November 6, 2020

Dear Sir, Madam:

Five Rivers RX appreciates the opportunity to provide comments to the Puerto Rico Department of Health's proposed regulation, No. 156B, *For the Operation of Establishments that Manufacture, Distribute, and Dispatch Medications in Puerto Rico*. Our firm represents over 30 drug manufacturers and distributors doing business in Puerto Rico. Please note, the views and opinions expressed in this letter are those of Five Rivers RX, and do not necessarily reflect the views and opinions of our clients.

Five Rivers RX promotes the quality, security, and integrity of the pharmaceutical supply chain through consulting and administrative solutions. We develop business strategies and provide high quality, scalable solutions through a dynamic partnership with our clients. Our comprehensive solutions leverage innovation, expertise, and technology, spanning federal and state requirements including state licensing, NABP DDA (VAWD) accreditation, DEA compliance, and more. We have assisted over 400 companies respond to industry changes and reach their compliance and commercialization objectives.

Five Rivers RX supports the aim of Puerto Rico Act 273-2018,[1] which seeks to expedite the importation and lower the cost of medicines in Puerto Rico by speeding consumer access to medicines upon approval by federal authorities, and reducing the burdens associated with product registration. To ensure the implementation of these regulations furthers these objectives, the proposed regulations should be clarified as to when particular licenses and fees are required and, consistent with the statute, a cap should be placed for medication registration fees. Without these clarifications, the proposed regulations may unnecessarily increase regulatory burdens and potentially limit access to medicines, particularly generic drugs, in Puerto Rico. Our comments are described in more detail below.

1. Clarify Medications Registry Related Fees and Processes

Chapter III of the proposed regulations addresses the fees associated with registering medications prior to distribution in Puerto Rico. We request that the Department of Health clarify the following, with respect to the fees and drug registration update process.

- **Drug Initial Registration Fee**
  The proposed regulation states that an initial registration authorization will cost $500 and will be valid for a two (2) year period. The statute provides that the initial registration will cost "$500.00, plus $25.00 for each drug (not dosage), up to a maximum of twenty thousand dollars ($20,000) for initial registration by a manufacturer or distributor."[2] Please clarify whether the $25 fee for each drug (not dosage), described in the statute, will continue to apply for product registrations or if the proposed regulations have eliminated this fee. If the $25 fee has not been eliminated, then please revise the regulations, consistent with the statute, to place a twenty thousand dollar ($20,000) cap on the registration fees.

- **Drug Registration Renewal Fee**
  The proposed regulation provides that the renewal of the registration authorization will cost $250 and will be valid for one (1) year. Please clarify whether this $250 renewal fee is a separate fee from the $250 drug registration update fee. We note that the statute does not appear to contemplate a separate renewal fee from the $250 drug registration

[1] Puerto Rico Law 273-2018 amended the Puerto Rico Pharmacy Act, Act 247-2004.
[2] 20 Laws of Puerto Rico Ann. § 410n(f)(1).

update fee. In addition, a separate extra $250 renewal fee seems unnecessary given the individual medicine fees associated with drug registration.

- **Drug Registration Update Fee**
  The proposed regulation states that when it is necessary to modify and/or update information for a registered medicine, a change of information notification must be submitted, and a $250 fee will be assessed for *each* notification. This appears to be inconsistent with the fee structure established in the statute, which provides that there will be a one-time $250 fee and a $25 fee for each notification of a change in information. In addition, the statute provides that the $25 fee only applies to changes in certain information, which is limited to a "new drug, change of dosage, size or package of any previously notified, or for the change of representative/agent."[3] Accordingly, we request that the proposed regulation be revised to be consistent with the fee structure established in the statute.

- **Drug Registration Update Process**
  The proposed regulation requires that any registration changes be completed at least five (5) calendar days before beginning any sales activity, donation, promotion or distribution of the product. While this requirement reflects the five day period in the statute, we request that the Department of Health consider whether there is any means to shorten this five day waiting period to speed consumer access to U.S. FDA-approved medicines in Puerto Rico and allow for new medicines to be available in Puerto Rico at the same time they are available in the continental United States.

  Also, in some scenarios, companies may need to make a large number of registration updates, e.g., if a company changes its name, or acquires a large number of products from another company. Please clarify if there will be a process for submitting bulk registration updates.

- **Device Registration**
  The proposed regulation requires the registration of FDA-approved devices which is not consistent with the statute. Please clarify whether the proposed regulation will require registration of only legend devices or all devices.

- **Unapproved Drug Registration**
  The proposed regulation requires the registration of FDA-approved medications. Please clarify whether a medication that is not specifically approved by the FDA, but otherwise legally manufactured and dispensed to a patient (e.g. DESI drug, compounded per Section 503B of the FD&C Act, etc.), will need to be registered.

2. Place a Cap on Medication Registration Fees

As noted above, the Pharmacy Act of Puerto Rico mandates a maximum fee threshold of $20,000 for initial drug product registration. Such a cap is of paramount importance for our clients who manufacture and distribute hundreds of different products in Puerto Rico, which is common within the generic drug industry. Accordingly, we request that the Department of Health apply a maximum registration fee threshold for all product registration related fees, including the initial registration fee and drug registration updates. Without such a set maximum, those who distribute high volumes of product in Puerto Rico would be unduly penalized for their continued commitment to medicines access for Puerto Rican patients.

[3] *Id.* at § 410n(f)(5).

3. Clarify When Particular Licenses are Needed

Chapter II of the proposed regulations identify a number of different licenses and the associated licensing fees. We request that the Department of Health clarify when the following licenses apply:

- **Pharmaceutical Industry License**
  Please clarify whether this license is required only for entities residing in Puerto Rico or if it also applies to companies located outside of Puerto Rico that distribute product within Puerto Rico.

  If this license is required for companies located outside of Puerto Rico that do business in Puerto Rico, please clarify that only one license is needed for a company, regardless of the number of divisions, subsidiaries, or affiliates of a single company that does business in Puerto Rico. For example, if such a license is required for companies located outside of Puerto Rico, then a parent company, which has multiple subsidiaries that do business in Puerto Rico, should be required to obtain only a single pharmaceutical industry license to cover the parent company and all subsidiaries. Because the proposed regulations establishes a pharmaceutical industry license fee of $1500, which is three times greater than the $500 fee established in the law and disproportionately higher than the other license fees listed in the proposed regulations, requiring each subsidiary or affiliate of a company to pay this fee would place a high burden on companies that use multiple subsidiaries to provide Puerto Rican consumers access to medicines.

- **Wholesale Distributor License**
  Please clarify when a wholesale distributor license is required. For instance, is it only required for businesses located in Puerto Rico or does it also apply to entities located outside of Puerto Rico that do business on the island? Also, if a company holds a pharmaceutical industry license, does it also need to hold a wholesale distributor license?

- **Biological Products License**
  Please clarify if a company that distributes biologic products in Puerto Rico needs to obtain a single biological products license for the company or if a separate biological products license is needed for each biological product that the company distributes in Puerto Rico. For example, if a company distributes five biological products, does the company only need to obtain a single biological products license? Or five biological products licenses, one for each product?

  Also, please clarify whether a company that holds a pharmaceutical industry license also needs to obtain a biological products license.

4. Clarify Definitions

- **Natural Products and Nutritional Supplements**

Chapter III of the proposed regulation notes that "natural products and nutritional supplements" do not require registration, but "homeopathic medicines" are subject to registration. The proposed regulations, however, do not contain definitions for these terms. Please clarify how the Department distinguishes between homeopathic medicines and natural products.

- **Business Models**

The proposed regulation makes references to business models including Manufacturers, Distributors and Pharmacies. However, the drug supply chain contains additional business models not included in the proposed regulation. Please provide clarification on whether the following business models are required to obtain licensing or are exempt from licensing:

  - Outsourcing facility – a company that compounds medication pursuant to Section 503B of the FD&C Act. Please advise whether they will qualify as a manufacturer, a wholesale distributor or will be exempt from having to obtain a license.
  - Repackager – a company that repackages changes the packaging of product provided by the manufacturer of the product. Please advise whether they will qualify as a manufacturer, a wholesale distributor or will be exempt from having to obtain a license.
  - Third party logistics provider - a company that provides or coordinates warehousing, or other logistics services of a medicine on behalf of a manufacturer, but does not take ownership of the product, nor the responsibility to direct the sale or disposition of the product. Please advise whether they will qualify as a wholesale distributor or will be exempt from having to obtain a license.

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Five Rivers RX appreciates the opportunity to submit the above comments. We believe the above described clarifications and revisions to the proposed regulations will help to better achieve the goal of increasing consumer access to affordable medicines in Puerto Rico.

Sincerely,

Sumeet Singh
President, Five Rivers RX