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Approved by: Hon. Luis G. Rivera Marin  
Secretary of State



On the part of: Eduardo Arosemena Muñoz  
Auxiliary Secretary  
Department of State  
Government of Puerto Rico

[emblem:] GOVERNMENT OF 2018  
PUERTO RICO

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**REGULATIONS OF THE SECRETARY OF HEALTH FOR THE OPERATION OF THE  
ESTABLISHMENTS ENGAGED IN THE MANUFACTURE, DISTRIBUTION, AND SALE  
OF NATURAL PRODUCTS AND NUTRITIONAL SUPPLEMENTS IN PUERTO RICO**

**GOVERNMENT OF PUERTO RICO  
DEPARTMENT OF HEALTH**

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**INDEX**

<b>CHAPTER I: LEGAL BASIS, APPROVAL, PURPOSE, AND APPLICABILITY</b>	<b>1</b>
<b>CHAPTER II: DEFINITIONS</b>	<b>2</b>
<b>CHAPTER III: CERTIFICATION</b>	<b>4</b>
<b>CHAPTER IV: REGISTRATION OF NATURAL AND NUTRITIONAL SUPPLEMENTS, AS DEFINED IN THESE REGULATIONS</b>	<b>8</b>
<b>CHAPTER V: AGENT</b>	<b>11</b>
<b>CHAPTER IV: MANUFACTURE OF NATURAL PRODUCTS AND/OR NUTRITIONAL SUPPLEMENTS</b>	<b>12</b>
<b>CHAPTER VII: CRAFTED MANUFACTURING OF NATURAL PRODUCTS</b>	<b>13</b>
<b>CHAPTER VIII: DISTRIBUTION OF NATURAL PRODUCTS AND NUTRITIONAL SUPPLEMENTS, AS DEFINED IN THESE REGULATIONS</b>	<b>14</b>
<b>CHAPTER IX: ADMINISTRATIVE PROVISIONS</b>	<b>16</b>
<b>CHAPTER X: GENERAL PROVISIONS</b>	<b>20</b>

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**CHAPTER I  
LEGAL BASIS, PURPOSE, AND APPLICABILITY**

**Article 1. Legal Basis**

Section 1. These Regulations are enacted pursuant to Act No. 81 of March 14, 1912, as amended, known as the "Organic Act of the Department of Health, Act No. 72 of April 26, 1940, known as the "Food, Drug, and Cosmetic Act of Puerto Rico"; the 21 Code Federal Regulation III, and the Act No. 170 of August 12, 1988, as amended, known as the Uniform Administrative Procedures Act, as well as Act No. 38 of June 30, 2017, better known as the "Uniform Administrative Procedures Act of the Government of Puerto Rico".

Section 2. All adjudicatory procedures established in these Regulations shall be carried out in accordance with Act No. 38 of June 30, 2017, better known as the "Uniform Administrative Procedures Act of the Government of Puerto Rico" and the Regulations for Adjudicatory Procedures in the Department of Health and its Dependencies, Regulations No. 5467 of August 27, 1996.

Section 3. By means of the provisions set forth in these Regulations, the Secretary of Health shall be empowered to regulate the operations of establishments engaged in the manufacture, distribution, and sale of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders, or liquids in the Commonwealth of Puerto Rico, as well as the compliance with all state and federal legislation and regulations and new standards applicable in Puerto Rico.

**Article 2. Approval**

These Regulations are approved to establish those rules and parameters that shall govern the operation of the establishments engaged in the manufacture, distribution, and sale of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders, or liquids in Puerto Rico. The adoption of these Regulations has the purpose of ensuring the efficient operation of the establishments to be certified.

**Article 3. Purpose**

The purpose of these Regulations is to protect the public health monitoring the integrity of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders, or liquids that are available and accessible to the citizenship. Thus, the Department of Health complies with its ministerial duty to protect public health by avoiding the indiscriminate use of products that are unfit for health. These products may contain active ingredients that have biological effects on the body or that may be harmful if used with other products, used as medications, replaced by medications or are taken in excess. These products are not medications, so they are not intended to diagnose, treat, prevent, or cure diseases.

In addition, these Regulations have the purpose of appointing the Division of Pharmacies and Drugs, assigned to the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities (SARAFS) as the governmental entity in charge of the implementation of these Regulations.

**Article 4. Applicability**

- Section 1. These Regulations shall be applicable to establishments engaged in the manufacture, distribution, and sale of natural products and nutritional supplements or dietary supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders, or liquids in Puerto Rico.
- Section 2. These Regulations establish the requirements that shall govern establishments engaged in the manufacture, distribution, and sale of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders, or liquids in Puerto Rico.
- Section 3. The provisions of these Regulations shall not apply to Cannabis and/or Cannabis products, as well as to hemp and/or hemp products containing cannabinoids such as THC, CBD, CBN, among others.
- Section 4. The Secretary of Health may impose additional requirements to those set forth in these Regulations when they are necessary in regard to the interest of the health and safety of the people.

**CHAPTER II  
DEFINITIONS**

For the purposes of these Regulations, the terms included herein shall have the following definitions:

- 1) Agent: Refers to any person authorized and registered by the Secretary of Health to represent a manufacturer or distributor of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders, or liquids in their market, with no contribution in regard to storage, distribution, or dispensation.
- 2) Food: Refers to an item used as food or drink by humans, chewing gum, item used as components of any such items. For the purposes of these Regulations, it refers to products that are marketed as nutritional supplements in the form of tablets, capsules, beads, gel capsules, powders, or liquids.
- 3) Craftsman: Refers to any natural person residing in Puerto Rico who, by means of their skills and abilities, makes a work mainly manually, called craft, as defined by Act No. 166 of August 11, 1995, as amended.
- 4) Department: Refers to the Department of Health of the Government of Puerto Rico and all divisions and administrative units assigned to such Department.
- 5) Wholesale distributor of natural products or food: Refers to any person duly authorized and registered by the Secretary of Health to sell wholesale natural products or nutritional supplements, as set forth in these Regulations.
- 6) Retail distributor of natural products or food: Refers to any person duly authorized and registered by the Secretary of Health to sell retail natural products or nutritional supplements, as set forth in these Regulations.
- 7) Division of Pharmacy and Medications: Refers to the administrative unit assigned to the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities of the Department of Health (SARAFS).
- 8) Drug: Refers to any substance of animal, vegetable, mineral or synthetic origin, or a combination thereof: (1) recognized in the official compendium of the United States/National Formulary, or Homeopathic Pharmacopoeia of the United States; (2) or to be used in the diagnosis, cure, relief, treatment, or prevention of a disease,

injury, or any other condition affecting the health of the human being or of an animal; (3) or for, without being food, being used to affect or evaluate the structure or function of the body of the human being or of another animal; (4) or the components thereof.

- 9) Drugstore: Refers to any establishment authorized and registered in accordance with these Regulations, to the wholesale distribution of drugs, devices, and products, including those related to veterinary practice or the practice of veterinary medicine.
- 10) Inspector: Refers to an official of the Department of Health appointed and authorized to ensure that the establishments that carry out the activities stipulated in these Regulations, and other applicable laws, comply with all the requirements set forth therein.
- 11) Pharmacy: Refers to the establishment of a health service, physically located in the jurisdiction of Puerto Rico, authorized and registered pursuant to the provisions of the Pharmacy Act, to engage in the provision of pharmaceutical services, which include: the distribution of prescribed medications, over-the-counter medications, devices and other health-related products, the provision of pharmaceutical care, and other services within the functions of the pharmacist set forth in the Pharmacy Act.
- 12) FDA: Refers to the Food and Drug Administration of the Federal Government or Government of the United States of America.
- 13) Manufacturing: Refers to the production, preparation, and processing of natural products or food, directly or indirectly, by extraction, distillation, fractionation, purification, concentration or fermentation to be used as natural products, nutritional supplements or dietary supplements. It includes the preparation and processing of a final product, its packaging, repackaging, and the labeling of its container.
- 14) Person: Refers to any natural person or legal entity, regardless of their denomination and the manner in which it is constituted.
- 15) Natural Products: Refers to those obtained when substances of herbs or plant material are subjected to treatments such as extraction, distillation, fractionation, purification, concentration or fermentation. This includes crushed or powdered herbal substances, dyes, extracts, essence oils, and extracted juices. The natural products may contain organic and/or inorganic active ingredients that are not of vegetable origin (for example, of animal or mineral origin) or excipients, inactive substances.
- 16) Crafted natural products: Refers to a product that is essentially manufactured by hand, that its ingredients or components are specifically of natural origin, and that they shall not contain any chemical ingredient with the exception of those required to complete the elaboration process.
- 17) Secretary of Health: Refers to the Secretary of the Department of Health of Puerto Rico.
- 18) Nutritional Supplement or Dietary Supplement: Refers to products, excluding tobacco, intended to supplement the diet that comprise or contain one or more of the following dietary ingredients: vitamin; mineral; herb or other botanical product; amino acid; dietary substance for human consumption to supplement the diet by increasing the dietary intake, or a concentrate, metabolite, constituent, extract or a combination thereof. In addition, they are products intended for intake, their use is not represented as conventional food or as a single item of food or diet, and are labeled as dietary supplements.

- 19) Craft workshop: Refers to a designated area for the processing, production, and manufacture of the crafted natural product.
- 20) Store of natural products or "Health Food": Refers to an establishment engaged in the sale of natural products and supplements, authorized and registered by the Secretary of Health for the retail distribution of these products.

**CHAPTER III  
CERTIFICATION**

**Article 1. Certification Requirement**

Section 1. Any natural person or legal entity that operates an establishment of those defined in these Regulations, as well as any person interested in being engaged in the manufacturing, distribution, and selling of natural products and nutritional supplements, in Puerto Rico, as defined in these Regulations, shall request and obtain the pertinent certification issued by the Secretary of Health, by means of the Auxiliary Secretary of the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities.

**Article 2. Application for Certification**

Section 1. Applications for certification to offer services under the provisions of these Regulations shall require at least the following information:

- a) Name, physical address, mailing address, e-mail address, web address, and telephone numbers of the establishment.
- b) Name, telephone, web address, and address of the person, company, cooperative, association or corporation that requests the certification including:
  - 1. if it is a natural person, the name of such person;
  - 2. if it is a company, the name of the company, the name of each partner, and of the managing partner;
  - 3. if it is a corporation, the corporate name, the name, title, and address of the officers and directors and the place of incorporation or authorization to do business in Puerto Rico;
- c) Operating hours of the establishment;
- d) Type or category of facilities,

Section 2. With the application, a copy of the following documents shall be included:

- a) License, Certification or Permit issued by the Auxiliary Secretariat of Environmental Health;
- b) The establishments to operate for the first time, of expansion, remodeling or new constitution, the permit for use granted by the Permit Management Office (OGPe);
- c) Current certificate of inspection and endorsement of the firefighters issued by the Fire Department of Puerto Rico;

- d) Valid copy of Municipal Patent or evidence that an application has been submitted to the Municipality;
- e) Certificate of Incorporation of the Department of State of Puerto Rico; this requirement shall only apply to corporations duly registered with the Department of State of Puerto Rico.
- f) Other documents that the Secretary of Health deems necessary may be required.

Section 3. Application for New Creation

- a) Any natural person or legal entity that requests a certification to operate an establishment or provide any of the services controlled by these Regulations, shall submit the application in the format provided by the Department of Health, with all the required information:
- b) Any request for newly created establishments, change of owner or premises must include, along with the certification application to offer services, the documentation required thirty (30) calendar days in advance of the date indicated to open to the public or the effective date of the change. At the time of submitting the application, the documents evidencing that the pertinent permits have been processed before the different government agencies shall be attached. At the time of the inspection, the permits must be available to be assessed by the inspector.
- c) The Department of Health, by means of the Division of Drugs and Pharmacies, shall make the initial inspection visit within the first fifteen (15) business days following the receipt of the application and shall determine its approval or rejection within fifteen (15) business days after the inspection. If there is any notice with remarks, it is the responsibility of the applicant to make the correction within the term of fifteen (15) calendar days, from the date of notification of the remarks. Otherwise, the application shall be rejected.
- d) In order for a newly created establishment to begin providing services to the public, it must have obtained the pertinent certification prior to its opening or commencement of operations, as applicable. In the case of establishments in operation at the time of approval of these Regulations, they shall be granted a term of thirty (30) calendar days, from the approval thereof, to request their certification and may continue offering services while completing the certification process.

Section 4. Application for Renewal

- a) Any application for certification renewal shall be in the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities (SARAFS), no later than forty-five (45) calendar days prior to the expiration date of the certification. The renewal shall be gradually carried out, in the format established by the Department of Health. In addition, it must be accompanied by the following documentation:
  - i. Sanitary License;
  - ii. Valid certificate of inspection and endorsement of the firefighters issued by the Fire Department of Puerto Rico;

- iii. Valid copy of Municipal Patent or evidence that an application has been submitted to the Municipality.
  - iv. Certificate of Incorporation of the Department of State of Puerto Rico; this requirement shall only apply to corporations duly registered with the Department of State of Puerto Rico.
- b) The facilities that have been without operation, closed to the public or without renewing the certification for a period of one (1) year or more, shall be considered closed so they are required submit the documents and comply with the requirements of a new application.

**Section 5. Certification Fees**

- a) The application shall be accompanied by the pertinent payment of the certification fees:
- 1. Agent, a certification of two hundred dollars (USD 200.00) shall be required.
  - 2. Wholesale distributor of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders or liquids, as defined in these Regulations, a certification fee of one hundred dollars (USD 100.00) shall be required.
  - 3. Retail distributor of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders or liquids, as defined in these Regulations, a certification fee of one fifty dollars (USD 50.00) shall be required.
  - 4. Registration of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders or liquids, as defined in these Regulations, a certification fee of one twenty-five dollars (USD 25.00) shall be required.
  - 5. Manufacturer of natural products and nutritional supplements that are marketed in the form of tablets, capsules, beads, gel capsules, powders or liquids, as defined in these Regulations, a certification fee of five hundred dollars (USD 500.00) shall be required.
  - 6. Certification for Manufacturing of Crafted Products (USD 50.00)
  - 7. Duplicates of certifications (USD 25.00)
- b) The payment of the fee for the certification application shall be made through money order, certified check of manager in the name of the Secretary of the Treasury of Puerto Rico, credit card, debit card or by means of Virtual Collection. Payments in cash may be made up to USD 50.00.

**Article 3. Certificate Issuance**

Section 1. The Department of Health shall issue a certification under the name of the owner of the establishment or craft workshop, which shall specify the name and address of the establishment for which such certification was granted.

Section 2. The certification or authorization shall be issued in the form and model determined by the Secretary of Health.

- Section 3. The certification shall be exposed to open view and the owner is required to keep it in good condition.
- Section 4. In event of loss or misplace of the certification, its holder shall immediately notify so to the Secretary of Health in writing and request, at his/her expense, a duplicate.
- Section 5. The certification may not be transferred or reassigned to another person or dependency.
- Section 6. Any change in the effective control of the certification holder shall be considered as a change in the owner entity for the purposes of these Regulations, which shall require a new certification application. The Department of Health shall issue a new certification for a minimum term of two (2) years.
- Section 7. Any change of place or facility shall be considered as a change in the action authorized in the certification granted by the Department of Health. The certification holder shall notify in writing, prior to any action, the plans for the move and submit a certification application for the new premises, duly documented.
- Section 8. Any change of postal address, website address, e-mail or telephone number indicated in the certification application shall be reported in writing to the Department of Health, Auxiliary Secretariat for Regulation and Accreditation of Health Facilities, Division of Drugs and Pharmacy within ten (10) calendar days after the change took place.
- Section 9. Failure to notify may be sufficient ground for the denial of the appropriate and timely renewal.
- Section 10. In the event of change of name of the establishment, an application for a new certification shall be submitted for a change of name before the Department of Health, the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities, Division of Drugs and Pharmacies, fifteen (15) calendar days in advance to the effective date of the change. All documents evidencing such change shall be attached.
- Section 11. When an establishment referred to in these Regulations changes owner or premises, the certification that is current at the time of the transaction shall be null and shall be submitted to the Department of Health in order to obtain a new certification. In the event of change of owner or premises, the application for a new certification shall be carried out in accordance with the provisions of these Regulations.
- Section 12. In the event of closure, the holder of the certification or authorization shall notify so in writing to the Department of Health, Auxiliary Secretariat for Regulation and Accreditation of Health Facilities, Division of Drugs and Pharmacy, and the holder is responsible for returning the certification to the Department of Health within ten (10) days after the closing.

#### **Article 4. Denial, Suspension or Revocation of Certification**

- Section 1. Upon prior notification to the applicant or holder of a certification, and after giving the latter the opportunity to be heard in a hearing, the Department of Health shall deny, suspend or revoke any certification if a substantial breach with the provisions of these Regulations is found or if its granting does not respond to the public interest.

Section 2. The Secretary of Health may deny the issuance or renewal of a certification, upon prior notification to the applicant, after giving the latter the opportunity to be heard in an administrative hearing pursuant to the provisions of the Uniform Administrative Procedures Act of the Government of Puerto Rico.

Section 3. The Secretary of Health shall be empowered to suspend, cancel, or revoke any certification or authorization set forth in these Regulations when it is determined that:

- a) It does not comply with the requirements and conditions set forth in these Regulations or in the state or federal laws or regulations applicable to the manufacture, distribution, and sale of natural products and nutritional or dietary supplements, as defined in these Regulations.
- b) It infringes any law or regulation applicable to the manufacture, distribution, and sale of natural products in Puerto Rico;
- c) It unfoundedly and repeatedly refuses to take certain measures or to correct any deficiency indicated by the inspectors, within the required term.

Section 4. Any procedure for the granting, denial, suspension, cancellation or revocation of specific certifications or authorizations shall be governed by the provisions of adjudicative procedures established in the Uniform Adjudicatory Procedure Act of the Government of Puerto Rico and by the Regulations of the Secretary of Health to Regulate Adjudicative Procedures in the Department of Health and its Dependencies.

**Article 5. Validity**

Section 1. All certifications issued under these Regulations shall be gradually valid for two (2) years.

**CHAPTER IV.  
REGISTRATION OF NATURAL PRODUCTS AND NUTRITIONAL SUPPLEMENTS,  
AS DEFINED IN THIS REGULATION**

**Article 1. Person responsible for the registration**

Section 1. Any natural person or legal entity engaged in the manufacture and distribution of natural products and nutritional supplements in Puerto Rico, as defined in these Regulations, shall be responsible for submitting the product to the Department of Health for registration.

Section 2. In event of manufacturers and distributors, they may delegate the registration of natural products and nutritional supplements, as defined in these Regulations, to an agent.

Section 3. Any natural person or legal entity that requests to register natural products and nutritional supplements, as defined in this regulation, shall have a certification, as applicable, granted by the Department of Health under this regulation.

**Article 2. Registration Procedure**

Section 1. Any natural person or legal entity engaged in the manufacture and distribution of natural products and nutritional supplements, as defined in these Regulations, shall be responsible and shall fill in the registration application for each of the products that it wants to register in the form provided by the Department, recording the following:

a) Applicant's Name

1. If the applicant is a corporation, it shall provide the full name of the corporation, date and place of incorporation, name, address, telephone number, web address, email address and title of the corporation's officers and their business address. In addition, the name, postal address, telephone and e-mail of the agent shall be supplied.
2. If the applicant is a company, it shall provide the names of the partners and their place of residence. In addition, the name, postal address, telephone and e-mail of the managing partner shall be supplied.
3. In the event of trademarks, the full name of the applicant's trademark and firm shall be provided, as well as the name of any person doing business under such trademark.
  - i. Preparation's name;
  - ii. Name, physical address, postal address, web address and electronic address of the entity where the natural product or food is prepared, manufactured or re-packaged, as defined in these Regulations;
  - iii. Name, physical address, postal address and electronic address of the distributor in Puerto Rico;
  - iv. Form, size and concentration in which the natural product and nutritional supplement is sold, as defined in these Regulations, specifying whether it is in solid or liquid form.

Section 2. Documentary evidence related to the following aspects shall be submitted:

- a) Processes to obtain the natural product and nutritional supplements, as defined in these Regulations, including their description and characterization;
- b) Sample of the labels to be used in order to identify the natural product and nutritional supplements, as defined in these Regulations;
- c) Promotional material or advertisements used for the natural product and nutritional supplements, as defined in these Regulations;
- d) Certificate of Analysis of the natural product and nutritional supplements, as defined in these Regulations by a laboratory registered by the Food and Drugs Administration (FDA) and licensed by the Department of Health including the following information:
  1. Manufacturer's name, including contact information.
  2. FDA registration number and license number of the Department of Health.
- e) Health warnings required by the natural product and nutritional supplements, as defined in these Regulations.

Section 3. The list of natural products and nutritional supplements, as defined in these Regulations to be registered that shall include in the upper part the name, address and telephone number of the distributor and/or agent in Puerto Rico.

Section 4. All documents shall be submitted in the digital format established by the Department of Health.

- Section 5. All requests must be accompanied by the payment of the amount of the registration fees of medications.
- Section 6. As of the validity of these Regulations, the registration of natural products and nutritional supplements distributed in Puerto Rico prior to the validity of these Regulations shall be gradually carried out and as set forth below:

<b>Volume per Gross Sale</b>	<b>Moratorium Time for Registration</b>
Establishments or entities with gross sales up to USD 1,000,000.00.	From the validity date of the Regulations up to 12 months.
Establishments or entities with gross sales over USD 1,000,000.00.	From the validity date of the Regulations up to 18 months.

- Section 7. While the Department of Health completes the process of registration of natural products and nutritional supplements, as defined in these Regulations, distributed in Puerto Rico on the validity of the Regulations, a moratorium shall be granted to continue distributing those natural products or food, pending for registration.
- Section 8. A payment of five dollars (USD 5.00) shall be required for each presentation of the natural products and nutritional supplements, as defined in these Regulations, to be registered, during the moratorium time established for the registration. After said term, a payment of fifteen dollars (USD 15.00) shall be required for each presentation of the natural products and nutritional supplements, as defined in these Regulations.
- Section 9. Payment of the fee for the registration of natural products and nutritional supplements, as defined in these Regulations, shall be made through money order, certified check of the manager in the name of the Secretary of the Treasury of Puerto Rico, credit card, debit card or by means of Virtual Collection. Payments in cash may be made up to USD 50.00.
- Section 10. Payment for registration shall be for life, unless there is a change in the product.
- Section 11. Any change in the information submitted in the registration of natural products shall be notified to the Department of Health, Auxiliary Secretariat for Regulation and Accreditation of Health Facilities, Division of Drugs and Pharmacy.
- Section 12. Any change in the information submitted in the registration of natural products and nutritional supplements, as defined in these Regulations, shall be submitted within a term not exceeding five (5) calendar days since the change took place, along with the payment of the pertinent fees.

**Article 3. Duties and Powers of the Secretary**

- Section 1. The Secretary of Health may not disclose the ingredients of the formulas, except by the issuance of a competent judicial order.
- Section 2. All documentation of each registered formula shall be archived by the Secretary of Health and shall be maintained in a "back up" of the digital information related to the registration of medications since the validity of these Regulations.
- Section 3. The Secretary of Health shall be empowered to revoke the registration

certificate of a natural product or nutritional supplement, as defined in these Regulations, if it finds that it is infringing any of the provisions thereof.

Section 4. The Department of Health shall guarantee access to the Department of Consumer Affairs (DACO), the Registry of Natural Products and Nutritional Supplements, in order to strengthen the effective performance of DACO's supervisory function, regarding the distribution of these products. The Secretary shall establish the mechanisms and/or procedures that are required in order to comply with this provision before the DACO's Secretary.

Section 5. The Department of Health shall provide access to citizenship in general, by means of its portal, to the Registry of Natural Products and Nutritional Supplements, as defined in these Regulations.

Section 6. The Department of Health shall not be responsible for the therapeutic purpose of the registered natural products and foods, as defined in these Regulations, so the adjudication of any responsibility of the Department of Health shall not be included, nor published in any label, advertisement, or in any other form of publicity, neither shall the name and logo of the Department of Health be used for promotion and marketing purposes of the product.

#### **CHAPTER V AGENT**

Section 1. Any person engaged in the representation of a manufacturer or wholesale distributor of natural products and nutritional supplements, as defined in these Regulations, or that represents natural products or nutritional supplements, as defined in these Regulations, of their property, without engaging in the storage or distribution thereof in Puerto Rico, shall request and obtain from the Secretary of Health a certification approving him or her as agent. This provision shall also apply to any person representing a distributor engaged in the reverse distribution of natural products and nutritional supplements, as defined in these Regulations. Reverse distribution of natural products and nutritional supplements, as defined in these Regulations, is understood as the coordination for the return to the manufacturer of natural products expired or not suitable for consumption, without entering into their possession.

Section 2. In the certification application, the agent shall provide at least the following information described in Article 2 of Chapter II of these Regulations. In addition, the following information shall be supplied:

- a) List of natural products and nutritional supplements that shall be distributed or represented.
- b) Name, physical and postal address, email and telephone numbers of the represented manufacturer or distributor and the certified authorization of the latter appointing him or her as agent.

Section 3. The agent shall have an office in Puerto Rico outside its official residence in order to carry out the administrative functions. The certification granted under these Regulations and the pertinent permits from other regulatory agencies shall be exposed to open view at the office.

Section 4. The agent shall keep in his or her office the registration of all transactions related to the purchase, distribution and sale of natural products and/or nutritional supplements, as defined in these Regulations, through the wholesale distributors duly authorized by the Department of Health. In addition, the agent shall keep copies of the licenses

or certifications authorizing each of his or her customers to acquire and distribute natural products and/or nutritional supplements in Puerto Rico, as defined in these Regulations; copy of the manufacturer's FDA number; and copy of the invoices of natural products and/or nutritional supplements, as defined in these Regulations, that the represented manufacturer or distributor distributed to each customer in Puerto Rico. These documents and other related documents shall be available for inspection and photocopy by authorized officers of the appropriate state and federal agencies.

- Section 5. The agent shall be responsible for requesting and obtaining the registration of the products and/or nutritional supplements, as defined in these Regulations, he/she represents if they have not been previously registered in Puerto Rico.
- Section 6. The agent shall be responsible for notifying his or her customers in writing and verifying that the orders for the removal of natural products and/or nutritional supplements are executed, as defined in these market Regulations and other notifications issued by the manufacturer or by federal or state agencies in regard to the natural products that the agent represents.
- Section 7. All manufacturers and/or distributors are responsible for notifying the Department of Health of the appointment and removal of the agent.

#### **CHAPTER VI MANUFACTURE OF NATURAL PRODUCTS AND/OR NUTRITIONAL SUPPLEMENTS**

**Article 1. Certification of Manufacturing of Natural Product and/or Nutritional Supplement, as defined in these Regulations**

- Section 1. Any establishment engaged in the manufacture of natural products and/or nutritional supplements in Puerto Rico, as defined in these Regulations, shall request and obtain a Certification of Manufacturing of Natural Product and/or Nutritional Supplement, as defined in these Regulations, from the Secretary of Health authorizing their wholesale distribution and manufacture in Puerto Rico, with the exception of pharmaceutical industries duly licensed and registered in accordance with the provisions of the Regulations of the Secretary of Health No. 156 To Regulate the Operation of Establishments Engaged in the Manufacture, Distribution and Dispensation of Medications.
- Section 2. Any person engaged in the manufacture of natural products and/or nutritional supplements, as defined in these Regulations, shall file an application with the Pharmacies and Medicines Division, assigned to the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities in the format established by the Department of Health.
- Section 3. In the application for Certification of Manufacturing of Natural Product and/or Nutritional Supplements, as defined in these Regulations, at least the information described in Article 2 of Chapter II of these Regulations shall be provided. In addition, the following documentation shall be supplied:
- a) Copy of the manufacturer's registration issued by the FDA as a manufacturer.
  - b) The manufacturing protocol to be implemented in the establishment. In an effort to guarantee the quality of the product, this protocol shall comply with the *Good Manufacturing Practice (GMP) and Standard Operating Procedures (SOP)*.

- b) Certificate of Analysis for manufactured products, from a laboratory registered by the FDA and licensed by the Department of Health, which includes the following information:
  - 1. Manufacturer's name, including address and contact information;
  - 2. Registration number with the FDA and license number of the Department of Health, if it is a duly licensed Manufacturing Industry;
  - 3. Content of the ingredients of the natural product and/or nutritional supplement, as defined in these Regulations.

Section 4. Any establishment engaged in the manufacturing of natural products and/or nutritional supplements in Puerto Rico, as defined in these Regulations, shall comply with the provisions of the 21 Code Federal Regulation 111.

Section 5. Any establishment engaged in the manufacturing of natural products and/or nutritional supplements in Puerto Rico, as defined in these Regulations, shall have among their personnel at least one (1) certified chemist or one (1) pharmacist who shall ensure compliance with the provisions of laws and regulations of the Department of Health and other government agencies regarding the manufacture, packaging, and distribution of these products.

Section 5. The functions of the chemist or pharmacist include:

- a) Be responsible for ensuring compliance with the provisions of laws and regulations of the Department of Health and other state and federal government agencies regarding the manufacture, packaging, and distribution of natural products in Puerto Rico.
- b) Participate in areas, such as, review and approval of changes in processes affecting the manufacture and packaging of products, changes to master documents of products to be manufactured or deviations from processes affecting the quality of the product and, therefore, public safety, or development and implementation of new processes for the manufacture of products.
- c) The chemist or pharmacist shall be appointed as the person in charge of the facility. The appointment shall be notified to the Department of Health within the next ten (10) calendar days after the appointment occurred.

**CHAPTER VII  
CRAFTED MANUFACTURING OF NATURAL PRODUCTS**

**Article 1. Certification of Registration of Natural Crafted Products**

Section 1. Any person who is engaged in the manufacturing of natural products shall be registered and obtain a certification from the Secretary of Health, as established in these Regulations.

Section 2. In order to be registered and receive the pertinent certification, the following requirements must be complied with:

- a) The crafted natural product shall be produced in Puerto Rico.
- b) It shall be produced by a Puerto Rican person or someone with *bona fide* residence or domicile in Puerto Rico.
- c) Local raw material shall be used.
- d) The work shall be based on manual labor or executed with his or her tools, equipment or instruments.

- e) He or she shall submit the formula of the natural crafted product and its manufacturing process.
  - f) The provisions contained in Act No. 166 of August 11, 1995, as amended, shall be complied with.
  - g) He or she shall have an area (craft workshop) designated for the production, manufacturing and/or production of the products; it shall have a sink with cold and hot water available and not connected to the main residence.
- Section 3. The crafted natural product to be presented shall be labeled, and such label shall include: presentation or identity of the product, name and telephone number of the craftsman, certification number of the Department of Health, ingredients, sub-ingredients, indications for use and the pertinent warnings, such as possible allergies, changes of color and/or smell of the natural crafted product.
- Section 4. The registration of crafted products shall be carried out by group and category (e.g., coconut soaps, oils, etc.).
- Section 5. During craft fairs, the craftsmen shall have exposed to open view the Certification issued by the Department of Health.

**CHAPTER VIII  
DISTRIBUTION OF NATURAL PRODUCTS AND NUTRITIONAL  
SUPPLEMENTS, AS DEFINED IN THESE REGULATIONS**

**Article 1.** Certification of wholesale distribution of natural products and nutritional supplements, as defined in these Regulations.

Section 1. Any person engaged in the wholesale distribution of natural products and nutritional supplements, as defined in these Regulations, shall request and obtain from the Secretary of Health a certification authorizing them to acquire, store and distribute them, except for the drugstores duly licensed and registered pursuant to the provisions of the Regulations of the Ministry of Health No. 156 To Regulate the Operation of Establishments Engaged in the Manufacture, Distribution and Dispensation of Medications.

**Article 2. Filing of Certification Application**

Section 1. Any wholesale distributor of natural products and nutritional supplements, as defined in these Regulations, shall file an application for certification in the format established by the Department of Health. In the certification application, the information described in Article 2 of Chapter II of these Regulations shall be provided. In addition, the following shall be supplied:

- a) List of natural products and nutritional supplements, as defined in these Regulations, which the applicant shall distribute. In addition, such list shall be available at the establishment for verification during its inspection.

**Article 3. Certification of Retail Distribution of Natural Products and/or Nutritional Supplements, as defined in these Regulations**

Section 1. Any person engaged in the retail distribution or sale of natural products and nutritional supplements, as defined in these Regulations, shall request and obtain a certification authorizing the acquisition, purchase, storage, distribution and sale of said products, with the exception of pharmacies duly licensed and registered in accordance with the provisions of the Regulations of the Ministry of Health No. 156 To Regulate the Operation of Establishments Engaged in the Manufacture, Distribution and Dispensation of Medications.

Section 2. Any retail distributor of natural products and nutritional supplements, as defined in these Regulations, shall file an application for certification in the format established by the Department of Health. In the certification application, the information described in Article 2 of Chapter II of these Regulations shall be provided. In addition, the following shall be supplied:

- a) List of natural products that shall be distributed by the applicant. In addition, such list shall be available at the establishment for verification during its inspection.

**Article 4. Acquisition of natural products**

Section 1. Natural products and nutritional supplements, as defined in these Regulations, may be acquired in pharmacies, and in establishments duly authorized and registered by the Secretary of Health as retail distributors of natural products.

**Article 5. Express Prohibitions**

Section 1. Establishments with wholesale or retail distributor certification of natural products may not distribute medications with said certification.

Section 2. It is forbidden to import natural products and nutritional supplements, as defined in these Regulations, to be re-packaged in Puerto Rico, unless it is a manufacturing industry duly licensed by the Department of Health.

Section 3. The use in natural products and foods, as defined in these Regulation, as well as during their process of promotion and marketing, of medical claims containing the following language "cures", "eliminates", "treatment", "prevention" or "relief" of a disease or condition affecting the health is forbidden. The provisions of the Regulation of the Secretary of Health No. 156 shall be applied to any natural product and food regulated by these Regulations performing the aforementioned medical claims. In addition, the federal regulations contained in 21 CFR § 101.71 are adopted by reference.

Section 4. In the case of natural products and nutritional supplements, pursuant to these Regulations, only the use of the health claims allowed in the federal regulations contained in 21 CFR §101.72- 101.83 shall be allowed. The federal regulations are adopted by reference.

**Article 6. Conservation and retail or sale of natural products**

Section 1. The establishments with distributor certification of natural products and nutritional supplement, pursuant to these Regulations, shall have an area or physical space, separated from any other items or products that are sold there for their conservation.

Section 2. The natural products and nutritional supplements, pursuant to these regulations, shall be preserved, sold or retailed in their original packaging, duly labeled by the manufacturer, indicating on its label its content, indications for use, the name of the manufacturer or distributor and any other information for its safe use, as required by law.

Section 3. Natural products and nutritional supplements, pursuant to these

regulations, shall be preserved in an appropriate environment with adequate temperature according to the specifications of the manufacturer so that their quality, purity and strength shall not suffer any deterioration or decrease.

**Article 7. Labeling and packaging of natural products**

Section 1. The labeling of all natural products and nutritional supplements, pursuant to these Regulations, to be traded and distributed in Puerto Rico shall comply with the FDA requirements.

**Article 8. File and Inventory**

Section 1. Any establishment certified to distribute natural products and nutritional supplements, pursuant to these Regulations, shall prepare and maintain an updated inventory and complete file of the acquisition and sale transactions of the products regulated by these Regulations. This file shall include, among other documents: invoices and records of the products issued by the FDA.

**CHAPTER IX  
ADMINISTRATIVE PROVISIONS**

**Article 1. Powers of the Secretary**

The Secretary of Health is responsible for enforcing and supervising compliance with the provisions of these Regulations. The Secretary shall be empowered to investigate, inspect, summon witnesses, and approve the necessary rules to make the purposes thereof viable. In addition, if necessary, the Secretary may request the voluntary delivery of products to be submitted to a validation process by the Department of Health.

**Article 2. Inspectors**

Section 1. The inspectors who shall ensure compliance with the provisions of these Regulations shall be assigned to the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities (SARAFS), Division of Drugs and Pharmacies.

a) The Inspector shall be a pharmacy technician duly certified by the Board of Pharmacy of Puerto Rico, with current professional license, and who has a minimum of one (1) year of experience as a pharmacy technician.

b) The Department of Health shall determine the training in the areas of food safety that shall be carried out by the inspectors.

Section 2. The Inspector may inspect and examine all documentation and activities subject to the certifications issued under these Regulations.

Section 3. The Inspector may inspect and examine all documentation and activities subject to the certifications and special authorizations issued under these Regulations, within the following establishments:

a) Agent

b) Wholesale Distributor of Natural Products and nutritional supplements, pursuant to these Regulations.

c) Retail Distributor of Natural Products and nutritional supplements, pursuant to these Regulations.

- d) Manufacturing of Natural Products and nutritional supplements, pursuant to these Regulations.

**Article 3. Inspections**

- Section 1. The Auxiliary Secretariat for Regulation and Accreditation of Health Facilities shall carry out inspections to the certified establishments with the purpose of determining the compliance with the provisions set forth in these Regulations.
- Section 2. The inspections may be initial, general or follow-up inspections, or as part of the investigation process of a complaint, or incident related to the services provided in the establishment in question.
- Section 3. At the time of the inspection, the permits must be available to be assessed by the inspector.
- Section 4. The amount for the inspection shall be USD 50.00 per hour per inspection. If the Secretary of Health determines that the applicant meets the requirements of these Regulations, he or she shall issue the pertinent certification.
- Section 5. If there is any notice, it is the responsibility of the applicant to make the correction within the term of fifteen (15) calendar days, from the date of notification of the remarks.
- Section 6. The inspections shall be carried out by inspectors duly authorized by the Secretary of Health, through the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities. They shall be duly identified during the inspection process.
- Section 7. The Secretary of Health may order inspections at any time he or she deems appropriate, without notification.

**Article 4. Authority to enter the premises and inspect the files**

- Section 1. The Auxiliary Secretary of the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities, and their authorized representatives, shall carry out the inspections or investigations that they deem necessary, and they shall be able to review any file of the establishment in such a way that compliance with each of the requirements of these Regulations can be verified. Such inspections may be carried out without prior notification.

**Article 5. Procedure for Inspection Visits**

- Section 1. The Secretary of Health may delegate the function of supervising compliance with the provisions of these Regulations, in addition to any other related functions, to the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities of the Department of Health.
- Section 2. The inspectors, as part of the inspection of the establishments applied by these Regulations, may carry out, among others, the following functions:
  - (a) Examine documents, inventories, goods, premises, properties, transactions, businesses or any other materials or activities related to the manufacture and distribution of natural products and/or nutritional supplements, pursuant to these Regulations.
  - (b) Seize or confiscate all natural products and/or nutritional supplements,

pursuant to these Regulations, that are not registered pursuant to these Regulations or that is not suitable for consumption.

- (c) Collect the necessary evidence for the prosecution of those infringing these Regulations, in order to be prosecuted in the pertinent administrative or judicial forum.

Section 3. Any document whose examination is relevant in light of the provisions of these Regulations, and which is related to the manufacture and/or retail or wholesale distribution of natural products and/or nutritional supplements, in Puerto Rico, pursuant to these Regulations, shall be available for inspection by the Secretary or his or her authorized representatives.

Section 4. Any person holding a certification under the provisions of these Regulations shall allow any inspection required by the Secretary.

Section 5. Inspections of the establishments to which the provisions of these Regulations apply may be carried out without prior notice during the regular business hours of the establishment.

Section 6. The absence of the owner or principal person in the establishment shall not be a reason or justification in order to prevent the execution of the inspection.

Section 7. In those events in which validly obtained documents are not to be used as provided in these Regulations, they shall be returned to their owner or legal guardian from where they were obtained.

#### **Article 6. Inspection Report and Correction Plan**

Section 1. The inspection report shall include all the indications of the deficiencies found during the evaluation process of the establishment and shall be submitted during the next fifteen (15) business days following the inspection.

Section 2. The Auxiliary Secretary of the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities may extend the delivery period of the inspection report under specific circumstances or by operative needs.

Section 3. The Department of Health shall grant a term of fifteen (15) calendar days, from the notification of the report, to the inspected establishment, so that it submits a Correction Plan for each of the specified deficiencies. In case of extraordinary situations or those constituting danger, the correction may be immediately required.

Section 4. The information contained in documents related to the inspection, including the deficiency correction plan, may not be examined or photocopied by third parties, except when:

- (a) The person, institution or establishment agrees in writing to grant the information and relieves the Department from responsibility;
- (b) The information is requested by an agency or division of the Government of Puerto Rico or the Federal Government for research purposes and while the agency is responsible for the confidentiality of the information.
- (c) The State initiates a procedure for sanctions or revocation of certification due to breach of the laws and regulations.
- (d) There is an order from a Court of Justice in place.

**Article 7. Conducts Constituting Infractions of the Regulations**

The following shall be considered conducts constituting an infraction to these Regulations:

- Section 1. Acquire, sell or deliver natural products and/or nutritional supplements, pursuant to these Regulations, in an establishment not having the pertinent certification.
- Section 2. Sell or deliver natural products and/or nutritional supplements, pursuant to these Regulations, which are not registered in the Department of Health.
- Section 3. Establish, direct, manage or operate an establishment engaged in the manufacture, distribution and sale of natural products and nutritional supplements, pursuant to these Regulations, without holding the current certification required by these Regulations.

**Article 8. Obstruction of the Inspector's Functions**

- Section 1. Any person obstructing or preventing, exercising force or intimidation, the performance of functions and activities of the inspectors of the Department of Health, of the Auxiliary Secretariat for Regulation and Accreditation of Health Facilities, in establishments subject to the provisions of these Regulations, shall incur in a conduct constituting infringements to the Regulations.

**Article 9. Administrative Fines and Penalties**

- Section 1. Any natural person or legal entity infringing the provisions of these Regulations shall be required to pay a fine no higher than five thousand (USD 5,000) dollars per infraction.
- Section 2. The refusal of the offender to pay the administrative fine shall be ground for the Secretary of Health to adopt any other remedy to punish the infraction and to suspend any issued certification. In addition, the Secretary may refer the case to the pertinent Board of Examiners for the corresponding action, when applicable.

**Article 10. Closure Order**

- Section 1. The Secretary shall order the closure of the establishments subject to the provisions of these Regulations that had their certification suspended, canceled or revoked and those that operate without the required certification.

**Article 11. Investigative and Adjudicative Procedures**

- Section 1. Any investigative or adjudicative procedure initiated by the Secretary of Health arising from the provisions of these Regulations, as well as the imposition and amount of administrative fines imposed due to their infractions, and the judicial review of the final decisions of the Secretary, shall be governed pursuant to *Act No. 38 of June 30, 2017, better known as the "Uniform Administrative Procedures Act of the Government of Puerto Rico"* and by Regulations No. 85 of the Secretariat of Health to Regulate Adjudicative Procedures in the Department of Health and its Dependencies.
- Section 2. The fine imposed by the Department of Health shall be paid by certified check in the name of the Secretary of the Treasury of Puerto Rico, within fifteen (15) days following the date on which the determination of the agency is notified.

**CHAPTER X  
GENERAL PROVISIONS**

**Article 1. Adoption of Federal Regulation Clause**

Section 1. The federal regulation contained in 21 CFR 111, related to nutritional supplements, shall be adopted by reference.

**Article 2. Interpretation and Severability**

Section 1. The words and phrases used in these Regulations shall be interpreted according to the context and the meaning endorsed in the common and current use. The voices used in these Regulations in the present time also include the future; those used in the masculine gender include the feminine and neutral gender, except in cases where such interpretation is absurd; the singular number includes the plural and the plural includes the singular, provided that the interpretation does not infringes the purpose of the provision.

Section 2. If one or more of the articles contained in these Regulations is amended, or in the event that a word, paragraph, article, section, chapter or part of the Regulations is ordered to be unconstitutional by the Supreme Court of Puerto Rico, or by another court with jurisdiction and competence, the remaining provisions of these Regulations shall remain in force.

**Article 3. Saving Clause**

Any matter not covered by these Regulations shall be resolved by the Secretary of Health in accordance with the laws, regulations, applicable orders, and to the extent that it is not contemplated therein, they shall be governed by the rules of sound public administration.

**Article 4. Validity**

These regulations shall become effective thirty (30) days after their submission before the Department of State of Puerto Rico.

Approved in San Juan, Puerto Rico, today, *May 14*, 2018.

[signature]

**Signed by Dr. Rafael Rodriguez Mercado  
SECRETARY OF HEALTH**