on This Topic:

- Authorization Letter
- Section 804 Importation Program Overview
- FDA Final Rule on the Importation of Prescription Drugs
- Guidance on Small Entity Compliance
- Tips for SIPs

For questions, please reach out to Vicky Jucelin.

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