McConnell Valdés LLC

Important Amendments to Regulation No. 156 Announced for Establishments that Manufacture, Distribute and Dispense Medications and Medical Devices in Puerto Rico

ATTORNEYS

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PRACTICE AREAS

- Health Care

An McV Health Care Practice Team Alert
October 21, 2020

On October 6, 2020 the Puerto Rico Department of Health issued a public notice to inform the general public of its intent to amend Regulation Number 156 for the Operation of Establishments that Manufacture, Distribute and Dispense Medications in Puerto Rico ("Regulation No. 156").

The proposed amendments to Regulation No. 156 include the following:

- The fees of licenses and authorizations issued by the Pharmacy Division of the Office of the Assistant Secretary for the Regulation and Accreditation of Healthcare Facilities (SARAFS) generally will increase.
- In addition to FDA-approved drug products, homeopathic drugs, veterinary products and medical devices will need to be registered with the Puerto Rico Department of Health. The registration of products must take place at least 5 days prior to the products' sale, donation, promotion or distribution in Puerto Rico.
- Products will need to be registered by a licensed manufacturer or distributor, or an administrative agent designated by such manufacturer or distributor. The manufacturer, distributor or administrative agent will need to obtain an authorization from the Puerto Rico Department of Health in order to register products with the agency.
- The Department of Health will be authorized to issue special permits for the use of temporary or mobile drugstores during a state of emergency declared by the Governor.

You can view the full document **here**.

Virtual public hearings on the proposed regulation are scheduled to take place on October 22, 2020 from 1:00p.m. to 4:30 p.m. and on October 23, 2020 from 9:00 a.m. to 12:00 p.m. The general public will have until November 5, 2020 to submit comments to SARAFS, by mail at 1090 Marginal Ruiz Soler, Bayamón, Puerto Rico 00961-7329, or by email at nilda.ortiz@salud.

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