



GOVERNMENT OF PUERTO RICO

Department of Health

Auxiliary Secretariat for Regulation and Health Facilities Accreditation (SARAFS)

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SARAFS

NOTIFICATION TO NON-RESIDENTS OF PUERTO RICO WHOLESALE DISTRIBUTORS OF NON-PRESCRIPTION AND PRESCRIPTION DRUGS, VETERINARY MEDICINES WITH OR WITHOUT PRESCRIPTION, HOMEOPATHIC PRODUCTS, NATURAL PRODUCTS, NUTRITIONAL SUPPLEMENTS, AND ARTIFACTS WITHIN UNITED STATES JURISDICTION.

The Department of Health of Puerto Rico (DH) was created under Law No. 81 of March 14, 1912, as amended, and elevated to constitutional rank through Article IV, Section 6 of the Constitution of the Government of Puerto Rico. Because of its constitutional rank, it is the only agency with the ministerial duty to supervise, care for, watch over, and protect the health and well-being of the citizenry.

One of the tools used by the DH to enforce its constitutional function is Law No. 247 of September 3, 2004, as amended, known as the "Puerto Rico Pharmacy Law" (Law 247-2004). By virtue of this Law, the Division of Drugs and Pharmacy attached to the Office of the Auxiliary Secretary for the Regulation and Accreditation of Healthcare Facilities (SARAFS, as per its Spanish acronym) was created, as an administrative unit for a more effective supervision of the manufacturing, distribution, and dispensing phases of drugs and the exchange of bioequivalent drugs in Puerto Rico.

Article 6.02 (a) of Law 247-2004 establishes that the Secretary of Health will have the power to approve and adopt the necessary rules and regulations to make viable the purposes of this Law.

Based on Article 6.02 (a) of Law 247-2004 three (3) regulations were approved: Regulation of the Secretary of Health No. 156 for the Operation of Establishments Dedicated to the Manufacture, Distribution and Dispensing of Medicines in Puerto Rico, as amended, Regulation of the Secretary of Health for the Operation of the Establishments Dedicated to the Manufacture, Distribution and Sale of Natural Products and Nutritional Supplements in Puerto Rico and, the Regulations of the Secretary of Health for the Operation of Establishments Dedicated to the Sale, Distribution and Manufacture of Pharmaceutical Products for Veterinary Use, which establish the requirements to distribute prescription and non-prescription drugs, veterinary medicines with or without prescription, homeopathic products, natural products, nutritional supplements and medical devices in Puerto Rico.

However, there are currently Non-Resident Distributors in Puerto Rico, located within the jurisdiction of the United States, who are interested in distributing wholesale prescription and non-prescription drugs, veterinary medicines with or without prescription, homeopathic products, natural products, nutritional supplements, and medical devices in Puerto Rico (hereinafter Non-Resident Distributors) and are restricted since there is no proper authorization for that activity.

Thus, as July 1, 2022, the Drugs and Pharmacy Division of SARAFS will issue Special Authorizations to Non-Resident Distributors. Interested Non-Resident Distributors will have to comply with the applicable regulatory provisions, as well as the requirements established in the Online Renewals portal (Portal de Renovaciones Online), including the documents entitled Self-Certification of Compliance, Clear Criminal History Record of Non-Resident Distributors, Certification of Compliance with Drugs Registration and Certification of Bond, among others. Once the Non-Resident Distributor completes the aforementioned documents, they must upload them in their application to proceed with their evaluation. The Special Authorization for Non-Resident Distributors will be renewed every two (2) years.

The Drugs and Pharmacy Division of SARAFS reserves the right to inspect Non-Resident Distributors and any cost of transfer, stay, diet, transportation, among others, will be paid by the Non-Resident Distributor. Note that non-compliance with Law 247-2004 and its applicable regulations could lead to sanctions by the Medicines and Pharmacy Division of SARAFS, including the issuance of fines and execution of the required bond.

Should you have any questions about what is described here, you may contact the Coordinator of the Drugs and Pharmacy Division of SARAFS, Amelia Díaz Ramos at (787) 782-0120 (ext. 4720) or through email amelia.diaz@salud.pr.gov.