COMMONWEALTH OF PUERTO RICO

17th Legislative Assembly

7th Ordinary Session

SENATE OF PUERTO RICO

Senate Bill 1599

April 12, 2016

Presented by Mr. *Dalmau Santiago*

Referred to the Health and Nutrition Commission

LAW

To add new paragraphs (yy) and (ggg); and renumber current paragraphs (yy) to (jjj) as well as paragraphs (zz) to (lll) in Article 1.03 to Article 5.04 of Law 247-2004, as amended, better known as the "Puerto Rico Pharmacy Act," in order to establish a definition for "natural products" and "nutritional or dietary supplements;" and for other purposes.

STATEMENT OF PURPOSE

In Puerto Rico, Law 47-2004, better known as the "Puerto Rico Pharmacy Act," establishes the legal parameters for the dispensation of medications in Puerto Rico. According to the Statement of Purpose of said legislation, its objective is to "*promote and protect health, safety and the public welfare*."

The Department of Health has the duty and authority to implement public health measures aimed at promoting and preserving the health of all. As part of these responsibilities, Law No. 133-2013 imposes upon it the duty of establishing that natural products, homeopathic products and devices must be registered with the Department of Health in order to be marketed, distributed and sold within the jurisdiction of the Commonwealth of Puerto Rico.

The above notwithstanding, there is a wide variety of natural products and nutritional or dietary supplements which were included to be regulated by Law 247-2004, and no definition was established for these products in the provisions set forth in Law 133-2013 where the registry was created.

In recent years, the inspection work done by the inspectors of the Medications and Pharmaceuticals Division, attached to the Auxiliary Secretariat for the Regulation and Accreditation of Health Care Facilities (SAFARS), has identified a significant increase in the availability an access to products considered to be natural and/or nutritional or dietary supplements in the various points of sale on the island. There has also been a palpable increase in the promotion of these products through the media.

Nutritional or dietary supplements may contain active ingredients that have biological effects on the body, and can be harmful when combined with other supplements, if used as medication, if used as a substitute for medications or if taken in excess. These supplements are not medications, and therefore they are not intended to diagnose, treat, prevent or cure diseases.

According to the Food and Drug Administration (FDA), a natural product can be a food (including dietary supplements and/or nutritional supplements), a drug or medication (including biological medications) or a cosmetic. The definition of natural product under any of the categories listed above will depend on the use for which it is intended. Said use is established in the information contained on the product label, advertisements for the products or circumstances related to their distribution, among other things.

This legislative initiative is intended to clearly establish within Law 247-004, better known as the "Puerto Rico Pharmacy Act," the definition of natural products and nutritional or dietary supplements to guarantee the health of all inhabitants of the country.

THE LEGISLATIVE ASSEMBLY OF PUERTO RICO DECREES:

Article 1. New paragraphs (yy) and (ggg) are hereby added, and current paragraphs (yy) to (jjj) are renumbered as well as paragraphs (zz) through (lll) of Article 1.03 of Law 247-2004, as amended, to read as follows:

"Article 1.03. Definitions

For the purposes of this Law, the following terms and phrases shall have the meanings indicated below:

(a) …

(b) …

…

…

(yy) "Natural Products" – These are those products obtained when herbal substances or plant material are subjected to treatments such as extraction, distillation, fractioning, purification, concentration or fermentation. This includes substances originating from ground or pulverized herbs, dyes, extracts, essential oils and extracted juices. Natural products may contain active organic and/or inorganic ingredients that are not of plant origin (for example, of animal or mineral origin) and excipients. However, natural products or mixtures of natural products to which chemically defined active substances have been added, including synthetic compounds or isolated components of herbal materials are not considered to be natural products. All natural products must comply with the requirements of the Food and Drug Administration (FDA) in terms of labeling, disclosures, and quality standards in order to be registered.

[(yy)] (*zz*) "Protocol"- …

[(zz)] (*aaa*) "Radiopharmaceuticals"- …

[(aaa)] (*bbb*) "Counter or prescription"- …

[(bbb)] (*ccc*) “Formulary”- …

[(ccc)] (*ddd*) “Doctor-patient relationship”- …

[(ddd)] (*eee*) “Representative or authorized representative”- …

[(eee)] (*fff*) “Secretary or Secretary of Health”- …

(ggg) *“Nutritional or dietary supplement” – is a product designed to supplement the diet which contains one or more of the following dietary ingredients: vitamins, minerals, herbs or botanical products, amino acids, dietary substances for human consumption to supplement the diet, increasing dietary intake or a concentrate, metabolite, constituent, extract or combination of any of these ingredients. All natural products must comply with the requirements of the Food and Drug Administration (FDA) in terms of labeling, disclosures, and quality standards in order to be registered.*

[(fff)] (*hhh*) “Pharmacy technician”- …

[(ggg)] (*iii*) “Electronically generated and transmitted prescription”- …

[(hhh)] (*jjj*) “Electronic signature”- …

[(iii)] (*kkk*) “Vaccine”- …

[(jjj)] (*lll*) “Vaccination or immunization”- …”

Article 2. Separable elements clause

If any article, section, paragraph, line, clause, subsection or part of this Law were to be annulled or declared unconstitutional by a competent court, the ruling to this effect shall not affect, prejudice, nor invalidate the remaining provisions and parts of the rest of this Law.

Article 3. Within a period of thirty (30) days counting from the date on which this Law enters into force, the Department of Health shall review its regulations, administrative orders, or memorandums in order to adjust them to the provisions of this Law.

Article 4. This Law shall enter into effect immediately upon approval.