

**COMMONWEALTH OF PUERTO RICO  
DEPARTMENT OF HEALTH**

**ADMINISTRATIVE ORDER NO. 346**

**TO ESTABLISH A PUBLIC POLICY REGARDING THE DISTRIBUTION OF  
NATURAL PRODUCTS OR NUTRITIONAL SUPPLEMENTS OR DIETARY  
SUPPLEMENTS IN THE COMMONWEALTH OF PUERTO RICO**

**WHEREAS:** The Department of Health was created pursuant to the provisions set forth in Law Number 81, dated March 14, 1912, as amended, and elevated to Constitutional status on July 25, 1952, by virtue of the provisions established in Article IV, Section 6 of the Constitution of the Commonwealth of Puerto Rico.

**WHEREAS:** In acknowledgement of its Constitutional duty to safeguard the health of the public and the fulfillment of the Commonwealth of Puerto Rico's public policy, the Department of Health is responsible for establishing health objectives for the Puerto Rican population and develop strategies for protecting Public Health.

**WHEREAS:** The Secretary of Health shall exercise all duties granted by the Constitution of the Commonwealth of Puerto Rico and Law No. 81, dated March 14, 1912, as amended, and all laws in effect related to health that require an effective system of health services.

*ACR*

**WHEREAS:** In accordance with the power and authority granted by Law Number 81, dated March 14, 1912, as amended, the Secretary of Health is authorized by Law to issue orders to prevent promote health and the public wellbeing. This authority conferred by the Constitution of the Commonwealth of Puerto Rico and the Department's Organizational Law serve the purpose of focusing on and taking the necessary measures to safeguard public health and the wellbeing of the Puerto Rican people.

**WHEREAS:** For the past two (2) years, through the inspection processes performed by the inspectors of the Drug and Pharmacy Division, in association with the Deputy Secretary for the Regulation and Authorization of Health Facilities [*Secretaría Auxiliar para la Reglamentación y Acreditación de Facilidades de Salud*] (SARAFS), a significant increase in the availability

and access to products considered *natural products and/or nutritional supplements or dietary supplements* has been identified at the different outlets on the Island. Similarly tangible is the increase in advertising of these products through all the media outlets.

**WHEREAS:** Nutritional supplements or dietary supplements may contain active ingredients that cause biological effects in the body; or they could be harmful if combined with other supplements, are used as medications, are substituted for medication or are taken in excess.

**WHEREAS:** The nutritional supplements or dietary supplements are not medications, and as such are not meant to diagnose, treat, prevent or cure illnesses.

**WHEREAS:** Law No. 247, dated September 3, 2004, as amended, establishes as a public policy that no person may exhibit, offer for sale, distribute, sell, deliver, store, gift, donate or promote natural products in any way, unless they have been registered with the Department of Health, for their marketing, distribution or sale.

**WHEREAS:** The Secretary of Health establishes and promulgates the following directive in accordance with the mission and vision of the Department of Health of the Commonwealth of Puerto Rico to guarantee the health of all the residents of Puerto Rico, and as such, sustain health as a state or condition of physical, mental, emotional and social wellbeing, which allow human beings to enjoy life to the fullest.

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**THEREFORE:** **I, ANA RIUS ARMENDARIZ, M.D., SECRETARY OF HEALTH OF THE COMMONWEALTH OF PUERTO RICO, ON THIS DAY PROMULGATE THIS ORDER IN ACCORDANCE WITH CURRENT LAWS AND BY THE AUTHORITY VESTED IN ME PURSUANT TO LAW NUMBER 81, DATED MARCH 14, 1912, AS AMENDED, HEREBY ORDER:**

**FIRST:** For purposes of this Administrative Order, **the term “natural product” shall refer to** products that include herbal substances or plant material

(complete, fragmented, or cut up), algae, fungi, or any combination thereof, normally in dry form but sometimes fresh. Furthermore, the definition of “natural products” includes nutritional supplements and dietary supplements.

**SECOND:**

According to the Federal Drug Administration (FDA), a natural product may be food (including dietary supplements and/or nutritional supplements), a drug or medication (including biological medications) or a cosmetic. The definition of a “natural product” under any of the categories listed above shall depend on the use for which it was intended. This use is established through the information contained on the product label, the advertising accompanying it, or circumstances related to its distribution, among others.

- a. “Natural products” are those that are obtained when herbal substances or plant material are submitted to treatments such as extraction, distillation, division, purification, concentration or fermentation, among other processes. This includes ground up or pulverized herbal substances or dyes, extracts, essential oils or extracted juices.
- b. Natural products may contain organic or inorganic active ingredients that are not derived from vegetables (for example, derived from animals or minerals) or excipients. However, natural products or mixtures of natural products to which chemically-defined active ingredients have been added, including synthetic compounds or isolated components of herbal materials, are not considered natural products.

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**THIRD:**

On the other hand, a nutritional supplement or dietary supplement is a product intended as a dietary supplement, which is comprised of or 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 a combination of any of these ingredients.

**FOURTH:** Interest in marketing or distributing any natural product in Puerto Rico shall be registered with the Drug and Pharmacy Division, in association with the Deputy Secretary for the Regulation and Authorization of Health Facilities [*Secretaría Auxiliar para la Reglamentación y Acreditación de Facilidades de Salud*] (SARAFS), in an application form designed by the Department of Health. The following documents shall be included with the Natural Product Registration application:

- 1. Quality Control data (Certificate of Analysis), e.g., specifications with limit values for its identification, microbial contamination, chemical residue (e.g., pesticides) and heavy metals, among others.
- 2. The process used to obtain the product, including its description and classification.
- 3. Label Sample
- 4. Promotional Material/Advertisements
- 5. Certificate of Analysis from a laboratory, including the following information:
  - a. Name of manufacturer, including address and contact information
  - b. Registration number with the FDA
- 6. Warnings

**FIFTH:** Any natural product shall comply with the requirements established by the FDA with regard to labels, statements, and quality standards in order to be registered with the Department of Health.

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**SIXTH:** The registration of any natural product shall be done digitally or electronically, as provided by the Department for this purpose.

**SEVENTH:** The amount of twenty-five Dollars (\$25.00) shall be paid for the registration of any natural product for each and every concentration and for each and every size of the product to be registered.

**EIGHTH:** Any person who manufactures natural products shall file an application with the Drugs and Pharmacy Division, in association with the SARAFS, through the application form designed by the Department of Health. The amount to be paid for the application and authorization shall be five hundred Dollars (\$500.00), every two (2) years. The following documentation shall be included with the Natural Product Manufacture application:

- 1. Copy of the manufacturing registry issued by the FDA.

- 2. Certificate of Analysis from a laboratory that includes the following information:
  - a. Name of manufacturer, including address and contact information
  - b. Registration number with the FDA

**NINTH:** The Drug and Pharmacy Division shall evaluate the application, as well as the documents attached thereto, and shall issue a Certification to Distribute Natural Products or a Certification to Manufacture Natural Products, as applicable.

**TENTH:** The amount payable for the “Certification” to Distribute Natural Products Wholesale shall be one hundred dollars (\$100.00) every two (2) years. The same shall be accompanied by a list of the products to be distributed and their packaging. The amount payable for the “Certification” to Distribute Natural Products Retail shall be one hundred dollars (\$50.00) every two (2) years. The same shall be accompanied by a list of the products to be distributed and their packaging.

**ELEVENTH:** All facilities and establishments shall be subject to inspection by SARAFS. The amount payable for the inspection shall be fifty dollars (\$50.00).

**TWELFTH:** Drug stores possessing a license issued by the Department of Health are except from having to obtain a Certificate to Distribute Natural Products wholesale; Pharmacies possessing a license issued by the Department of Health are except from having to obtain a Certificate to Distribute Natural Products Retail.

**THIRTEENTH:** The marketing of natural products to diagnose, treat, prevent or cure illnesses is prohibited.

**FOURTEENTH:** This order shall not apply to those cases indicated in Regulation 155 of the Department of Health, “For the Use, Possession, Growing, Manufacture, Production, Fabrication, Dispensing, Distribution and Research of Medicinal Cannabis.”

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This Administrative Order shall be effective immediately and shall remain in effect unless otherwise revoked by a subsequent Order. All memoranda and Administrative Orders issued previously by any Health Secretary to the extent that their provisions are inconsistent with the provisions set out herein shall be repealed and shall have no legal effect whatsoever.

IN WITNESS WHEREOF, I hereby sign this Administrative Order and stamp the seal of the Department of Health of the Commonwealth of Puerto Rico, on the 9<sup>th</sup> day of February of the year 2016, in San Juan, Puerto Rico.

*[signature]*

**ANA C. RIUS ARMENDARIZ, M.D.  
SECRETARY OF HEALTH**