

Non-Resident U.S. Distributors Now Required to Obtain Special Authorization to Distribute Medications and Medical Devices in Puerto Rico

ATTORNEYS

- Lizzie M. Portela-Fernández
- Samuel T. Céspedes Jr.
- Francisco J. Pavía
- Adrián P. Goyco-Vera

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On June 29, 2022, the Puerto Rico Department of Health informed that, effective July 1, 2022, U.S. distributors that desire to engage in the wholesale distribution of prescription and non-prescription drugs, homeopathic products, natural products, nutritional supplements and/or medical devices in Puerto Rico (“Non-Resident Distributors”) will need to apply for a Special Authorization issued by the Office of the Assistant Secretary for the Regulation and Accreditation of Healthcare Facilities (SARAFS).

To obtain the Special Authorization, the Non-Resident Distributors will need to file a self-certification form with the Puerto Rico Department of Health, a criminal background report, a drug registration certificate of compliance and a bond certificate, among other documents. The Special Authorization for Non-Resident Distributors is renewable every two (2) years.

The Drugs and Pharmacy Division of SARAFS reserves the right to inspect Non-Resident Distributors and any costs of travel, lodging and transportation will be borne by the Non-Resident Distributors.

Pursuant to the Department of Health, this new requirement is adopted in accordance with the provisions of the Puerto Rico Pharmacy Act, Act No. 247-2004, as amended, and related regulations. Failure to comply with said Act and its regulations may result in sanctions by the SARAFS, including the imposition of fines and forfeiture of the required bond.

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