

**Law No 774**

The president of Nicaragua Republic make non to his people that

**Law No 774** , Approved on October 5, 2011

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**THE NATIONAL ASSEMBLE**

Order the following

**LAW OF NATURAL MEDICNE COMPLEMENTARY THERAPHY AND NATURAL PRODUCTS**

**CHAPTER I**

**GENERAL DISPOSITION**

**Article 1 Object of the law**

The present law has as objective institutionalize, promotes, protect, and regulate the collective, individual or personal exercise **in the whole country. The traditional medicine and complementary therapy including the production distribution and commercialization of the natural products from the natural medicine**

**Article. 2 Objectives**

***The objectives also of this law:***

a) Integrate the natural medicine, complementary therapy and natural products in the national health system ensuring the establishment of national policies and programs that apply and guaranty this purpose.

b) Foment security, efficacy and the quality of the natural medicine Practice of the complementary therapy and natural products at a national level as a viable alternative and effective health benefit for the town.

c) Foment and promote the access of the people to natural medicine, complementary therapy and the use of natural product in the whole country.

c) Promote the rational and sustainable use of natural resources use in the practices of natural medicine, Complementary therapy and Natural products in our country..

e) Support the formulation of policies that foment investigation that stimulate the production distribution and Trade of the Nicaraguan natural products

f) Regulate the .preparation distribution and sale/Tradeof the natural products derivate from plants animal and mineral using in the exercise of natural medicine and complementary therapy

g) Foment and promote the preparation of technical professional and specialist of the natural medicine complementary therapy and natural product.

g) Foment the scientific development in the different areas of the natural medicine Complementary therapy and natural product of the country.

To spread the benefits and benefits of natural medicine, complementary therapies and

natural products especially in the promotion and preservation of health, as a complementary and strategic contribution to the National Health System.

### **Art. 3 Principles that support the insertion of Natural Medicine, Complementary Therapies and Natural Products into the National Health System**

The insertion of natural medicine, complementary therapies and the use of natural products in the National Health System, is based on the following principles:

**a) Alternability:** consist in transform one therapeutic approach to another according to treatment that is needed and the interest of the person in what is considered more convenient for his or her recovery.

**b) Articulation:** Referring to the harmonious and coherent link or union of the different medical practices existing in the country (conventional, traditional / ancestral and natural / complementary therapies) in order to contribute more effectively to the achievement of preventive health, Rehabilitation, healing and healing of the population.

**c) Complementarity:** It refers to the interrelation and mutual help of the different practices in the health system. From this notion focuses on the recognition of the contributions of natural medicine, complementary therapies and natural products as aneed and convenient resources to support and treat efforts to the conventional health model

**d) Optional:** Referring to the right of the town to decide on the type of medicine or therapy under which they prefer to be treated, with natural medicine, complementary therapies, traditional / ancestral or conventional medicine or a combination of them

### **Art.4 Conception of Natural Medicine and Complementary Therapy**

For the purpose of this law, it is understood as Natural Medicine, one of the oldest way of healing of humanity, whose theory, practices and skills are based on essential elements of nature and the universe, its laws and principles as a therapeutic resource, Which are applied through the different techniques and procedures that are performed in complementary and alternative therapies under academic knowledge or from experience. It considers the human being a important unit of the universe.

Natural Medicine and Complementary Therapies correspond to a clinical-therapeutic model and health-strengthening that is based on a world view or Cosmo vision different from the conventional medical model, which are used to prevent, rehabilitate, diagnose or treat Physical, mental and energy diseases. to Restore and preserve health. Its application and effectiveness is integrative with conventional medicine.

### **Art. 5 Right to the Access of Natural Medicine and Complementary Therapies**

The town in accordance with the legal framework of the country, has the same right to access and use of natural medicine, complementary therapies and natural products, so as the institutions, establishments, services and programs of conventional medicine within the National Health System.

### **Art. 6 Integration of Natural Medicine with Conventional Medicine**

The State will foment and promote a broad and harmonious vision of the health care of the town that integrates and articulates natural medicine, complementary therapies and natural products within the National Health System.

**Art. 7 Responsibility to spread health models**

The Health Ministry will inform users about the different health models that include natural medicine and complementary therapies and their right to decide the type of therapy with which they want to be treated or with.

**Art 8 Promotion for the application of the practices**

The Ministry of Health will promote the combined application of conventional medicine, traditional / ancestral medicine and natural medicine, in the care of patients to do a more efficient and effective work in the health care of the town. .

**Art. 9 Incentive of research and practice of Natural Medicine**

The health Ministry will encourage incentives that promote the research and practice of natural medicine, complementary therapies and the use of natural products.

**Art 10 Respect to the Cosmo vision of Natural Medicine.**

The health Ministry will promote respect for worldview, procedures and management of natural medicine and complementary therapies, promoting the development of a coordinated and harmonious practice among workers in this sector and other health workers

**Art. 11 Integration of agencies to the National Health Council**

Representatives of organizations, organizations, foundations and non-profit organizations and other denominations dedicated or linked to the practice of natural medicine, complementary therapies and natural products, may be part of the instances of citizen participation in health and integrate into all levels of management, from the community or neighborhood to the national level.

## CHAPTER II CONCEPTS AND DEFINITIONS

**Art. 12 Concept and definitions.**

As the first law on Natural Medicine, Complementary Therapies and Natural Products, and to facilitate their understanding in the application of the law it include the following concepts and definitions:

**GENERAL TERMS**

**Essential oils:** Essences extracted from leaves, flowers, bark of trees, seeds, roots or specific fruit peel, which are applied to treat ailments in the body.

**Center of Natural / Integrative Medicine:** It is the establishment that complies with large conditions of space equipment, quality and sanitary-hygiene, in which medical care is provided, complementary therapies are applied, natural products and other establishments are prescribed and sale is attended by a large group and diverse professionals and / or therapists of natural medicine or complementary therapies

**Clinic of Natural Medicine / Integrative:** It is the establishment that meets minimum conditions of space, quality and sanitary hygiene, in which medical care is provided, complementary therapies are applied, natural products and other establishments are prescribed and sold. It is managed and attended by a small group of professionals and / or therapists of natural medicine or complementary therapies.

**Cosmo vision of Natural Medicine:** The universe, the Earth, the kingdoms of nature and the human being must maintain a harmonious relationship that allows the balance and

the awareness that we are one in the whole, being that everything is of energy. Conceive the human being in a holistic way. When there is an energy imbalance the disease is manifested and for its healing all aspects must be harmonized and the energies must be balanced.

**Establishments Producers of Natural Products:** It is the establishment that is dedicated to the elaboration of natural products in different levels of processes.

It is all establishment that is dedicated to the dispensation and its direct minister to the public of natural products, natural beauty products, personal hygiene products, food formulations, herbal products, homeopathic products

**Ethno botany:** Study the relationships between human groups and their plant environment, the use of plants in different cultural spaces and in time.

**Natural Pharmacopoeia:** Compendium summary that contains descriptions, recipes, activity, standards of purity and dosage of medicinal plants, animals or minerals, of which its active principles are used, with all its accompanying substances. These are therapeutic preparations with natural substances that have been used all over the world for the Cure of various disorders

**Phytotherapy:** It is the study and use of plants for the treatment and prevention of diseases in humans. It includes the identification, extraction methods and applications of the active principles of Different vegetables

**Herbalist:** It studies the properties and curative powers of the great diversity of plants and herbs that Mother Nature provides us. It has its beginnings in the very origin of man and in his need to cure his pains, illnesses and diseases.

**Indology:** Diagnostic auxiliary method by means of which the doctor or therapist determines the state of health of the person, through the observation and analysis of the marks or signs in the iris of the eye that reflect the conditions of the different affected bodily organs.

**Natural medicine raw material:** All active or inactive substances from the vegetable, animal and mineral, which are used in natural medicine for the production of therapeutic and / or beauty products.

**Ayurveda Medicine:** (Ayur means life and Veda knowledge), “The science of life”, Hindu Medicine. It is an auxiliary science of Vedic culture aimed at developing the potential of our life and discovering our inner reality. Health is the basis for achieving this goal. Its components are: detoxification, massage, breathing techniques, meditation, asana (postures), vegetarian nutrition, fasts, medicinal plants, herb mineral, rejuvenation therapy, and philosophy of yoga.

**Medicine Naturo-Ortopática General:** Is one that deals with the correct application of medicine or natural remedy to the different sickness of human beings, it attends the causes rather than the symptoms of the ailments, appropriating knowledge and elements from conventional medicine to Natural Medicine, Which prevails with its principles and advantages, of natural and holistic harmony, understanding this medicine as a socio - biological science.

**Holistic Medicine:** It is the branch of medicine that contemplates the global well-being of the human being from the physical, mental and emotional point of view, looking for the

underlying causes that produce imbalances in the different body systems, it also seeks the improvement of the immune system by Means of preventive treatment.

**Integrative Medicine:** An approach to medicine that combines treatments of conventional medicine and complementary medicine and alternative; There is high quality scientific evidence that guarantees its safety and efficacy.

**Naturo-Orthopatico General doctor:** Is a Natural Medicine professional that attends different sickness, incorporating elements, scientific and technological advances of conventional medicine, having as focus that the body self-healing is a response of the diseased body, being an interpreter, server and holistic facilitator for the purpose To promote prevention, cure and improve the lifestyles of human beings.

**Germanic new medicine:** Scientific approach to medicine that conceived the human being as a conjunction indivisible between psyche, brain, and the organic base, in connection with all living beings and the environment, in its socio-economic and cultural aspects. It considers the identification of biological conflict that lies at the root of all disease, and scientifically guide the therapeutic process that facilitates patient self-awareness, and their responsibility for own healing potential. It is based on the five biological laws of Ryke Geerd Hamer.

**Nutraceuticals:** Refers to the use of nutrients for therapeutic purposes. Those products are natural (food, therapeutic and beauty), with beneficial effect on human health.

**Natural Medicine therapists:** Are those people with the knowledge, skills, experience, some of whom have technical training, being duly recognized for its effectiveness the use and application of complementary and alternative therapies.

**Medicinal plants:** those whose quality and quantity of active ingredients have therapeutic properties scientifically proven for the benefit of human health. Also considered medicinal plant to all plant species that has manifested in its traditional use favorable to the restoration of health properties taking into account their degree of toxicity and dose.

**Prana:** It is the Sanskrit expression to refer to the vital energy, strength, or breath of life. Called in Hebrew 'ruah', in Chinese "chi" in Japanese "ki" in Polynesian "mana", in Greek "pneuma". Is it interpenetrated in air, water, the Earth and all living beings. This subtle energy flows through the fields, centres and energetic channels, also called auras and chakras

**Producers of natural supplements:** are professionals, therapists established, technical and people with experience, dedicated to the development of nutraceuticals, products or natural supplements, therapeutic or beauty in humans, through simple low or medium transformation processes, which sometimes include the cultivation of medicinal plants used.

**Products or natural supplements:** are those of origin and natural origin that are used for food, healing purposes, rehabilitation, care, beauty and personal hygiene. Some of which are also known as nutraceuticals.

**Natural beauty products:** They are natural products directly from plants, minerals and animals, in order to care, beauty and personal hygiene.

**Positions of sale of natural products:** are those who are engaged in the marketing of natural products. They are authorized by the Ministry of health in the same way that the

posts of sales of drugs as the law No. 292, "Law of medicine and pharmacy".

#### TERMS OF COMPLEMENTARY THERAPIES:

**Acupuncture:** non-drug therapeutic clinical model based on stimulation of various points of the human body in channels called meridians, through the insertion and manipulation of metal needles, and other related methods. At the same time works as a diagnostic and therapeutic, method based on stimulation of the points of the energy body, using different technologies whether traditional or modern. It involves a comprehensive worldview of the human being, coming from traditional medicine Chinese or oriental medicine.

**Aromatherapy:** It is a therapy which uses scents of essential oils as a therapeutic resource, known for its excellent properties, relaxing, healing and antiseptic, taking a physical, emotional, mental and spiritual balance in the levels effect. The methods of application are diverse, including massage using essential oils that penetrate into the body, or by inhaling through the olfactory system.

**Ayunoterapia:** Therapeutics which consists of abstinence from eating some foods for short periods and prescription in order to purify and remove toxins from the body.

**Public: Also known as Geotherapy** is the use of the silty clay with certain chemical properties for therapeutic use, joint to treat pain, inflammation, and elimination of toxic substances in the body, also has application in the aesthetic field.

**Bioenergetics:** It is the study of the energy changes that accompany the biochemical reactions, study of existing energy law and its application to living organisms, especially to the body. This therapy was created by Alexander Lowen and puts the accent in body structure and the identification of the mind and the body, which means that thinking and feeling are equivalent. Behind these conscious processes are energy factors which finally determine all the other vital functions. In addition to interventions with hands bioenergetics puts his accent in the physical exercises and breathing.

**Family constellations:** Transgenerational systemic family therapy. It is a therapeutic method that is based on the general theory of systems, help to establish a diagnosis and to arrive at a solution of the problem, sometimes in a single session. Its focus is part of that beyond our individuality and no matter where we are, always are part of several systems, the family being the most important. Works from the issues that were not resolved in the families. These manifest themselves in future generations and are living in conflict and traumatically if they are not addressed and resolved. The singular history of each family, their conflicts and unresolved problems mark the life of its members and are transmitted from generation to generation. Within each family and social system, the conduct of each of its members influences the others and, at the same time receives its influence, either favorable or unfavorable.

**Chromatherapy:** Is a medicinal form originating in the India and China, regarding the use of the colors of the Rainbow in the so-called energy centers, these being the following: violet, indigo, blue, green, yellow, Orange, and red, their therapy is It is mainly used to reset the body energy.

**Energy healing:** It is the balance of the vital energy also known as Chi, Qi or Prana taking into account the various centers and channel energy that holds our body to obtain health. Within this field can incorporate all energetic and vibrational type used in natural medicine and practices which have correlation with the principles of body - soul - power and that its

foundation comes from the Asian medicine) Traditional Chinese and Japanese), Arabic, German, English, Hindu among others.

**Acupressure:** Chinese massage called Tui - Na, and literally translates as press and push. Use the snakelike (buds) of thumbs with the other fingers. Applies its maneuvers in the body making pressure on the meridians which govern the flow of energy in the internal organs. Relieves different pathologies. Also referred to as acupressure and acupressure (dian xue) and the Japan as Shia Tzu.

**Lymphatic Drainage:** It is a therapeutic method consisting of a series of very gentle and rhythmic manual maneuvers to decongest the stagnant lymph in an area of the body. This massage is to evacuate excess of toxic lodged in the lymphatic system. For the softness and care that it requires discipline and patience.

The lymph is a liquid that forms the little known lymphatic system which performs 3 functions: It is the system of body purification, possesses the immune and defensive activity of the body and is one of the responsible for the corporal beauty

**Electro acupuncture:** A technique of stimulation consisting of the passage of electrical current in distal points of acupuncture, with which it can balance the presence of disorders or unhealthy processes in a patient using electronic equipment.

**Gemoterapia:** Is the use of transparent or colored gems or minerals that contain energy and that reinforce the healing of the body and the mind, in a safe and economic therapy.

**Heliotherapy:** Treatment that makes use of the natural elements to provide / a particular solar energy for strengthening of the dermal and musculoskeletal system

**Hydrotherapy:** It refers to the various therapeutic uses and applications of water for health, including that related to the S.P. A (Health by Water), hot springs, spring waters.

**Hypnosis:** Is a type of treatment that uses hypnotism to influence the mental part of the patient to accelerate their recovery. These techniques are very effective when stress, depression and some types of fare that affect the health of the person..

**Homeopathy:** Is a medical, clinical-tactical system in the treatment of a multitude of sickness, based on the law of similarity, the smallest dose, the individualization and the cure of Hring; Which states that the disease can be treated by very small amounts of plant and animal substances and minerals that in greater quantities produce a healthy person the same symptomatic effects of the disease. The role of emotions in diseases is emphasized by assigning it a determining weight in diagnostic and therapeutic procedures.

**Hemotoxicology:** Is the study of the harmful influence of toxic substances on humans. It is part of Biological Medicine dealing with the detoxification of the human organism mainly through homeopathic treatments of complex or anti hemotoxic origin, it is a bridge between complementary medicine and conventional medicine

**Massages:** This is a set of frictions and pressures, practiced mainly by hand or with the aid of instruments, on a part or whole of the body or organism, in order to produce changes of direct order or reflex, which are Translate into therapeutic effects. Being some of them: Therapeutic Massage, Deep Massage, Reductive Massage, Relaxing Massage, Swedish massage, Thai Massage, Tantric Massage, among others.

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**Moxibustion:** Therapeutic method using "MOXAS" (preparations that are made from the medicinal plant called Artemisia or others as required), which is applied by fire. Is of Chinese origin that apply local heat in specific points of the body for the sickness. It is usually practiced with acupuncture or alone.

**Ozone therapy:** It is a method that involves the use of ozone (O<sub>3</sub>) or hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) in order to eliminate sickness-causing microorganisms, thereby improving cellular function and promoting healing of wounded tissues.

**Phrenic Psychotherapy:** It is panics healing applied to prevention, healing and treatment of mental illnesses. Its objective is to complement conventional medicine and heal the suffering of people with psychological disorders, using energy principles and techniques.

**Chiropractic:** The term “hand-made” means the therapeutic clinical model that deals with the diagnosis, treatment and prevention of disorders of the spine, and its effects on the nervous system and health in general, using manipulations and other strategies that look to restore functional normality.

**Reiki:** Therapeutic form of Japanese origin that allows the canalization of the energy of the universe by means of the hands (it uses the imposition of hands without touching the physical body and techniques of visualization) with the objective to improve (luxury of vital energy in persona. This technique is related to the energetic, mental and corporal bodies. It is widely used in the current in hospital centers of Spain and the United States.

**Reflexology:** It is a natural diagnostic-therapeutic method that stimulates the body to perform its own healing process. This is done by pressure and stimulation of the predefined reflex zones in the feet, hands, ears, face or other part where the body reflects.

**Sauna:** Steam baths with the use of essential oils that come from some medicinal plants to aid in the elimination and purging of existing toxins in the body.

**Pranic Healing:** It is a modern science and ancient art of healing that is based on the transference of vital energy or prana to heal and balance the human being and other living beings in their physical, emotional, mental and spiritual aspects increasing the body's capacity of Auto regenerate by the harmonization and the balance of the energy body. It has other applications such as agriculture, veterinary, aesthetics and body sculpting, among others

**Thalassotherapy:** Therapeutics that deals with the use and benefits of sea water. In Nicaragua it is known as Marine Hydrology or Marine Therapy. In Europe with the name Plasma of Quinton, in Canada like Ocean Plasma. It comes in different dosage forms and is applied intravenously, subcutaneously, intramuscularly, rectally and vocally.

Sea water is tolerated by different living organisms without problems. The dose, frequency, route of absorption and duration determine the efficacy of the treatment.

**Floral Therapy:** A therapeutic method that aims to help people discover the real emotional causes that originate their suffering, seeking their prevention, relief and healing through the use of flower essences. The mechanism of action is related to the liberation of emotional conflicts and, on the other hand, to the places where these effects manifest themselves as a disease.

**Neural Therapy:** A treatment technique that, through repolarization of interfering or interfering fields, reprograms the physiological suitability of organs governed by neural fields. The repolarizer is therefore a regular local anesthetic, and the most active points are intra dermal, acupuncture points, nerve ganglia and terrain referring to the neural segment corresponding to the vertebrae of the sector.

**CHAPTER III**  
**AUTHORITY AND SCOPE OF APPLICATION**

**Art. 13 Scope and application of the law**

The provisions of this Law shall apply to all activities related to the development and practice of natural medicine, complementary therapies and the use of natural products

**Art. 14 Governing bodies.**

The Ministry of Health, as the governing institution for health and the National Health System, shall be the competent authority in the application of this Law and its Regulations.

**Art. 15 Powers of HEALTH MINISTRY**

The Health ministry, through the General Directions of Health Regulation will be responsible for coordinating the development of medical practice and ensuring the quality of the elaboration and dispensation of natural products or supplements of Natural Medicine, Complementary Therapies and Natural Products, object of this Law, in the different levels of functioning of the National Health System and other State institutions, universities, companies and private institutions. It will also be responsible for elaborating the Natural Pharmacopoeia or Vademecum and for extending the appropriate Sanitary Register and Sanitary License, as determined in this Law.

**Art. 16 Organizational Instances**

The Health, Ministry of to fulfill the functions indicated by this Law, will organize the necessary instances within the Directorate General! Of Regulation for the Health, counting on personnel properly qualified in the matter that has the sufficient knowledge and experience.

**Art. 17 about the development and thing that has to be done**

The instance mentioned in the previous article will be responsible for ensuring the development and competitive protection of Natural Medicine, Complementary Therapies and Natural Products of the country with respect to imported products and operating benefits of other countries in the area; This instance will attend to the procedures for regulating, classifying and authorizing the establishments that produce and commercialize these activities.

**Art. 18 Classifications of Natural Products**

The Health Ministry, through the body created for this purpose, will classify as Natural Supplements the natural products that are obtained using plants, animals or minerals, or a combination of them whose use is therapeutic or beauty. For classification, production and presentation will use Pharmacopoeia or Natural Vademecum.

**Art. 19 Natural Medicine IN EACH SILAIS**

The Health Ministry in each SILAIS of the country will organize the process of regulation / inspection of Natural Medicine, Complementary Therapies and Natural Products with properly trained people in the matter, which will coordinate the practice of this medical practice in each territory.

**Art. 20 Incorporation of Natural Medicine into the National Health System**

The Health Ministry will promote the incorporation of natural medicine and complementary therapies, within the National Health System, creating the basic conditions in the various existing health establishments.

**Art. 21 Acknowledgments and stimuli to the practice of Natural Medicine**

The Health Ministry in coordination with associations, foundations and societies, which regulate natural medicine and complementary therapies, will establish recognitions and incentives for this medical practice.

**Art. 22 Analysis of the quality of care**

The analysis of the quality of natural medicine, complementary therapies and natural products will be established by the health Ministry, through medical audits, for which representatives of existing associations, foundations or confederations must participate. Educational institutions related to the topic of natural medicine, complementary therapies and natural products

**Art 23 Consultation body**

In all matters related to Natural Medicine, Complementary Therapies and Natural Products, the Health Ministry will consult with associations, foundations or existing confederations and educational institutions related to the topic of natural medicine, complementary therapies and natural products.

**CHAPTER IV  
MEDICINAL PLANTS AND OTHER NATURAL INPUT**

**Art. 24 Preservation of National Flora and Fauna**

Assuming that the flora and fauna in general are patrimony of humanity, through this Law, it is established that the production, use and sustainable use of the same, will be done by ensuring its preservation, in harmony with the social balance, Environmental, health and economic situation of the country. The biodiversity of the native flora and fauna of Nicaragua, especially those of therapeutic and / or beauty use, will enjoy the proper state protection.

**Art. 25 Programs of order and rational use**

The Ministry of Health, by itself or in conjunction with other state and educational institutions in the country, will promote the formulation and execution of programs, plans and policies for the rational use, respect and conservation of plants and animals for therapeutic use, for which you may:

- a) To make out evaluations that determine the existing biomass and register the varieties of plants with medicinal properties.
- b) Promote and encourage programs for the replant of species of flora of medicinal use.
- c) Promote the creation of productive units of medicinal plants, as well as botanical gardens, nurseries and seed beds with the active participation of the inhabitants and the support of public and private sector institutions
- d) Establish a preventive protection regime and promote a program of replant of those plants and animals of therapeutic use that are in the process of extinction to ensure their conservation and sustainable use.
- e) To encourage the practices and techniques of cultivation, collection, storage, processing, distribution and manipulation of plants and other products used in the practice of natural medicine and complementary therapies.

Art. 26 Pharmacopoeia or Natural Vademecum

The Health Ministry will promote the participation of other ministries, institutions, guilds and organizations related to the matter to elaborate, approve and put into effect the Pharmacopoeia or Natural Vademecum of plants, animals and minerals for therapeutic use and / or Beauty, both domestic and foreign.

#### **Art. 27 Use of toxic plants**

The Health Ministry in its training programs or in collaboration with universities and training centers, will establish the forecasts to be taken in the use of toxic plants, as well as the use and application of good practices of manufactures of natural products

#### **Art. 28 Promotion, dissemination of uses and consumption of medicinal plants**

The Health Ministry and existing associations, foundations or confederations and educational institutions related to the topic of natural medicine, complementary therapies and natural products, the promotion and dissemination of therapeutic, nutritional, toxicological and clinical uses, and And of the forms of consumption of medicinal plants duly validated.

The advertising of Natural Medicine, complementary therapies and natural products must be educational, guiding, exact and true.

### **CHAPTER V OF THE EXERCISE OF NATURAL MEDICINE, THERAPIES**

#### **Art. 29 Regulation of the professional practice of Natural Medicine**

The present Law generally regulates the exercise of natural medicine, complementary therapies and the elaborators of natural products.

In the case of people working for the public sector, they will be regulated by Law No. 760, "Health Care Law".

#### **Art. 30 Exercise of Natural Medicine**

They can be dedicated to the practice of natural medicine, complementary therapies and natural products, those people who have received the corresponding training through authorized national or foreign universities, institutes or training centers (professionals, specialists, therapists and technicians), having their Registered title in the Ministry of Health and those people with experience who have been transmitted to them in a traditional way and who are recognized by the population for its effectiveness.

#### **Art. 31 Granting of the Professional Sanitary Register**

For the exercise of natural medicine, complementary therapies and natural product elaborators, the Ministry of Health, upon request, will grant the appropriate Sanitary Register to those persons with professional and technical training, who must have diplomas and degrees that accredit them. In the case of people who do not hold diplomas or degrees, they will validate their trajectory, experience, practice and recognition of the community

#### **Art. 32 Enabling establishments of Natural Medicine**

The Ministry of Health, through the General Direction of Health Regulation, will enable the clinics and centers that attend and apply the natural medicine, complementary therapies and natural products, granting them the corresponding Sanitary License, which will have a validity of four years renewable, when they meet the criteria of safety, efficacy, social acceptability, space and sanitary hygiene.

#### **Art. 33 Professional ethical code for the exercise of Natural Medicine**

For the professional practice of the doctors of Natural Medicine and Complementary Therapies, the Ministry of Health will approve the own Code of Ethics and special for this medical sector.

**Art. 34 Equal benefits for medical graduates of Natural Medicine**

Graduated doctors and in the exercise of their profession of Natural Medicine and Complementary Therapies in the National Health System, will enjoy all the benefits, prerogatives and rights that have the health professionals of the same level in this System.

**Art. 35 Equal benefits for therapists, technicians and other personnel of Natural Medicine**

In the case of therapists, technicians and other personnel of the Natural Medicine and the Complementary Therapies in the National Health System, they will be equated in all the benefits, prerogatives and rights that the other health workers have in this System

**Art. 36 Clinical file**

Physicians and therapists, in the exercise of Natural Medicine and Complementary Therapies, must duly keep a record of the care of each of their patients, according to the norm dictated by the Health.

Ministry

**Art. 37 State support for the workers of Natural Medicine**

The State will provide the necessary support, whether technical or economic, to persons who exercise natural medicine, complementary therapies and natural products, either personally or in the companies they organize, in their investment and development plans

**Art. 38 Intellectual Property**

The knowledge, inventions and findings produced by natural health practitioners, complementary therapies and natural products may be patented and, therefore, due to the protection of their intellectual property rights, in compliance with the provisions of the laws of the country and their agreements with international organizations

**Art. 39 Function of Regency by technicians or professionals qualified in this field**

The clinics and centers that attend and apply the natural medicine, complementary therapies and natural products will be supervised by qualified technicians or professionals in this field, in the case that there are establishments where there is no professional fallow up, this personnel will be trained and for this purpose, which will perform a function similar to that of Dispenser and Regent.

**Art. 40 Permanent update of the Pharmacopoeia or natural Vademecum**

The Health ,Ministry through the General director of Health Regulation, for the elaboration of the Pharmacopoeia or Natural Vademecum in its different editions will take into account and incorporate the corresponding of the different complementary therapies of natural medicine, recognized and Proven trajectory, both existing when this law comes into force, as those that arise in the future.

**Art. 41 Recognition and validation of Complementary Therapies**

The different complementary therapies of natural medicine that are applied in the different centers and clinics that function at the entry into use of this Law, or which arise in the future and that are recognized, taking into consideration their precedence and provenTrajectory, will continue to function and operate, in accordance with the laws of the Republic, according to their nature and purposes for which they were created

**CHAPTER VI  
PRODUCT PRODUCTION AND MARKETING  
OF NATURAL MEDICINE**

**Art. 42 Quality of preparation, processing, distribution and marketing of natural products**

The Ministry of Health, through the General Directorate of Health Regulation, will be responsible for ensuring the quality of preparation, processing, distribution and dispensing of natural products for therapeutic and / or beauty use.

**Art. 43 Compliance with quality, safety, efficacy**

The Health Ministry, through the General Direction of Health Regulation, shall ensure that all establishments working with therapeutic and / or beauty products comply with the provisions, in terms of quality, safety, efficacy, good manufacturing and technical and sanitary conditions.

**Art. 44 Basic transformation of its productive matrix**

A period of three years, will be given from the entry into force of this Law, so that producers of natural products, with state support and external cooperation, improve their operation and / or carry out the basic transformation of their productive matrix, according to the good practices of natural manufacture and the technological advances.

**Art. 45 State incentive to the production of natural products**

It will encourage monetary, fiscal, credit and development policies that protect and allow the best development of the national production of natural products for therapeutic and / or beauty use, in order to equate it and make it competitive at the regional level

**Art. 47 Protection of national natural products**

The Development Ministry, Industry and Trade in cooperation with the Ministry of Health, will ensure that the importation of natural products of therapeutic use and / or beauty of foreign origin does not affect or threaten the national production.

**Art. 48 freeing of taxes and import duties**

The importation and sale of natural medicines, complementary therapy products and natural products, as well as the machinery, equipment, spare parts, supplies and raw materials necessary for the elaboration of these products, will not be subject to the payment of IVA VAT, DAI and the SC.

The Ministry of Finance and Public Credit, in coordination with the Health Ministry and the Development ministry, of Industry and Trade, will determine the classification of goods, for the purpose of applying the exemption of the previous paragraph, according to the nomenclature of the Central American Price list System.

**Art. 49 Export Promotion of small and medium producers**

The State will promote and establish the necessary mechanisms so that small and medium processors of natural products can export with flexibility and in similar conditions to the large establishments that have a trademark.

**Art. 50 Use of the natural vademecum in the customs classification**

The customs classification of all raw materials, inputs, equipment, accessories and instruments related to the production, marketing, export and import of natural medicine products, complementary therapies and natural products at the different border posts, ports and airports will be made Accordance with international instruments on the subject.

**Art. 51 Sanitary registration of national natural products**

The Regulations of this Law will establish an expedited procedure for the sanitary registration of natural products processed in the country, registration fees and the establishment of quality controls equivalent to those of the region.

**Art. 52 Qualification of commercial establishments**

The Naturopathic establishments where the different natural products for therapeutic and / or beauty use are marketed will be authorized by the General Direction of Regulation for Health of the Ministry of Health.

**Art. 53 Single window**

The State will facilitate the streamlining of the procedure for the regularization and classification of establishments producing and marketing natural products and complementary therapy services through the General Directorate of Health Regulation of the Ministry of Health, whose field of competence will be production , Dispensing, exporting, importing, advertising and marketing

This instance will act as a one-stop shop with simplification of procedures related to: Licenses, certificates, notices, registrations, licenses and others.

**Art. 54 Consultation Instance**

The Directorate-General for Health Regulation of the Ministry of Health shall act as an advisory body when required by the appropriate departments of the State, where there is a presumption or indication against producers and / or marketers of natural and / or beauty products , For the use of toxic or dangerous substances and plants.

**Art. 55 Instance to resolve complaints or administrative appeals**

The General Directorate for Health Regulation of the Ministry of Health will act as an instance to resolve complaints or administrative appeals related to non-compliance of procedures for producers and / or marketers of natural and beauty products, in accordance with the provisions of Article 53 The present Law.

**Art. 56 Validity of the sanitary license**

For the operation of establishments producing natural products, it will be necessary to have a Sanitary License granted by the General Direction of Regulation for Health, which will have a validity of four years and may be renewed for the same period, as long as it is requested with two months of anticipation to the expiration of the same

**Art. 57 Basic material and human resources to demonstrate productive capacity**

Producers of natural therapeutic and beauty products must demonstrate that they have the basic material and human resources and the capacity and experience to carry out this activity.

They should also have a gradual compliance plan for the implementation, development and application of best practices.

**Art. 58 Operation only with Sanitary License of stall**

In the case of professionals and therapists who are producers and who manage and direct their clinics and centers of natural or integral medicine, and the technicians and producers who elaborate, distribute and commercialize natural therapeutic and beauty products in small and medium scale, with Quality, safety, using hygienic sanitary measures and adequate storage conditions, may only operate with the Sanitary License of natural supplement sales stalls.



**Art. 59 Definition of small and medium-scale producers**

Small and medium-scale producers will be understood as people who, in their own premises, manufacture, distribute and market therapeutic and beauty products, including medicinal products in bulk and natural supplements.

**Art. 60 Recognition of producers and marketers of natural and beauty products**

Producers and commercials of natural and beauty products that operate at the entry into force of this Law, or that arise in the future and are recognized, taking into consideration their precedence and proven trajectory, will continue to function. In accordance with the laws of the Republic, according to their nature and purposes for which they were created

**CHAPTER VII  
ACADEMIC MANAGEMENT**

**Art. 61 Promotion of research and technical studies of natural medicine and complementary therapies**

The State, especially MINSAs, will promote technical studies or scientific research on natural medicine, complementary therapies and natural products, as well as the protection and use of intellectual property in accordance with current legislation. At the same time will stimulate the participation of universities and private and state bodies that comply with the regulations in use

**Art. 62 Participation of guilds and organizations in regional and national events**

The MINSAs will promote the participation of guilds, organizations, professionals, experts and health technicians related to the topic of natural medicine, complementary therapies and natural products and related topics, in the regional, national and international events that take place.

**Art. 63 MINSAs will promote forums on Natural Medicine**

The MINSAs should include in its activities forums, seminars or workshops on natural medicine complementary therapies and natural products in the departments and regions that allow greater participation and assistance of the specialists of the health personnel.

**Art. 64 University Educational Development in Natural Medicine**

The Health Ministry in coordination with the National Council of Universities will coordinate the promotion in the legally constituted universities, so that they develop besides undergraduate and graduate studies, post-graduate programs, master's and doctoral programs, as well as education programs Medical continuum in the field of natural medicine, complementary therapies and natural products.

**Art. 65 Incorporation of foreign titles of natural medicine and complementary therapies**

According to Law No. 89 "Law of Autonomy of Institutions of Higher Education", state universities will recognize academic degrees, degrees and diplomas in Natural Medicine, Complementary Therapies and similar aspects, obtained abroad, by professionals, Nicaraguan therapists and technicians. In cases where the subject of degrees and diplomas not included in the offer of careers of the state universities, these through their medical faculties, once received the application process, will try to establish the forms or ways necessary to respond to the requested recognition.

**Art. 66 Recognition of institutions and organizations of teaching and training**

Institutions and organizations that, upon the entry in to use of this Law, provide teaching, courses or degrees, postgraduate courses, seminars and degrees in natural medicine,

complementary therapies and natural products, according to their academic level, taking into consideration their precedence and Proven course, operating in accordance with the laws of the Republic, according to its statutes and according to their nature and purposes for which they were created.

**Art. 67 Professional card.**

The General Direction of Regulation for Health in addition to granting the Register or Sanitary Code, will issue the respective professional card, to the professionals, technicians and therapists of the Natural Medicine or Complementary Therapies that request it.

**Art. 68 Documentation Center for Natural Medicine**

The General Directorate of Health Regulation should organize a section of Natural Medicine, Complementary Therapies and Natural Products in the Documentation Center, which will serve as a theoretical reference to students, interested and professionals of the same.

**Art. 69 Technical-scientific cooperation for the development of Natural Medicine**

The MINSA, in coordination with other national and international institutions or organizations, will establish scientific and technological cooperation agreements for the strengthening of research and training in Natural Medicine, Complementary Therapies and Natural Products.

**CHAPTER VIII  
OF THE FAULTS AND SANCTIONS**

**Art. 70 Grounds of sanction**

Faults and breach of this law and its regulations constitute grounds for sanction.

**Art. 71 Suspension or cancellation of ratings, Records licenses**

It will be reason for suspension or cancellation of the registries or licenses, when the following faults are committed:

- a) When statements made to the health authorities to obtain license or fraud has been committed, or information has been omitted in a malicious way; background that if known by the competent authorities would have prevented the granting of the authorization, registration or license.
- b) When the owner of the registry has altered or modified the terms of the functions, for which it was authorized, registered or authorized.
- c) When any ingredient of a registered natural product is considered to be toxic to human health or the environment, based on new scientific or technological medical knowledge

**Art. 72 Punishment for Risks and Damages to the health of the people /Population**

Every professional, therapist, technician as well as producer of Natural Medicine and Complementary Therapies commits when their professional practice puts at risk or damages the health of the population and, Environment.

**Art. 73 Punishment/Sanction for falsify, adulteration of national natural products**

The Health Ministry will sanction administratively the falsification, adulteration, and impersonation, usurpation of national natural products and smuggling of foreign natural products. The foregoing without prejudice to what is established in the Penal Code.

**Art. 74 Mild failure due to non-compliance with the clinical file**

Physicians and therapists, in the exercise of Natural Medicine and Complementary Therapies, who do not properly carry the clinical file of each of their patients, will commit a slight lack.

**Art. 75 Mild or serious lack due to non-compliance with the Safety Criteria and minimum standards of space and hygiene**

Failure to comply with safety criteria and minimum standards of space and sanitary hygiene, both by professionals and therapists of Natural Medicine and Complementary Therapies in their clinics and care centers, as well as the producers of natural therapeutic products And beauty, including in this case, the non-application of good practices of natural manufacture in their establishments, will imply a slight or serious lack according to the typification of the case.

**Art. 76 Procedure and resources.**

The Regulations of this Law will establish the corresponding procedures, mechanisms and legal resources

**CHAPTER IX**

**FINAL AND TRANSITIONAL PROVISIONS**

**Art. 77 Budget assignment**

The Executive Branch and the Legislative Branch shall ensure the allocation of a sufficient budget to the Ministry of Health to ensure compliance with the provisions of this Law

**Art. 78 Complementary Rules**

Complementary rules for the application of this Law are considered, the provisions established in Chapter I. Common rules and ways of acquiring rights and Chapter II. Of the biodiversity and the national genetic heritage, both of Title III of Law No. 217, "General Law of the Environment and Natural Resources".

**Art. 79 Regulation**

This Present law will be regulated by the President of the Republic within a period of sixty days

**Art. 80 Duration**

This Law will come into effect as its publication in the official Gazette or in any media of social communication.

Given in the city of Managua, in the Hall of Sessions in the National Assembly of the Republic of Nicaragua, on the fifth day of October of the year two thousand and eleven. **Eng. Rene NunezTellez**, President of the National Assembly. Dr. Wilfredo Navarro Moreira, Secretary of the National Assembly.

Likewise. Take it as Law of the Republic. Publish and comply Managua, twenty-three of December of the year two thousand and eleven. Daniel Ortega Saavedra, President of the Republic of Nicaragua.

**Legal norms of Nicaragua**

**Matter: Health**

**Rank: Executive decrees**

**REGULATION OF THE LAW No 774 "NATURAL MEDICINE LAW, COMPLEMENTARY THERAPIES AND NATURAL PRODUCTS IN NICARAGUA ".**

**DECREE No 26-2014**, Approved the 29 of April of 2014

Published in the Newspaper No 86 of the 13 of May of 2014

**Government of Reconciliation and National Unit**

**United Nicaragua triumph**

El President of the Republic

Commander Daniel Ortega Saavedra

**CONSIDERING**

**I**

That the natural medicine and others therapies have being used and accepted like methods to cure and heal by some sectors of the population Nicaraguan, considering they beliefs, customs or worldview and In consequence must be considered like complementary in the National System of Health.

**II**

That is the State of Nicaragua interest to guarantee the security, efficiency and quality for practice natural medicine, complementary therapies and the natural product use at national level like alternative treatment in health benefit for the population.

**III**

That the National Assemble of Nicaragua, approved the Law No. 774 "Law of Natural Medicine, Complementary Therapies and Natural Products in Nicaragua ", published in The Gazette, Official journal No. 10 the 18 of January of 2012. That establish in his articulate 79 that will be regulated by the President of the Republic, in conformity with the article 150 of the Nicaragua Republic.

In use of Faculties that the Constitution Policy confers him

**HAVE DICTATE**

The following

**DECREE**

**REGULATION OF LAW No 774**

**"NATURAL MEDICINE LAW, COMPLEMENTARY THERAPIES AND NATURAL PRODUCTS  
IN NICARAGUA**

**CHAPTER I  
GENERAL DISPOSITIONS**

**Article 1. Object.** The present Regulation it intends to establish the procedures for the application of the Law 774 "Natural Medicine Law, Complementary Therapies and Natural Products in Nicaragua" published in The Gazette, Official journal No. 10, the 18 of January of 2012.

**Article 2. Application for the Regulation** To the Ministry of Health like governing institution of health, corresponds the application of this Regulation in the terms that the Law No 774, "Natural Medicine Law, Complementary Therapies and Natural Products in Nicaragua" determines.

**Article 3. Abbreviations** When in the present Regulation reference to the word "Law", it will have to be understood that the Law talks about the Law No 774, "Natural Medicine Law, Complementary Therapies and Natural Products in Nicaragua", and the word "Regulation", to the present Regulation.

Similarly when reference to the name "Main Directorate of Sanitary Regulation" it must be understood that talks about "Main Directorate for Regulation of Health", that is the text used in the Law.

**Article 4. Conception of natural medicine and complementary therapies and respect to worldview**

The Ministry of Health will guarantee the application, respect and will maintain the conception of the natural medicine and complementary therapies expressed in articles 4 and 10 of the Law, by means of the update clinical guides, protocols and norms, in agreement with new knowledge, discoveries, conceptions and updates scientifically validated

**Article 5. Right to access Natural Medicine and Complementary Therapy**

In conformity with articles 5 and 6 of the Law, the Ministry of Health will promote the access and use of the health services where provide allopathic medicine, natural-orthopathic, traditional ancestral, natural and complementary therapies, in conformity with the laws that regulate each one of these specialties.

**Article 6. Responsibility to reveal the natural medicine and others therapies**

Like integrate part of the National Policy of Health that impels the Ministry of Health, will be divulge among the Nicaraguan population the attention in allopathic medicine, natural-orthopathic, traditional ancestral medicine, natural and complementary therapies. The population has the right to choose the therapeutic method, like part of the respect to the humans' rights of beliefs, worldview, customs and practices.

**Article 7. Promotion for the application of practice**

The process of joint and adaptation of the models of attention and management of the conventional, traditional/ancestral medicine and natural medicine will be reign by model of attention in health that the Ministry of Health implements in the municipalities of the Pacific, Center and North of the country and by the intercultural models of health "of the autonomous Regions of the Atlantic of Nicaragua and other Regional health models that are implemented.

**Article 8. Promotion of the investigation and practice of the Medicine Natural**

In conformity with articles 9 and 21 of the Law, the Ministry of Health will promote the investigation and practice of the natural medicine, the complementary therapies and the use of natural products.

**Article 9. Integration of organisms to the National Council of Health**

The Ministry of Health must summon a delegate of organization, organisms, institutions of superior education, foundations and nonprofit unions and other denominations dedicated to the exercise of the natural medicine, complementary therapies and natural products in order to integrate the National Council of Health.

**Article 10. Concepts and definitions**

In a complementary form to the concepts and definitions given in the article 12 of the Law will be understood by:

**Therapeutic Activity:** The therapeutic activity talks about the prevention, the diagnosis and the satisfactory treatment of physical and mental diseases, alleviate of sickness symptoms and beneficial modification of the physical and mental state of the organism.

**Bio health:** It is another form to live based on the confidence and total care of our body, in our self, in bioenergy of the universe and the love of God.

**Good Practice of Manufacture:** Set of procedures and norms destined to guarantee the uniform production of the loads of natural medicinal products so that they fulfill the norms of quality.

**Registry Certificate:** Official document emitted by the competent authority that authorizes to commercialize a natural medical product.

**Committee of experts:** Group of people who by their suitability is recognized by regulatory authority to endorse documents supporting the use and safety of natural active substance or of a natural medicinal product.

**Office, clinic, or natural medicine center or complementary therapies Center:** This is the place that provide health services where offer natural medicine attention, complementary therapies, and prescribed or prescribe natural products, under the responsibility of a professional or therapist of natural medicine or complementary therapies, that can function with one or more professionals or therapists.

**Naturist facilities:** Are those authorized for manufacture, package, import, export, store, distribute and commercialize natural product in medicinal use. In the case of the manufacturing establishments that in addition they are drug dealers, each one of these activities worked in separated areas and will fulfill the requirements demanded in the present regulation, granting him to the Sanitary License of operation like manufacturing and spending establishment.

**Labeled:** Obligatory information including in the label, label, image or another descriptive or graphical matter that has been written, printed, marked in relief, that adheres or includes in the package of a medicinal natural product.

**Extract:** Product that is obtained from the natural resource of medicinal use by the action of a dissolvent according to the recognized methods of extraction.

**Naturist pharmacy:** Establishment properly authorized by the MINSA, through the Departmental Delegations of Pharmacy of the SILAIS of the country, that dedicates to the dispensation and direct provision to the natural product public, skillful or officials formulas of natural products, including which they contain controlled substances.

**Date of expiration or victory:** Date established for each lot placed in the primary and secondary packing until which the medicinal natural product is hoped that, stored suitably

fulfills the quality specifications.

**Phytoterapic:** Pharmaceutical preparation with vegetal material of which therapeutic activity by tradition has been demonstrated, preclinical or clinical experimentation.

**You formulate officinal's:** It is that medicinal natural product elaborated and guaranteed by, low naturist or pharmaceutical a professional its direction, given in its establishment, naturist pharmacy or pharmaceutical service, enumerated and described by the Form, destined to the direct delivery the patients to whom it supplies to this establishment or pharmacy.

**Skillful formulas:** It is all formula prescribed and prepared at the moment for each case, detailing its coaly-quantitative composition, its naturist form and its way to provide it ".

**Sanitary license of operation:** It is the document sent by the Ministry of Health through the Direction of Pharmacy or the Departmental Delegations of Pharmacy of the SILAIS of the country, to the establishments that fulfill good specifications, sanitary and hygienic for the manufacture, packaging, import, export, storage, distribution and commercialization of natural products of medicinal use.

**Vegetal material:** Complete medicinal plants or any organ or exudates of the same ones, pulverized or crushed used in the elaboration of phytoterapic.

**Allopathic medicine:** System by which the doctors and other professionals of attention of the health (for example, nurses, pharmacists and therapists) treat the symptoms and the diseases by means of medicines, radiation or surgery. Also it is called biomedicine, conventional medicine, current medicine, western medicine, and orthodox medicine.

**Modality of sale:** Variants, by means of which the natural products can be commercialized, being these following ones:

- a) Product of sale under medical prescription or product of sale with medical prescription.
- b) Product of free sale.

**Monograph of Finished product:** technical scientific description of the profile of security and effectiveness of a natural product.

**Scientific name:** Binary name of the species, formed by sort and specific epithet.

**Common name:** Denomination with which it is known a plant, animal or mineral in a certain region popularly.

**Sanitary record number:** It is the numerical code assigned by the instance corresponden- ce, to the product that has fulfilled the prescribed process of obtaining of sanitary registry.

**Positions of natural product Sale:** It is all establishments in where exclusively national natural products are sold or mattered, packaged or happened frequently, that by their rela- tion favorable benefit-risk do not expose the patient to greater risks and whose delivery or administration does not require of the facultative authorization or prescribes medical, being able to work without it runs. They are excluded of the classification of the Law and the present Regulation the traditional positions where they are sold you cracked, roots, leaves, seeds, among others, in the municipal markets of the country or of traveling form.

**Natural preparation:** She is the obtained one from the natural raw material by means of division process, extraction with dissolvent's, expression, distillation, purification, fermentation, concentration or any other physical or biological process.

**Active principle:** They are the ingredients of the natural products process that have therapeutic activity. In the case of the herbariums medicines whose active principles have been identified, its preparation is due to standardize, if it is had suitable analytical methods, so that they contain an amount guaranteed of them. In the cases that cannot be identified the active principles, it is possible to be considered that all the herbarium medicine is a single active principle.

**Medicinal natural product:** Processed, industrialized and labeled product with medicinal properties, that contain in their formulation obtained ingredients of the plants, animals, minerals or mixtures of these. It can contain excipient in addition to the natural material. The medicinal natural products, to which active substances of chemical or isolated synthesis of natural material like people in charge of the pharmacological activity are added to them, are not considered like medicinal natural products.

**Natural product of medicinal use:** Finished and labeled medicinal product, whose active ingredients are formed by any part of the natural resources of medicinal use or combinations of these; like crude drug, extract or in a recognized pharmaceutical form, that is used with therapeutic aims.

If the natural resource of medicinal use is combined with defined active substances from the chemical points of view; inclusively constituent of natural, isolated resources and chemically defined, natural product of medicinal use is not considered.

**Traditional medicinal natural product:** Are that whose use and natural active security of the substance are justified by ethno medicine information, technical and scientific documentations, indexed publications or documents guaranteed by a committee of experts. Oral or topical route or another route are used by that do not require sterility.

**Responsible professional:** naturists, nature orthopatic, pharmaceutical professional 0 Pharmaceutical Chemistry, responsible technician for the sanitary before the Regulating Authority, authorized registry by the holder of the product or his legal representative through a notarized and legalized power.

**Radiance:** it is a complementary therapy of remote power treatment that is used to diagnose, to come up, to rehabilitate, and/or to treat physical, mental, and emotional and power the diseases. It uses connected power special instruments to the radiestésica faculty of the human being; in addition it uses a method I specify of analysis, and the operator is authorized for it by means of the technical preparation and professional of the Italian Society I gave Radiance.

**Sanitary registry:** Procedure of approval by the Competent Authority of a country for the commercialization of a medicinal natural product, once he himself has passed the process of evaluation relative to the quality, effectiveness and security.

**Natural active substance:** Chemically defined substance or groups of substances, whose pharmacological action is known and been responsible for present therapeutic effects in the medicinal natural product. When the mentioned chemical substances are not known previously, active substance to the natural drug or the natural preparation is considered.



**To title of the product or holder of the registry:** Physical person or legal proprietor of the product.

**Crushed:** Selected parts of the natural product (leaves, flowers, roots, tubercles, etc.) that are dried, they break, they crumble, they section or they crush until obtaining the wished consistency, vegetal employees for the elaboration of capsules, tablets and products that require the water addition before their use

**Traditional use:** He is the sustained one with documentary evidences that they point out that the natural drug that is used in a product, has been used during three more decades with medicinal aims.

**Life utility:** period during which a product is hoped that, if is stored correctly, conserves the established specifications

### **CHAPTER III AUTHORITY AND ITS SCOPE OF APPLICATION**

**Article 11.** Scope of application of the dispositions of the regulation. The development and practice of the natural medicine, complementary therapies will be regulated by the guides of clinical practice or protocols that the Ministry of Health dictates.

The dispositions as far as natural products of the present regulation, are applied to the products industrially of medicinal use process that traditionally have been used in empirical form with therapeutic aims, that demonstrate to be extents of risks for the human health through the bibliographical sustentation, chemical analyses and toxicological tests, that they make, package, store, distribute and sell, in all the national territory.

**Article 12.** Competent authority. The competent authority to demand the observance of this regulation, is the Ministry of Health through the Main directorate of Sanitary Regulation, the Main directorate of Extension and Quality of the Attention and the SILAIS of the country.

In the case of the Independent Regions of the Caribbean Coast of Nicaragua, the Ministry of Health will incorporate the Natural Medicine, complementary therapies and natural products in the Agreements with the Governments and Regional Councils of pertinent and adapted form to the necessities, world view, tradition and indigenous culture of the towns and descending communities and afro.

**Article 13.** Organizational instance. In accordance with articles 15 and 16 of the Law, they are instances of application of the Law and the present Regulation, the following ones:

- 1) The Direction of Pharmacy, as far as the emission of Sanitary Licenses of such products to establishments that make or produce industrialist mind, distribute, commercialize products of natural origin; and the granting of the Sanitary Registry. The sanitary license of granted operation has a use of four years as of the date of emission;
- 2) The Direction of Regulation in Health, as far as the rating of the establishments' suppliers of services of health where one offers to attention using natural medicine and complementary therapies;
- 3) The Direction of Regulation of Professionals, Technology and Legislation in Health, as far as the granting of the Record number or Sanitary Code of the professionals and withdrawn Technicians of national or foreign centers of superior education with specific natural medicine formation and complementary therapies; and

4) The Direction of Food Regulation as far as the granting of the Sanitary product Registry or nutritional supplements of natural origin or the emission of Sanitary Licenses of establishments that make or produce and distribute or commercialize nutritional products or supplements.

**Article 14.** Facilitation of processes and proceedings. Each one of the instances indicated in the previous article, in the scope of their faculties facilitated the processes and proceedings for the opening and authorization of the establishments and the registry of natural products to the natural or legal people who dedicate themselves to the manufacture, production, import, export, distribution and complementary commercialization of natural products and of another nature that are used in the allopathic medicine, nature-orthopathic, natural and therapies.

**Article 15.** Natural product classification. The Direction of Pharmacy, once elaborated the natural Vademécum, classified obtained natural products of plants, animals or minerals, that have specific therapeutic indications, and that are object of sanitary registry. The elaborated natural products by means of the regime of formulas skillful or prepared officials, do not require sanitary registry.

**Article 16.** Regulating function of the natural Medicine, complementary therapies and establishments natural product drug dealers in the SILAIS. The Local Systems of Integral Attention in Health, SILAIS regulate and control the complementary practice of the natural medicine and therapies, as well as the establishments that commercialize natural products that article 19 of the Law establishes, through the Departmental Delegations of Pharmacy, created by virtue of the Law No medicine 292, "Law and Pharmacies", and the equipment of regulation in relation to the attention protocols and standards of rating.

**Article 17.** Incorporation of the Natural Medicine in the National System of Health. El Ministry of Health, from the entrance in use of the present Regulation, qualified to the establishments suppliers of services of health, that offer to natural medicine attention and complementary therapies, with the purpose of promoting and regulating the quality of the attention and the security of the people who make use of this type of services of health.

For such aim the specific standards for the services of natural medicine health and complementary therapies are assumed, defined in Manual of Rating of Establishments the Suppliers of Services of Health.

**Article 18.** Complementary audits of the quality of the attention of the Natural Medicine and Therapies. The audits of the quality of attention that are made of office or at the request of part, on attention offered in natural medicine or complementary therapies, will follow the procedure established in Chapter IV, Of the Audits of Quality of the Medical Attention, articles 149 to the 161, of the Decree No 001-2003, "Regulation of the General Law of Health", and the Norm of Audit of the Quality of the Medical Attention.

**Article 19.** Elaboration of guides of clinical practice or protocols. The Ministry of Health and its different instances permanently and according to article 23 leaned in the organisms, educative associations and institutions that they develop and they guard by the natural medicine, complementary therapies and natural products for the respective consultations on the elaboration of the protocols or guides of clinical practice of each specialty.

#### **NATURAL CHAPTER IV OF THE MECHANISMS OF PRESERVATION OF FLORA, FAUNA AND OTHER INSU- MOS. NATURAL VADEMECUM OF NICARAGUA.**

**Article 20.** Mechanisms to preserve the flora and national fauna. In accordance with article

24 of the Law, the Ministry of Health in coordination with the Ministries of the Atmosphere and Natural Resources and Farming and Forest, will actually establish the mechanisms for a rational operation of the used natural resources of the natural medicine, complementary therapies and natural products, based on the sustainable development, with fairness and social justice and taking into account the cultural from the country and respecting the rights recognized the independent regions of the Atlantic Coast and/or Caribbean diversity and Municipal Governments.

**Article 21.** Of the ordering and regional advantage.

FOR MARENA AND MAG FOR. The MINSA in coordination with the Natural Ministry of the Atmosphere and Resources and the Farming and Forest Ministry, and the municipalities of the country, elaborated the existing listing of plants, animals and medicinal minerals in their corresponding territories, will establish repoblación programs, prioritizing those species of plants and animals on the way to extinction, and will stimulate the practices and techniques of culture and procreation of such species, as well as the rational mineral use and other extracted elements of the Earth and the masses of water; as well as in the protection of the ecosystems

**For the MINED. El Ministry of Education will include:**

- i) In its educative and curricular policies in the different levels and modalities, it will establish oriented lineaments to guarantee the protection, promotion, and diffusion of the practices and knowledge of the natural medicine, complementary therapies and natural products, in accordance with the practices that are recognized by the MINSA.
- ii) In the Curriculum Basic National of Primary, Secondary Education and Initial formation of Educational, in Natural Sciences, Social Sciences, Language and Literature, Civisms, Direction Technical and Vocational and Cultural and Artistic Expression, knowledge, abilities and complementary skills of the natural medicine and therapies as a form of conservation of the culture and to fortify the identity, cultural of and the students.
- iii) To obtain data and knowledge of the natural medicine and complementary therapies, in order to elaborate material didactic and of support that fortifies the development of these contents and contributes to the actions of qualification with the educational ones. IV) To develop in the scholastic orchards the medicinal culture of plants and trees.

**For MINSA**

El Ministry of Health through the main directorates of Sanitary Regulation, of Extension and Quality of the Attention, Planning and Development and Teaching and Investigation, it incorporated in the models of attention, management and provision of services, protocols and guides of clinical practice, the natural medicine and complementary therapies, allowing this way gradual integration within the system of health of the country.

**Article 22.**

Natural Vademécum. In accordance with articles 18, 26 and 40 of the Law, the Ministry of Health with the participation of the Ministries of the Atmosphere and Natural's Recourses (MARENA), Promotion, Industry and Commercial (MIFIC), of Education (MINED), Farming and Forestall (MAGFOR), the Universities public or deprived and associations or organisms that are related to the natural medicine, complementary therapies and the natural products elaborated in the period of five years from the entrance in use of the present Regulation, the Natural Vademécum, which will be approved by means of Ministerial Resolution.

El Natural Vademécum will be updated every two years, by means of a process of consultations or opinions made by the indicated organs in the previous paragraph.

**Article 23.**

Use of toxic plants. El Ministry of Health with the participation of the Ministries of the Atmosphere and Naturals Recourses (MARENA), Promotion, Industry and Commercial (MIFIC), of Education (MINED), Farming and Forestall (MAGFOR), the Universities public or deprived and associations or organisms that are related to the natural medicine, complementary therapies and the natural products, will define the listing of toxic plants and its derivatives and will establish the qualification plans, the forecasts and protocols of attention in case of poisoning by medicinal plants.

The guides of Good Practices of natural product Manufacture, will be fit by the National Center of Diagnosis and Reference

**Article 24.**

Promotion, spreading of uses and consumption of medicinal plants. El Ministry of Health, with the publication by any spreading or mass media of the Natural Vademécum, guaranteed therapeutic, nutritional, toxicological and clinical the promotion and uses of the medicinal plants.

The institutions of superior education that offer the medicine races, chemistry, pharmacy, infirmary and others related to sciences of the health, incorporated in their curriculums the subject of the medicinal plants and its allopathic, nature-orthopatic medicine uses and in complementary therapies.

**CHAPTER V  
OF THE EXERCISE OF THE NATURAL MEDICINE AND COMPLEMENTARY THERAPIES, RATING OF ESTABLISHMENTS AND THE REGENCY.**

**Article 25.**

Exercise of the Natural Medicine. The people authorized for the exercise of the natural medicine and complementary therapies, are professional, specialist, therapists and technicians, must register their titles and other academic qualities before the National Registry of Professionals and Technicians of the Health, of the Ministry of Health, as she indicates herself in Article 26 of the present Regulation.

The natural product Manufacturers, importers, exporter, distributors and drug dealers must register themselves in the Direction of Pharmacy, with the requirements that settle down in articles 43, 44, 45, 46 and 49 of the present Regulation.

The people with experience and traditional knowledge will have to register themselves in each Municipal Direction of Health.

**Article 26.**

Of the Code or Sanitary Registry of the Professionals and Technicians. In accordance with 30 articles and the initial part of the article 3 Is of the Law, the professionals and technicians formed in natural medicine and complementary therapies, must register in the National Registry of Professionals and Technicians of the Health that administers the Ministry of Health. For it they must present/display the following requirements:

1. Title Graduates/Certified: original and copy authenticated by Notary.
2. Copy of the Identity card. In the case of resident foreigners in Nicaragua it applies the Certificate of Resident emitted by the Main directorate of Migration.
3. Original and it copies of the Certification emitted by the training Institution where the interested course its studies.

4. Original and its copies of the Certificate of Qualifications emitted by the training Institution where the interested one attended its studies and that they sustain I title or its graduates.
5. For the titles or extended diplomas abroad in addition to the previous requirements, the interested one must present/display the original one and authenticated copy of the Certificate of Incorporation granted by the Independent National University of Nicaragua, UNAN Managua or UNAN - Leon.
6. Timbre of public prosecutor of Maxima value.
7. Payment of tariff, in box of the Ministry of Health, previous elaboration of payment order in the National Registry of Professionals and Technicians of the Health

In accordance with the final part of articles 30 and 31 of the Law, for the case of people who only count on the knowledge, practice and experience acquired by tradition, validated and recognized by the organized expressions of the community, they will have to be registered in the Municipal Directions of Health in the corresponding SILAIS, presenting/displaying in writing the recognition of pertinent the communitarian organ.

In accordance with articles 30 and 31 of the Law, and article 13, interjection 1 of the Regulation, the producers, manufacturers or elaborators of natural products must be registered in the Direction of Pharmacy.

**Article 27.**

Complementary rating of establishments of the Natural Medicine and therapies. The establishments suppliers of services of health, where natural medicine attention offers and complementary therapies will be qualified by the Ministry of Health, having to fill in which he will be to him applicable the requirements established in article 55 of the Law No 423 and I capitulate II, Of the Rating to the Establishments of Health, articles 125 to the 143, of the Decree No 001-2003, "Regulation of the General Law of Health" and Manual Norma 080 "of Rating". The Ministry of Health will have to elaborate and to dictate the standards of rating for this type of establishments

The establishments that make, import, export, distribute and commercialize natural products, will be authorized in accordance with the requirements established in the Law No medicine 292, "Law and Pharmacies" and the Decree No 6-99, Regulation of the Medicine Law and Pharmacies.

The Sanitary License will have a validity of four years, being able to be renewable per equal periods, of conformity to article 32 of the Law.

**Article 28.**

Benefits for the doctors, therapists, and technicians of the natural medicine and complementary therapies. The benefits, prerogatives and rights for the doctors, therapists and technicians of the natural medicine and complementary therapies, that indicate articles 34 and 35 of the Law, will be such that the workers enjoy who toil the public sector; and in the private sector the rights are those that establish their corresponding contracts.

**Article 29.**

Clinical file. The doctors and therapists, as much of establishments' suppliers of services of health deprived public or, in their processes of attention in health and the exercise of the natural medicine and complementary therapies, will have to fulfill Norm 004 - 2008, "Norm for Manejo of the Clinical File".

**Article 30.**

Intellectual property. El Registry of the Intellectual Property of the Ministry of Public Works and the Economy, Industry and Commerce, with the purpose of avoiding the illegal appropriation of the knowledge, inventions and findings of the people who exert the natural medicine and complementary therapies, as well as the natural product elaboration, guaranteed that the proceeding of the invention patent is expeditious, without reduction of which the requirements of the study, systematization are fulfilled or investigation that gives origin to the request of invention patent.

When the invention or finding is of collective character or comes from descending the indigenous towns or afro will be come in accordance with article 34 of the Law No ancestral Traditional Medicine 759, "Law", having to register the collective property by declaration before public notary.

**Article 31.**

Of the Regency in establishments suppliers of services of health and natural product drug dealers. The people interested in executing a regency of establishments where practical the natural medicine and complementary therapies or natural product commercialization, must fulfill the following requirements:

1. Request in writing, of the interest of fungir as it runs of the natural product establishment.
2. Photocopy of the Title Certified Diploma/, authenticated by Notary and who contains the sanitary code.
3. Copy of the Identity card.
4. For the titles or extended diplomas abroad in addition to the previous requirements, the interested one must present/display the original one and authenticated copy of the Certificate of Incorporation granted by the y National Autonomy University of Nicaragua, UNITES - Managua or UNITES - Leon.
5. Fiscal timbre of maximum value.
6. Original of exclusive the labor contract for the regency of the natural product establishment.
7. Recent photography, so large card. 8. Record of Police. 9. Certificate of health extended by the MINSa.
8. Police Record
9. Health Certificate extended by the MINSa.

The establishments suppliers of services of health, natural medicine or complementary therapies and the establishments that elaborate or make, distribute or commercialize natural products will be directed by professionals or related technicians of the type of attention or products, being the regency exerted by professionals of the natural medicine and complementary or specialist therapies in ethno botanic or phi to therapeutic, pharmaceutical pharmacists or chemistry; these last ones that has studies related to products used by the natural medicine or complementary therapies.

**Article 32.**

Update of the national vademécum. The update of the Natural Vademécum will be made every 2 years, without damage of later incorporations of new substances or natural products

to he himself; the update will be made in the National Commission of Norms, Guides and Protocols, and in the same one the natural medicine and complementary therapies and natural products will participate professional in.

**Article 33.**

New complementary therapies. The complementary therapies of new appearance will be subject to the verification of their effectiveness for their recognition and incorporation in protocols or guides of clinical practice, which will be approved by the National Commission of Norms, Guides and Protocols of the Ministry of Health.

If the new complementary therapy uses new natural products, these will be incorporated to the Natural Vademécum.

**CHAPTER V I**

**SAW OF THE ESTABLISHMENTS AND the SANITARY REGISTRY, OF THE  
PROMOTION AND FACILITACIÓN TO the PRODUCTION AND NATURAL PRODUCT  
COMMERCIALIZATION**

**Article 34.**

Pertinent actions to guarantee the quality of natural products. In accordance with articles 42 and 43 of the Law, to guarantee the quality, security and effectiveness of natural products for therapeutic use, they were made periodic inspection to the establishments that elaborate, distribute or give such products.

The National Laboratory of Control of Quality of Medicines verified the operation and fulfillment of the Good Practices of Manufacture of the manufacturing natural product establishments, as well as the specific analyses of each product, which will be able to make with the support of the Laboratory of Control of Quality of Medicines of the Independent National University UNITE - Leon, or another similar establishment properly credited; the Direction of Pharmacy verified in the importers and distributors, the fulfillment of the good practices of storage, distribution and commercialization.

The Departmental Delegations of Pharmacies of the SILAIS will verify in the naturists pharmacies the good practices of storage, distribution, commercialization and dispensation, in accordance with the Law No medicine 292, "Law and Pharmacies" and their Regulation.

**Article 35.**

Protection to national natural products. The Ministry of Health, guaranteed that the natural product imports of therapeutic use, are made by establishments authorized by means of Sanitary License of effective operation and that such products are registered properly for their commercialization in the national territory.

**Article 36.**

Exemption of fiscal taxes and tariffs of import. El Ministry of Property and Public Credit, the Ministry of Health and the Ministry of Public Works and the Economy, Industry and Commerce, by means of technical dispositions, will elaborate the taxativa list of machinery, equipment, spare parts, insumos and necessary the raw materials for the natural product elaboration, used in complementary therapies that will enjoy the benefit of the exemptions of the IVA, DAI and ISC.

The technical disposition that is dictated, indicated the requirements that must fulfill the natural product manufacturers that ask for the benefits of the exemptions indicated in Article 48 of the Law. For all the effects the Direction of Pharmacy of the Ministry of Health, will emit corresponding endorsement.

**Article 37.**

Support to the small and medium natural product producers. El Ministry of Public Works and the Economy, Industry and Commerce and the Nicaraguan Institute of Support to the Small and Medium Company (INPYME), will have to develop to plans and special programs of support to the small and medium natural product manufacturers so that they improve his productive processes and they assimilate new techniques of manufacture, that as much guarantees to them to be competitive at national level as in the foreign markets to which they can accede.

**Article 38.**

Customs tariff classification. Customs the Main Directorate of Logistics, in accordance with the CAUCA, RECAUCA and System Central American (SAC), classified the raw material, inseams, equipment, accessories and instruments related to the production, commercialization, export and product complementary import of the natural medicine, therapies and natural products taking in consideration or reference the effective natural vademécum.

**Article 39.**

Requirements to present/display the requests of sanitary national natural product registry.

The requirements that must fill for requests of sanitary natural product registry, are the following ones:

1. El establishment this legal authorized mind by the Direction of Pharmacy.
2. To present/display each foliate, free file of amendments or blotches, properly bound.
3. The requests appeared in writing in paper common, in original and a copy, signed by the Legal representative and Regent. The requirements for the sanitary natural product registry, will be established in accordance with the Central American regional norms that are approved, and will have to contain the following information at least:

**1. Data of product**

- a) Name of Product
- b) Name of the natural active substances.
- c) It forms Pharmaceutics.
- d) Via of administration.
- e) Presentation of the product.
- f) Propose Vida útil.
- g) Therapeutic group.
- h) Modality of sale.
- i) Category of Registry (new, renovation)

**2. Data of the Conditioning Manufacturer and.**

**3. Data of Titular of the Product.**

**4. Data of or the Distributors.**

**5. Data of the Legal Representative.**

**6. Data of Responsible Professional.**

**7. El sanitary registry was given in the time established in the procedures that such effect stops dictates the Direction of Pharmacy.**

**Article 40.**

The natural product tariffs: In accordance with Article 51 of the Law, the tariffs that must be aware in the unique box the Ministry of Health by means of order of payment extended by the Direction of Pharmacy, for the natural, import product laboratories and distributing wholesalers, as well as distributing retailers of such settle down; and by the SILAIS for the naturistas



pharmacies by means of order of payment according to the concepts that are described next:

**CONCEPT TARIFF**

Natural Product Registry.....	C\$ 1,250.00
Analyses for Registry natural Products .....	C\$ 1,250.00
Certificate of Free .....	C\$ 150.00
Sale Visa of invoice to desaduanar .....	C\$ 35.00

**REGISTRY OF ESTABLISHMENTS**

Naturist Pharmacies .....	C\$ 1,000.00
Laboratories of natural product .....	C\$ 4,000.00
Distributing whole sales retail .....	C\$ 5,000.00
Distributing minor sale's retail .....	C\$ 2,000.00
Shop for natural product Sale .....	C\$ 1,000.00
Services for Inspection, opening and renovation of license .....	C\$ 500.00

**OTHER SERVICES THAT CONCEPT OFFERS TO THE PHARMACY DIRECTION**

Certified TARIFF of Export .....	C\$ 50.00
Title deed Replacement of Natural Products .....	C\$ 150.00

**Article 41.**

Authorization of operation of establishments that commercialize natural products. For effects of the article the 52 naturists establishments that commercialize natural products are the following ones: 1) Naturista pharmacy; 2) Importer and wholesale distributor; 3) Retail distributor; 4) Position of Sale; and 5) Manufacturing laboratory.

**Article 42.**

Authorization of naturist pharmacy. The interested ones in opening an establishment of naturist pharmacy, must fulfill the requirements established by the Direction of Pharmacy, same that must be presented/displayed before the Departmental Delegation of Pharmacy of the corresponding SILAIS:

- 1- Request in writing of the proprietor or legal representative of the establishment.
  - 2- To fulfill the requirements of the areas of office, reception and storage that to the effect settles down in the present Regulation.
  - 3- Labor contract of Regent with the requirements that settles down in the present Regulation.
- Presentation of request with the following information:

**1) Applicant:**

Complete name.  
Address and Telephone  
Trade name of the Propose  
Address of establishment.  
Specify if it will prepare skillful or officinal's formulas.  
Large Photo  
Health Certificate

**2) Runs Professional proposed for the Regency (complete name, address, age, telephone).**

Proposal of schedule, in which it will exert his functions.  
Large photography recent card.  
Contract of Work of Regent.  
Certificate of Health of the Professional.  
Photocopy of the Title of the Pharmaceutical Professional in whom the Sanitary Code is

visible, granted by the National Registry of Professionals and Technicians of the Health. The naturists Pharmacies will have to fulfill, in addition with the following requirements:

**Administrative area:** containing the Equipment with it was helped (Calculating, Writing-desk, File, Material of Office, Seal of the establishment, Bibliography: Natural Vademécum. Human resources; among others).

**Area of Office:** Shelves, Display cabinets, Refrigerator,

**Area of Storage:** Pollens Existing

**Area of Preparation of Skillful Formulas or Oficinales (When It comes):** Furniture of Formica or Tiles, Faucet, de stainless Aluminum dishwasher, Test tubes, Pipettes, Mortars and Pylon, Beakers, Burner, Agitators of Magneto, Sterilizer and balance).

The physical structure of all the areas must be of walls smooth, flat sky, fluorescent brick floor, lamps, medical facilities (odorless and sink), visible label that it identifies to the establishment.

The SILAIS practiced an inspection in the premises of the establishment with the object of verifying that the premises reunite all the conditions and that is counted on all the materials demanded by this Regulation.

In case that the result of the inspection was positive, the SILAIS will come to extend Order of Payment, so that the interested one makes it effective in the Unique Box of the Ministry of Health. With the presentation of the payment receipt, the SILAIS you give to the applicant to the Sanitary License of operation.

### **Article 43.**

Authorization of operation of distributor and wholesale importer. The interested ones in opening to a Distributing establishment and Import natural product wholesaler must present/display to the Direction of Pharmacy a request in writing, containing the following information:

- 1) Complete name of applicant.
- 2) Address and Telephone.
- 3) Proposal of location of the establishment.
- 4) Proposal of schedule of operation of the establishment.
- 5) Name of the professional proposed to the Regency and the following data, address, telephone, age, sanitary code, schedule proposal in which will exert its functions and a recent photography of so large card.

### **The request will be accompanied by the following requirements:**

- Certificate of Police of the Representative or Proprietor.
- Act of Constitution of the society when it comes.
- Contract of Work of Regent of the establishment.
- Certificate of Health of the Proprietor and Regent.
- Photocopy of the title of Regent, in which the Sanitary Code granted by the National Registry of Professionals and Technicians of the Health is visible.
- To be able of Representation properly authenticated, of ( ) the manufacturing Laboratory (s) natural product (s), when it comes.
- Document extended by ( ) the manufacturing Laboratory (s) natural product (s) that credits it to concern natural products before making any management of purchase.

***The establishment will have to count on:***

- 1) Administrative area, the one that must have: Material and Equipment of Office Seal of the establishment.
- 2) Area of Office
- 3) Area of Storage with the following sections:

Products that require special temperature a Central section (pollens, shelves, conditioned air or ventilation no greater of 25° and suitable illumination).

The Direction of Pharmacy, received the request and documentation, will come to make inspection in the place of the establishment, with the object of verifying if this reunites the conditions indicated in the present Article.

If the result of the inspection is positive, the payment order was authorized in the unique Box of the Ministry of Health.

With the presentation of the payment receipt, the license of operation of the establishment was given.

**Article 44.**

Authorization of operation for retail distributor.

The interested ones in opening a retail Distributing natural product establishment, must present/display to the Direction of Pharmacy a request in writing, containing the following information:

- 1) Complete name of the applicant.
- 2) Address and Telephone.
- 3) Proposal of location of the establishment.
- 4) Proposal of schedule of operation of the establishment.
- 5) Name of the professional proposed to the Regency and the following data, address, telephone, age, sanitary code, schedule proposal in which will exert its functions and a recent photograph of so large card.

***The request will be accompanied by the following requirements:***

- Certificate of Police of the Representative or Proprietor.
- Act of Constitution of the society when it comes.
- Contract of Work of Regent of the establishment.
- Certificate of Health of the Proprietor and Regent.
- Photocopy of the title of Regent, in which the Sanitary Code granted by the National Registry of Professionals and Technicians of the Health is visible.

**The establishment will have to count with::**

**1) Administrative area, the one that I must have:** Material and Equipment of Office Seal of the establishment.

**2) Area o Office**

**3) Area of Storage with the following sections:** Products that require special temperature a Central section (pollens, shelves, conditioned air or ventilation no greater of 25° and suitable illumination).

The Direction of Pharmacy, received the request and documentation, will come to make inspection in the place of the establishment, with the object of verifying if this one reunites the conditions indicated in the present Article. If the result of the inspection is positive, the

payment order was authorized in the Box of the Ministry of Health.

With the presentation of the payment receipt, the license of operation of the establishment will be given.

**Article 45.**

Authorization for operation post Sale.

The interested ones in opening a Position of natural product Sale, must present/display before the Departmental Delegation of Pharmacy of the SILAIS, a request in writing, containing the following information:

- 1) Complete name of the applicant.
- 2) Address and Telephone.
- 3) Proposal of location of the establishment.
- 4) Proposal of schedule of operation of the establishment.

***The request will be accompanied by the following requirements:***

- Certificate of Police of the Proprietor.
- Certificate of Health of the Proprietor.

**The establishment will have to count on:**

***a) Structure of the Position of Sale:***

- \* Walls: Solid smooth
- \* Floor: Of smooth tiled brick or
- \* Illumination: Natural or fluorescent lamps
- \* Medical facilities: Toilets and sink or Latrine (when it comes)
- Ventilation: Flow of natural ventilation, or ventilators of ceiling or wall, (when it comes).

***b) Area of Dispensation and office:***

- Existing and/or display cabinets
- Label: The one that must have form the name or trade name with which registered in the Ministry of Health and that is legible according to their size.
- Bibliography: Natural Vademécum.

The departmental delegation of pharmacy of the corresponding SILAIS, will practice the inspection in the premises of the establishment, to verify that it reunites to the conditions and requirements demanded in this Regulation, being raised the act of respective supervision. If the result of the inspection were positive, the departmental delegation of pharmacy of the corresponding SILAIS, will extend to the applicant the sanitary license of operation.

**Article 46.**

Unique window of Foreign trade.

The processes for the proceedings related to the import and export of natural products will be integrated in the System that handles Customs the Main Directorate of Logistics in coordination with the areas of the Main directorate of Sanitary Regulation, so that the proceedings of the authorizations of imports and exports are made agile.

**Article 47.**

Instance to solve reclamations.

El procedure to interpose the reclamations to that Article 55 of the Law talks about, when a proceeding of which it indicates Article 53, of the Law also refuses or rejects, initiates with the presentation of the reclamation by writing in common paper, indicating the following thing:

- 1) Identification of the competent organ
- 2) Identification of the reclamers
- 3) Legal accreditation
- 4) Relation succinct of the object and instance that denies the proceeding
- 5) Place for notifications
- 6) Date and address of the reclamers
- 7) Company/signature

The Main directorate of Sanitary Regulation, will have to solve the reclamation in a term maximum of 7 working days, and passed he himself without it has had answer, authorizes to the reclamers to interpose the administrative resources that indicates to the Chapter IV, Of the Procedures and Administrative Conflicts of Law 290, "Law of Organization, Competitions and Procedures of the Executive authority ".

**Article 48.**

Granting and use of the sanitary license for establishments that make natural products.

The interested ones in opening a manufacturing natural product laboratory , must present/display to the Direction of Pharmacy of the central MINSA a request in writing, containing the following information:

- 1) Complete name of the applicant.
- 2) Address and Telephone.
- 3) Proposal of location of the establishment.
- 4) Proposal of schedule of operation of the establishment.
- 5) Name of the professional proposed to the Regency and the following data, address, telephone, age, sanitary code, proposal of schedule in as will exert its functions and a recent photography of so large card.

The request will be accompanied by the following requirements:

- Certificate of Police of the Representative or Proprietor.
- Act of Constitution of the society when it comes.
- Contract of Work of Regent of the establishment.
- Certificate of Health of the Proprietor and Regent.
- Photocopy of the title of Regent, in which the Sanitary Code granted by the National Re-

gistry of Professionals and Technicians of the Health is visible .

For the granting of the Sanitary License of manufacturing natural product establishments they must fulfill the following requirements:

**1) The opening request appeared in original and copies, specifying the following thing:**

- a) Name of the Laboratory, Telephone number, Fax.
- b) Direction of the Laboratory.
- c) Name and Direction of the Proprietor.
- d) Name of the Manager.
- e) Name of Regent.
- f) Name of the Person in charge of Control of Quality.
- g) Professional in charge of production.
- h) A recent photography of the Manager and Runs of the Laboratory.

**2) The additional information that it will accompany the request by opening will be the following one:**

**2.1) Architectonic description of the plant that it includes:**

- a) Name of atmospheres and areas;
- b) Specifications ({area, type of ceiling, ect.);
- c) Planes

2.2) People proposed for each area and its qualification.

**2.3) Equipment available in each area, material of which is constituted and their use.**

**2.4) Norms of cleanliness for personnel, equipment and area of work.**

**2.5) First draft of:**

- a) Products to make
- b) Formulas and methods of preparation
- c) System of quality control
- d) Flu gram of production process
- e) Organization and operation

**2.6) In addition to the described requirements the following documents will appear:**

- a) Scripture de Constitution of the establishment if she is legal person.
- b) Request of the professional who will run the proposed laboratory, for which it must have his title registered in the Ministry of Health.
- c) Contract of work between Regent and the Proprietor of the Laboratory in accordance with the labor laws.
- d) Certificate of Health of the Manager, Runs and of the personnel of production extended by the Ministry of Health.

The National Laboratory of Control of Quality of Medicines of the MINSA, made inspection in the manufacturing laboratory, to verify the fulfillment of the requirements established in the present Regulation. If the result of the inspection is positive, the payment order will extend to the applicant, the one that must become effective in the Unique Box, of the Ministry of Health.

With the presentation of the payment receipt, the Direction of Pharmacy gave to the applicant the sanitary license of operation of the manufacturing natural product Laboratory.

For the renovation of the Sanitary License, it will have to be asked for with two months of anticipation to its victory.

**Article 49.**

Use of the Sanitary License of Position of Sale.

The Sanitary License for the Positions of Natural Product Sale single is applicable for the natural product commercialization.

The natural medicine doctor's offices will be qualified of conformity with the standards that such aim stops establishes the Ministry of Health, and the naturists professionals and technicians must be credited and registered in the Ministry of Health.

**Article 50.**

Formalization and recognition of the naturists establishments.

To the entrance in use of the present Regulation, the manufacturing laboratories, the importers and wholesale distributors, the retail distributors, the Pharmacies Naturist and natural product Posts sell that is working, will have a term of an anus, to fulfill the requirements established in articles 44, 45, 46, 47 and 51 of the present Regulation.

**CHAPTER VII  
OF THE SCIENTIFIC AND ACADEMIC DEVELOPMENT**

**Article 51.**

Of the investigations and technical studies of the natural medicine, complementary therapies and natural products.

El Ministry of Health in accordance with articles 61 and 69 of the Law, by means of agreements of cooperation with universities and research centers caused the accomplishment of technical studies or scientific researches on natural medicine, complementary therapies and natural products.

The investigations that are made in indigenous territories and protected areas, must be made according to the established thing in articles 57 and 58 of the Decree No 01-2007,

Regulation of Areas Protected of Nicaragua, published in the Newspaper, Official Newspaper No 8 of the 11 of January of the 2007.

**Article 52.**

Events on Natural Medicine and Complementary Therapies.

The Ministry of Health in accordance with articles 62 and 63 of the Law, will promote events of scientific update of the natural medicine, complementary therapies and natural products with the participation of professionals and technicians of the natural medicine and complementary therapies.

**Article 53.**

Complementary integration of professional or technical races on Natural Medicine, therapies and natural products in national universities.

Of conformity to the faculties granted to the national institutions of superior education in the Law No 89, "Law of Autonomy of the Institutions of Superior Education ", will promote the incorporation of professional or technical races, in the field of the natural medicine, complementary therapies and natural products.

El Ministry of Health, acted in accordance with article 7, numeral 18, of the Law No 423 "General Law of Health", as far as the coordination that can develop with institutions of the superior education.

**Article 54.**

Obtained incorporation of natural medicine titles and complementary therapies abroad.

The natural medicine titles and other degrees academic, complementary therapies or related to natural products, obtained by Nicaraguan in the outside or of foreigners who will exert in Nicaragua, will have to be gotten up before the Independent National University of Nicaragua - Leon (UNAN-Leon) or before the Independent National University of Nicaragua - Managua (UNAN-Managua), in accordance with article 9, numeral 2 of the Law No 89, "Law of Autonomy of the Institutions of Superior Education", published in the Newspaper No 77 of 20 of April of 1990.

Once incorporated the title before anyone of the universities before indicated, the record number or sanitary code will be due to obtain before the National Registry of Professionals and Technicians of the Health of the Ministry of Health.

**CHAPTER VIII  
OF the LACK and punish**

**Article 55.**

Classification and graduality of the sanctions.

For effects of the application of the sanctions by infractions to the Law, indicated in article 70 of the Law, the following graduality settles down :

- a) Minor offenses: 1) professionals and technicians nonregistered; 2) not to fulfill the norms and dispositions dictated by the Ministry of Health.
- b) Serious offenses: 1) To put in risk the health of the people or environment; 2) to cause reversible damages to the health of the people or environment; 3) to violate the principles of the natural medicine and complementary therapies; and 4) the commission of two minor offenses in the period of a year, counted from the commission of the first minor offense.
- c) Very Serious lack: 1) To cause irreversible damages to the health of the people or environment; 2) the complementary practice of the natural medicine or therapies without counting on the required or recognized professional or technical qualities; and 3) To operate



establishments no authorized by competent authority; 4) Overcome, adulterated natural product import, distribution, possession and commercialization, without sanitary registry and falsified; 5) The commission of two serious offenses in the period of a counted year from the commission of the first serious offense.

**Article 56.**

Suspension or cancellation of sanitary registries and closing of naturists establishments.

a. - The registry of a natural product will be suspended, when this it does not adjust or it does not reunite to the specifications or requirements that the Law fixes, the practical standards and other applicable dispositions.

b. - It will be come to the cancellation of the registry when the situations referred in the previous interjection stay, after the competent authority has even oriented that are corrected.

c. - You come yourselves to definitive the temporary closing or from a naturist establishment in the following cases:

1. Not to have runs, except the positions of natural product sale;
2. Breach of norms and regulations of health;
5. Verified, injustificadas or total temporary absences of run;
6. In all the cases in that it is necessary to impose this measurement to protect the health of the population.

Once verified the faults that the procedure of suspension or cancellation of the ratings indicates to Article 71 of the Law it will fit to the established thing in article 77 of the Law No 423, "General Law of Health " and articles 430 to the 440 of the Decree No 001-2003, "Regulation of the General Law of Health", in which he will be to him applicable.

**Article 57.**

Sanction by the exhibition to risks and damages to the health of the population. The exhibition to risks to the health of the patients who are taken care of in natural medicine establishments authorized, complementary therapies or which they use in his treatments natural products, as well as to environment, considers a serious offense and will be sanctioned of conformity to article 83 of the Law No 423 and article 443 of the Decree No 001-2003.

If of the offered attention using the natural medicine or the complementary therapies and natural products damages to the health of the people or environment will be caused, they will come as Article 84 from the Law No 423, "General Law of Health" and I articulate 444 of the Decree No 001-2003, "Regulation of the General Law of Health".

**Article 58.**

Sanction to the falsification, natural product adulteration and contraband. The natural product falsification, adulteration and contraband to that article 73 of the Law talks about, typeface as a very serious lack and will be sanctioned in accordance with article 84 of the Law No 423, "General Law of Health" and article 444 of the Decree No 001-2003, "Regulation of the General Law of Health", if it will be committed by natural people or naturists establishments no authorized. If they will be committed by natural or legal people of naturists establishments authorized, the closing or definitive temporary closing or of the same ones will be sanctioned with . Once verified and graduated the infraction, the MINSA will come, by means of motivated Administrative Resolution, to the application of the corresponding sanction. In both cases it will come the seizure and the destruction from the products, whose costs will be assumed by the violator.

In the imposition of the sanctions that merited closing or definitive temporary closing or will follow the procedure established in Article 77 of the Law No 423, "General Law of Health" and articles 430 to the 440 of the Decree No 001-2003, "Regulation of the General Law of Health", in which he will be to him applicable.

If in opinion of the corresponding authorities of the National Police, Customs Main Directorate of Logistics or Ministry I publish, the fact constituted crime, was acted in accordance with articles 332 to the 335 of Title XIII, Crimes Against the Health Publishes, I capitulate Only, of the Law No 641, "Penal Code", published in the Newspapers, Official Newspaper, No 83, 84, 85, 86 y 87 del 5, 6, 7, 8 y 9 de Mayo del 2008, respective.

**Article 59.**

Minor offense by the breach of the clinical file.

Minor offense was considered to fail to fulfill with the Norm No 004-2008, "Norm for Manage of the Clinical File" and "Guide for Manage of the Clinical File ", and as sanction the dispositions of article 82 of the Law were applied No 423, "General Law of Health " and Article 442 of the Decree No 001-2003, "Regulation of the General Law of Health " .

**Article 60.**

Breach to security norms and hygiene.

a) In the processes of attention in natural medicine and complementary therapies they are minor offenses:

- 1- Not to be qualified like lending establishment of services of health.
- 2- Not to fulfill the minimum norms of security and hygiene.
- 3- Not to be properly registered the professionals and technicians in natural medicine and complementary therapies.

b) In the processes of natural product elaboration that they have therapeutic indication is serious offenses:

- 1- Not to be qualified like manufacturing natural product establishment.
- 2- Not to fulfill the manufacture practices.
- 3- Not to be properly described the professionals and technicians in charge of the direction in the elaboration or natural product manufacture .
- 4- Unsuitable final elimination of the dangerous remainders.

If by the breach of the norms of security and hygiene in the offered attention using the natural medicine or the complementary therapies and in the natural product manufacture damages to the health of the people or environment will be caused, they will come as article 83 and 84 from the Law No 423, "General Law of Health" and Article s. 443 and 444 of the Decree No 001-2003, "Regulation of the General Law of Health".

**Article 61.**

Administrative resources.

The administrative resources that can interpose the people who consider affected their rights, by the imposed penalties or by the performances of the civil employees under protection of the Law and the present Regulation, will be regulated of conformity to the arranged thing in Chapter IV, Of the Procedures and Administrative Conflicts of the Law No 290, "Law of Organization, Competitions and Procedures of the Executive authority ".

**CHAPTER IX  
FINAL AND TRANSITORY DISPOSITIONS**

**Article 62.**

Natural products that contain controlled substances or that are considered products nutritional. The Ministry of Health elaborated the requirements for the import, export, distribution, commercialization, promotion and publicity of natural products that contain controlled substances.

Similarly it will establish the requirements for the manufacture, import, export, distribution, commercialization, promotion and publicity of considered natural products like nutritional supplements.

**Article 63.**

Use. - The presents/displays Regulation entered use from their publication in the Newspaper, Official Newspaper.

Dice in the City of Managua, House of Government, Republic of Nicaragua, day twenty-nine of April of year two thousands fourteen. **Daniel Ortega Saavedra**. President of the Republic of Nicaragua. **Sonia Castro González**.

**National assembly of the Republic of Nicaragua.**

**Legislative complex Carlos Núñez Téllez.**

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**To send its commentaries a: Division of Legislative Information**

**Note:** Any existing Difference between the Text of the printed Law and the published one here, we are to be communicated to the Division of Legislative Information of the National Assembly of Nicaragua

