LAW No 6,360, OF SEPTEMBER 23rd, 1976.

Makes provisions on the health surveillance to which medications, drugs, pharmaceutical supplies, healthcare products, cosmetics, sanitizers, and other products are subject, and makes other provisions.

THE PRESIDENT OF THE REPUBLIC: I hereby make it public that the National Congress decrees and I sanction the following Law:

TITLE I - Preliminary Provisions

Article 1. Medications, drugs, pharmaceutical suppliers, and healthcare products, defined by Law no. 5,991, of December 17th, 1973, are hereby subject to the health surveillance standards herein established, as well as hygiene products, cosmetics, perfumes, household cleaning products, products intended for aesthetic corrections, and other products henceforth defined.

Article 2. Only companies authorized by the Ministry of Health and whose establishments have been licensed by the health surveillance authority of their respective state may extract, produce, manufacture, transform, synthesize, purify, fraction, package, repackage, import, export, store, or ship the products aforementioned in Article 1 hereof.

Article 3. For the purposes of this Law, in addition to the definitions provided in subsections I, II, III, IV, V and VII of Article 4 of Law no. 5,991, of December 17th, 1973, the following definitions are hereby adopted:

I - Dietary Products: products technically elaborated to meet the dietary needs of people under special physiological conditions;

II - Nutriments: substances with nutritional value present in food, including proteins, fats, carbohydrates, water, mineral elements, and vitamins;

III - Hygiene Products: products for external use, whether antiseptic or not, intended for body cleaning and disinfection, including soaps, shampoos, dentifrices, mouthwashes, antiperspirants,

deodorants, shaving and post-shaving products, styptic products, and others;

IV - Perfumes: products with aromatic composition obtained from natural or synthetic substances, which, in proper concentrations and media, are especially intended for environmental and people scent, including extracts, scented water, cream perfumes, products for bathing and environmental scent, whether liquid, gel, pasty, or solid;

V - Cosmetics: products for external use, intended for protecting or beautifying different body parts, such as face powders, talcum powders, beauty creams, hand creams and others similar, face masks, beauty lotions, milky, creamy and cleansing solutions, hand lotions, makeup bases and cosmetic oils, rouges, blushers, lipsticks, lip liners, sunblocks, tanning lotions and simulators, mascaras, eyeshadows, eyeliners, hair dyes, hair bleaching agents, solutions to curl or straighten hair, hairsprays, hair lacquers, pomades and others similar, hair, waxing and skin lotions, solutions for nails and others;

VI - Dyes: substances added to medications, dietary products, cosmetics, perfumes, hygiene products and others similar, household cleaning products and others similar, intended for providing them with color and, in certain types of cosmetics, for transferring color to skin surface and skin appendages;

VII - Household cleaning products: substances or solutions intended for cleaning, disinfecting, or disinfesting houses, collective and/or public spaces, places of common use, and used in water treatment, consisting of the following products:

a) insecticides - intended for fighting, preventing, and controlling insects in housings, spaces and places of public use and their surroundings;

b) raticides - products intended for fighting rats, mice, and other rodents in housings, boats, spaces and places of public use, that contain active, isolated or associated substances that do not pose risk to the life or health of humans and of endothermic domestic animals when applied in compliance with the recommendations contained in their packaging;

c) disinfectant - intended for destroying, either indiscriminately or selectively, microorganisms when applied to inanimate objects or environments;

d) detergents - intended for dissolving fats, for cleaning pots and containers, and for domestic use.

VIII - Label: printed, lithographed identification, as well as painted phrasings or heat, pressure, or self-adhesive affixed phrasings, directly applied to containers, pots, wrapping, packaging, cartridges, or any other packaging protector;

IX - Packaging: wrapping, container, or any kind of packaging, removable or not, intended to cover, package, bottle, protect, or maintain the products herein addressed, whether specifically or not;

X - Registration: registration of the products herein addressed, in an official book, granted by the authority of the Ministry of Health, under an order number, with the indication of their name, manufacturer, origin, intended use, and other characteristic elements;

XI - Manufacture: all operations required for acquiring the products herein addressed;

XII - Raw Materials: active or inactive substances used in the manufacture of medications and other products herein addressed, regardless of remaining unaltered or of being possibly submitted to changes;

XIII - Batch or Consignment: quantity of a medication or product herein addressed, produced by a manufacturing cycle and whose essential characteristic is homogeneity;

XIV - Batch Number: designation printed on the label of a medication or product herein addressed that enables the identification of their batch or consignment and the localization and review of all manufacturing and inspection operations throughout production, if needed;

XV - Quality Control: set of measures intended to ensure, at any moment, the manufacture of batches of medications and other products herein addressed and that complies with the standards of products activity, purity, efficacy, and innocuity;

XVI - In-Process Product: all substances or mix of substances that are in the middle of the manufacturing process;

XVII - Purity: degree of foreign materials in a certain drug.

XVIII – Brazilian Common Denomination (DCB) – denomination given to a medicine or a pharmacologically active principle approved by the federal health surveillance authority; (subsection included by Law no. 9,787, of 02/10/1999)

XIX – International Common Denomination (ICD) – denomination given to a medicine or pharmacologically active principle and recommended by the World Health Organization; (subsection included by Law no. 9,787, of 02/10/1999)

XX - Similar drug - medication that has the same active principles, concentrations, pharmaceutical form, administration route, dose and therapeutic indication as the medication registered at the federal health surveillance authority, allowed to differ solely in the features regarding the product size and shape, expiration date, packaging, labeling, excipients and vehicles, and being mandatory to be identified by its commercial name or trademark; (phrasing established by Provisional Measure no. 2,190-34, of 2001)

XXI – Generic Drug – medication similar to a reference or innovating product that intends to be interchangeable with such, usually manufactured after the expiration or waiver of the patent protection or other exclusive rights, after having its efficacy, safety, and quality proven and after having been named by the DCB, or by the ICD should there be no DCB; (subsection included by Law no. 9,787, of 02/10/1999)

XXII – Reference Drug – innovating product registered at the federal health surveillance authority and commercialized in the country, whose efficacy, safety, and quality have been scientifically proven upon registration at the competent federal authority; (subsection included by Law no. 9,787, of 02/10/1999)

XXIII – Interchangeable Pharmaceutical Product – therapeutic product equivalent to a reference drug, that has had the same effects of efficacy and safety been essentially proven; (subsection included by Law no. 9,787, of 02/10/1999)

XXIV – Bioequivalence – demonstration of pharmaceutical equivalence between products that have the same pharmaceutical form, that contain active principles with identical qualitative and quantitative compositions and that have comparable bioavailability when studied according to the same experimental design; (subsection included by Law no. 9,787, of 02/10/1999)

XXV – Bioavailability – rate and extension of absorption of an active principle according to its dose and based on its concentration-time curve in the systemic circulation or in its excretion in urine. (subsection included by Law no. 9,787, of 02/10/1999)

Sole Paragraph. In case of imported generic drugs whose bioequivalence testing has been performed overseas, the comparative dissolution tests between the test medication, the international reference drug used in the bioequivalence study, and the national reference drug shall be submitted until June 30th, 2003. (phrasing established by Law no. 10,669, of 05/14/2003)

Article 4. Products intended for use by children shall have packaging free of sharp parts and may not contain corrosive or irritating substances or come in the form of aerosol.

Article 5. The products herein addressed may not have names or designations that lead to mistakes. (phrasing established by Law no. 6,480, of 12/01/1977)

Paragraph 1. It is hereby forbidden to adopt equal or similar names for products with different compositions, even if produced by the same manufacturer; registration priority shall be given on the grounds of the chronological order of the registration applications submitted to the competent authority of the Ministry of Health, should no previous registration exist.

Paragraph 2. The product name whose registration has been requested later may be approved should the previous registration application have been rejected for technical or scientific reasons.

Paragraph 3. Should a trademark conflict have been proven, a change in the product name or designation shall be requested within 90 days, counted from the date of its publication on the Brazilian Official Gazette (DOU), under the penalty of registration rejection.

Paragraph 4. Notwithstanding the provisions of this Article, medications containing a sole widely known active substance, at the Ministry of Health's discretion, immunotherapeutic products, drugs, and pharmaceutical supplies shall be identified by the denomination provided in the Brazilian Pharmacopeia, being hereby prohibited to have commercial names or designations under any circumstances. (included by Law no. 6,480, of 12/01/1977)

Article 6. The proof that a certain product, until then considered useful, is harmful to health or does not meet the lawful requirements hereby requires its immediate withdraw from the market, as well as changes in the product composition and in the phrasings on labels, product inserts, and packaging, under the penalty of registration cancellation or product arrest in the entire national territory.

Sole Paragraph. Registrations and permissions to use medications shall be the Ministry of Health's exclusive assignment, as well as the approval or requirements to change their components.

Article 7. As a health surveillance safety measure and in view of well grounded reasons provided by the competent authority, the Ministry of Health may suspend at any time the manufacture or sales of any product herein addressed that, although registered, has been suspected of having harmful effects to human health.

Article 8. No establishment that manufactures or industrializes any product herein addressed may operate without effective assistance and responsibility of a legally licensed technical manager.

Article 9. The establishments herein addressed part of or created by the Public Administration shall not depend on operating permits and licenses, being, nonetheless, subject to the pertinent requirements as to adequate facilities, equipment, instruments, and technical assistance and responsibility.

Sole Paragraph. For the health surveillance control purposes addressed in the legislation in force, the communication to the Ministry of Health, by the bodies referred in this Article, about the existence or establishment of the facilities addressed in this Law is hereby mandatory.

Article 10. Medications, drugs, pharmaceutical supplies and other products herein addressed are hereby forbidden to be imported for

industrial and commercial purposes and without previous, clear and favorable statement of the Ministry of Health.

Sole Paragraph. The requirements of this Article also comprise acquisitions or donations that involve public or private persons and whose quantity and quality may compromise the implementation of national health programs.

Article 11. Drugs, medications and any medical pharmaceutical supplies, hygiene products, cosmetics, and household cleaning products, whether imported or not, shall solely be shipped for use in their original packaging or in other packaging previously authorized by the Ministry of Health.

Paragraph 1. In order to develop plans and programs of the Federal Government pertaining to the manufacture and shipping of medications to low-income populations, the Ministry of Health may authorize the use of special packaging and repackaging that enable cost reduction without affecting product purity and efficacy.

Paragraph 2. Imported products whose domestic commercialization does not depend on medical prescriptions shall have clarifying Portuguese phrasings about their composition, indications, and instructions for use added to their labeling.

TITLE II - Registration

Article 12. None of the products herein addressed, including those imported, may be manufactured, exhibited for sale or shipped for use before being registered at the Ministry of Health.

Paragraph 1. The registrations addressed in this Article shall be valid for five years and may be revalidated for equal and successive periods of time, remaining with their original registration number.

Paragraph 2. Registration and revalidation validity periods of dietary products are hereby not enclosed by the provisions of the previous paragraph, as their validity period is two years.

Paragraph 3. Registrations shall be granted within 90 days, counted from the date of application submission, except in cases of failure to comply with this Law and its regulations.

Paragraph 4. Acts referring to registrations and registration revalidations shall only have effects after the date of their publication on the Brazilian Official Gazette.

Paragraph 5. Registrations, their revalidations and their previous and control reviews, as appropriate, shall be subject to the payment of public service prices addressed in Article 82 hereof.

Paragraph 6. Registration revalidations shall be requested in the first semester of the fifth year (last year) of the registration validity period, being automatically granted regardless of the decision, should such decision has not been made until the registration expiration date.

Paragraph 7. Product registrations shall be declared expired if their revalidation request has not been submitted within the time frame set forth in Paragraph 6 of this Article.

Paragraph 8. Registrations of products that have not been industrialized within the first validity period shall not be revalidated.

Paragraph 9. Product composition, the used ingredients and their respective dose shall be compulsorily indicated upon product registrations addressed in this Article.

Article 13. Any change in the product composition, elements, or in their quantitativeness, any addition, subtraction, or innovation in the product shall depend on previous clear authorization of the Ministry or Health and shall be included in the registration application upon such authorization.

Article 14. Commercial names and designations of products licensed and manufactured before this Law has come into force are hereby exempt from the requirements hereof. (phrasing established by Decree no. 6,480, of 1201/1977)

Article 15. The registration application of the products herein addressed shall be rejected whenever the conditions, requirements, and procedures established in Law, regulations or instructions of the competent authority are not met.

TITLE III - Registration of Drugs, Medications, and Pharmaceutical Supplies

Article 16. Registrations of drugs, medications, pharmaceutical supplies and healthcare products are hereby subject to the following requirements, in addition to the compliance with their own requirements, given their sanitary, drug or prophylactic, curative and mitigating characteristics, or even their diagnostic purposes: (phrasing established by Law no. 10,742, of 10/06/2003)

I - products shall comply with the provisions in Article 5 hereof and its paragraphs. (phrasing established by Decree no. 6,480, of 12/01/1977)

II - products shall have their safety and efficacy scientifically and analytically proven for their intended use and shall have the required identity, activity, quality, purity, and innocuity;

III - in the case of a new product, wide information on its composition and intended use shall be provided for the assessment of its nature and determination of the required safety and efficacy levels;

IV - samples shall be submitted, whenever requested, for analyses and experiments considered necessary by the competent authorities of the Ministry of Health;

V - in the case of new substances in the composition of medications, samples shall be submitted along with chemical and physico-chemical data that identify them;

VI - in the case of drugs or medications whose production requires technical and specific apparatus, proves that the establishment is duly equipped and maintains trained personnel to handle such equipment or has hired subcontractors for this purpose shall be submitted;

VII - the following financial information shall be submitted: (phrasing established by Law no. 10,742, of 10/06/2003)

a) price of the product quoted by the company in other countries; (included by Law no. 10,742, of 10/06/2003)

b) paid price to acquire the product's active substance; (included by law no. 10,742, of 10/06/2003)

c) treatment cost per patient if using the product; (included by Law no. 10,742, of 10/06/2003)

d) potential number of patients to be treated; (included by Law no. 10,742, of 10/06/2003)

e) list of prices intended to be quoted in the domestic market, along with the discrimination of their tax burden; (included by Law no. 10,742, of 10/06/2003)

f) discrimination of the product commercialization proposal, including probable expenses related to sales, publicity, and marketing; (included by Law no. 10,742, of 10/06/2003)

g) price of the product that underwent changes, in the case of changes in its composition or presentation form; and (included by Law no. 10,742, of 10/06/2003)

h) list of all substitute products in the market and their respective prices. (included by Law no. 10,742, of 10/06/2003)

Paragraph 1. (Revoked as sole paragraph by Law no. 6,480, of December 1st, 1977). (included by Law no. 10,742, of 10/06/2003)

Paragraph 2. The submission of the information required in subsection VII may be partially or entirely dismissed according to the specific regulation. (included by Law no. 10,742, of 10/06/2003)

Article 17. The registration application of the products addressed in this Title shall be rejected whenever the conditions, requirements, and procedures established in Law, regulation or instructions of the competent authority are not met.

Article 18. Registrations of drugs, medications, and pharmaceutical supplies of foreign origin shall depend on the compliance with the conditions, requirements and procedures set forth in this Law and its regulation, as well as on the proof that the product is already registered in the country of origin.

Pargraph 1. Should it not be possible to comply with the **caput** of this Article, proof of a valid registration shall be submitted, provided by the health surveillance authority of the country where the product is commercialized or by an international health surveillance authority and approved by the National Health Surveillance Agency of the Ministry of Health. (included by Provisional Measure no. 2,190-34, of 2001)

Paragraph 2. Upon the registration of medications of foreign origin, the manufacturer shall submit proof of compliance with the Good Manufacturing Practices acknowledged within national territory. (included by Provisional Measure no. 2,190-34, of 2001)

Article 19. Registrations of drugs, medications, and pharmaceutical supplies shall be cancelled whenever an unauthorized change take place in the product composition, dose, manufacturing conditions, indications for use, and specifications declared in the product insert, label, or publicity.

Sole Paragraph. Should the composition, posology or therapeutic indications for use of technically elaborated pharmaceutical products need to be changed, the company shall request authorization to the Ministry of Health, supporting this request according to the regulation of this Law.

Article 20. Medications whose preparation requires special cares of purification, dose, sterilization, and storage shall only be registered, if:

I - their composition has a new substance;

II - their composition has an acknowledged substance to which a new or advantageous therapeutic application is given;

III - they improve their formula or presentation form from the pharmaceutical and/or therapeutic point of view.

Sole Paragraph. Medications that do not contain in their composition an acknowledged beneficial substance from the clinical or therapeutic point of view shall not be registered. (phrasing established by Law no. 9,782, of 01/26/1999)

Article 21. The right to register medications similar to others already registered is hereby enforced as long as the requirements hereof are met. (phrasing established by Law no. 9,782, of 01/26/1999)

Paragraph 1. Similar drugs to be manufactured in the country shall have their registrations granted 120 days after the submission date of their respective applications if not rejected until then. (included by Law no. 9,782, of 01/26/1999)

Paragraph 2. The aforementioned period for registration shall be interrupted until the applicant meets requirement of the health

surveillance authority, which may not exceed 180 days. (included by Law no. 9,782, of 01/26/1999)

Paragraph 3. The registration granted under the conditions of the previous paragraphs shall have its validity cancelled, regardless of notification or appeal, should the product not be commercialized within the period of one year after registration, postponable for six more months, at the health surveillance authority's discretion, upon written justification of the interested company. (included by Law no. 9,782, of 01/26/1999)

Paragraph 4. Application for a new registration may be submitted two years after verification of the fact that led to the expiration of that previously granted, unless not imputable to the interested company.(included by Law no. 9,782, of 01/26/1999)

Paragraph 5. The provisions of this Article are hereby applicable to products registered and manufactured in countries of MERCOSUR for domestic commercialization if the product corresponds to an already registered national similar product. (included by Law no. 9,782, of 01/26/1999)

Article 22. Drugs, medications and pharmaceutical supplies that contain narcotic substances, cause physical or mental dependence, and are subject to the special control addressed in Decree-Law no. 753, of August 11th, 1969, and to other legal instruments, regulations and other pertinent standards, as well as medications in general, shall have their registrations granted or renewed if their packaging and labeling meet the requirements approved by the Ministry of Health and if they comply with the conditions, requirements, and procedures established in this Law and in its regulation. (phrasing established by Law no. 10,742, of 10/06/2003)

Article 24. New medications exclusively intended for experimental use under medical control are hereby exempt from registration and may be imported after clear authorization of the Ministry of Health. (phrasing established by Law no. 10,742, of 10/06/2003)

Sole Paragraph. The aforementioned exemption shall solely be valid for a period up to three years, after which the product shall be compulsorily registered under the penalty of product arrest imposed by the Ministry of Health.

TITLE IV - Registration of Healthcare Products

Article 25. Devices, instruments, and accessories used in medicine, odontology, similar activities, physical education, beautification activities, and in aesthetic corrections may be solely manufactured, or imported in order to be shipped for use or for sales exhibitions after the Ministry of Health has announced whether their registration is mandatory or not.

Paragraph 1. The devices, instruments or accessories herein addressed shall be exempt from registration if included in lists compiled by the Ministry of Health for this purpose, being, nonetheless, still subject to health surveillance as to the other effects of this Law and its Regulation.

Paragraph 2. The regulation of this Law shall prescribe conditions, requirements, and procedures related to the registration of the devices, instruments, or accessories addressed in this Article.

TITLE V - Registration of Cosmetics, Hygiene Products, Perfumes, and others

Article 26. Only products intended for external or environmental use and in accordance with their aesthetic, protective, hygienic or odorous purposes, without causing skin irritations or harms to health, shall be registered as cosmetics, personal hygiene products, perfumes, and others with similar nature and intended uses.

Article 27. In addition to being subject to their specific regulatory requirements, registrations of cosmetics, personal hygiene products, perfumes, and other products with similar intended uses shall depend on the fulfillment of the following requirements:

I - they shall be included in the list of substances declared innocuous, compiled by the Ministry of Health's competent authority and published on the Brazilian Official Gazette, which shall contain the relevant specifications for each category, as well as for drugs, supplies, raw materials, dyes, solvents, and for other allowed substances in the manufacture of these products;

II - should they not be included in the aforementioned list, the innocuity of their formula shall be acknowledged in conclusive

technical and analytic opinions provided by the Ministry of Health's competent authorities.

Sole Paragraph. The list of substances referred in subsection I hereof may be changed in order to exclude substances that may come to be deemed as harmful to health or to include others that may come to be approved.

Article 28. Registrations of cosmetics, personal hygiene products, and other products with identical intended uses that contain medicinal substances, even if in lower therapeutic doses, shall comply with the requirements set forth in Articles 16, 17, 18, 19, 20, and 21 hereof and with the regulation of this Law.

Article 29. The products referred in Article 26 hereof shall only be registered if they contain in their composition raw materials, solvents, dyes or pharmaceutical supplies included in the list compiled by the Ministry of Health's competent authority, published on the Brazilian Official Gazette, and if their restrictions of use are clearly stated in their labels and packaging, as appropriate, according to the body part they shall be applied.

Sole Paragraph. When in the form of aerosol, the products referred in Article 26 hereof shall only be registered if they comply with the technical standards approved by the Ministry of Health and with other specific requirements and standards.

Article 30. Cosmetics, personal hygiene products intended for use by children and adults, perfumes, and similar products may have their formula changed, as long as the changes thereof be approved by the Ministry of Health on the grounds of competent technical reports.

Article 31. Changes in formulas shall be recorded in the product registration application in accordance with the provisions of regulations.

Article 32. The Ministry of Health shall publish on the Brazilian Official Gazette the list of the organic natural, artificial and synthetic dyes, including their salts and lacquers, allowed in the manufacture of the products addressed in Article 29 and 30 hereof.

Paragraph 1. Any and every dye that presents potential or active toxicity shall be precluded from the list referred in this Article.

Paragraph 2. The inclusion or exclusion of dyes and their consequences shall comply with the provisions of regulations.

TITLE VI - Registration of Household Cleaning Products

Article 33. Registrations of household cleaning products, disinfectants, and detergents shall comply with the provisions of regulations and with specific complementary standards.

Article 34. Only insecticides with the following features may be registered:

I - they shall be able to be correctly applied, in strict compliance with the instructions on their labels and with other explanatory elements;

II - they shall not have any possibility of posing risks to human life and to life of endothermic domestic animals if used as indicated;

III - they shall not be corrosive or harmful to treated surfaces.

Article 35 - Only insecticides that comply with the following may be registered:

I - they shall have their presentation forms addressed in the regulation of this Law;

II - insecticide and synergetic substances in their composition, whether natural or synthetic, shall observe the adequate concentration rates established by the Ministry of Health;

III - their composition formula shall follow the required precautions, observing their handling and therapeutic measures in case of accidents in order to indispensably preserve human life according to the instructions of the Ministry of Health.

Sole Paragraph. The regulation of this Law shall establish the requirements, conditions, and procedures for the registration of insecticides.

Article 36. For the purpose of registration of insecticides, the substances in their respective formula shall be considered the following:

I - solvents and extenders, used as vehicles for insecticide preparations;

II - propellants, propelling agents used in compressed preparations.

Article 37. The Ministry of Health shall compile and publish on the Brazilian Official Gazette the list of allowed solvents, extenders, and propellants, along with their maximum concentrations.

Article 38. Combinations of insecticides are hereby permitted and shall have the concentrations of their active elements proportionally reduced if they are from the same class.

Article 39 - Combinations of insecticides shall comply with the requirements of Article 35 hereof as to their toxicity for animals subject to efficiency testing.

Article 40. Registrations shall solely be granted to insecticides intended for the following:

I - domestic purposes, to be applied by any person;

II - professional purposes, to be applied and maintained by specialized person or organization.

Article 41. Preparations whose composition formulas include active, isolated or associated substances in several concentrations and in certain presentation types and forms shall be registered as raticides.

Sole Paragraph. Combinations of raticides from the same class shall be reduced in a proportional manner to the concentrations of their active principles.

Article 42. The provisions hereof are hereby applicable to registrations of raticides and other specific requirements for this product class shall be established in regulations and instructions provided by the Ministry of Health.

Article 43. Registrations of disinfectants shall be granted according to the provisions contained in the regulation of this Law and in instructions provided by the Ministry of Health.

Article 44. For the purposes of this Law, detergents, disinfectants and similar products intended to be applied to inanimate objects and environments are hereby deemed as household cleaning products, being hereby subject to the same requirements and conditions pertaining to their registration, industrialization, shipping for use, and inspection.

Article 45. The commercialization and shipping for use of raticides shall be exclusively restricted to those products classified as of low and medium toxicity, being hereby responsibility of specialized companies or of bodies and entities of the Direct and Indirect Public Administration the supply and application control of those classified as of high toxicity.

TITLE VII - Registration of Dietary Products

Article 46. Products intended for oral use whose sales or use depend on medical prescription shall be registered as dietary products if not enclosed by Decree-Law no. 986, of October 21st, 1969, and if intended for the following :

I - supplying special dietary needs;

II - supplementing and enriching usual feeding practices with vitamins, amino acids, minerals and other elements;

III - deceiving the feeling of hunger, appetite, and taste, replacing usual food in restriction diets.

Article 47. Only products constituted by the following shall be registered as dietary:

I - natural food modified in their composition or characteristics;

II - natural products, even if not considered usual food, containing nutrients or nutrient-added substances;

III - mineral or organic products, whether pure or associated, able to contribute for special regimen;

IV - isolated or associated substances, without nutritional value, intended for restriction diets;

V - food supplements with vitamins, minerals, or other nutrients;

VI - other products that may be characterized as dietary by the Ministry of Health, whether isolated or associated.

Article 48. The dietary products addressed herein may have the usual presentation forms of pharmaceutical products, observing their own nomenclature and characteristics.

Article 49. In order to ensure minimal required dietary efficiency and avoid to mistake dietary products for therapeutic products, the proportion of the components of dietary products, which justifies their indication for special diets, shall comply with the internationally accepted patterns, according to the lists compiled by the Ministry of Health.

Paragraph 1. Should no pattern have been established for the purposes of this Article, the nutritional rate of dietary products shall depend on the Ministry of Health's announcement.

Paragraph 2. The proportion of vitamins to be added to products shall correspond to the patterns established by the Ministry of Health.

TITLE VIII - Operating Permits and Sanitary Licenses

Article 50. The operation of the companies herein addressed shall depend on the operating permit granted by the Ministry of Health according to their respective industrial activity and product's nature and type, as well as on the proof of technical, scientific, and operational capability and on the compliance with other requirements made in regulations and administrative acts of this Ministry.

Sole Paragraph. The permit addressed in this Article shall be valid in the entire national territory and shall be renewed whenever there is a change or inclusion of activity or of business partner or director in the position of the company's legal representative.

Article 51. The license granted by the local authority to industrial or commercial establishments that perform the activities herein addressed shall depend on the operating permit granted by the Ministry of Health and on the compliance of each establishment with

the technical and sanitary requirements established in regulations or instructions of this Ministry, including those with regard to the effective assistance of technical managers licensed to several sectors of activities.

Sole Paragraph. Each establishment shall have specific and independent licenses, even if more than one belongs to the same company in the same location.

Article 52. The supplementary local legislation shall establish the requirements and conditions for the establishment licenses herein addressed, observing the following principles:

I - when one single establishment industrializes or commercializes products with different natures and intended uses, separate facilities shall be required for the manufacture and storage of materials, substances, and finished products;

II - adequate facility location and prohibition of residences and housings in their property and in adjacent areas;

III - previous approval from the state health authority for the projects and plants of buildings, and inspections to check their respective compliance.

TITLE IX - Technical Management

Article 53. Companies that conduct the activities herein addressed are hereby obliged to have sufficient legally licensed technical managers, qualitatively and quantitatively, to cover the different production processes in each establishment in an adequate manner.

Article 54. Technical managers are hereby responsible for preparing the report to be submitted to the Ministry of Health for product registration purposes and for providing effective technical assistance to the sector under their professional responsibility.

Article 55. Should the technical assistance cease to be provided to the establishment or should the establishment cease operations, the technical manager's liability for the acts performed until then shall endure for one year, counted from the date of ceasing.

Article 56. Regardless of other legal penalties, including those criminal, to which technical and administrative managers are subject, the

company shall be administratively and civilly liable for sanitary violations resulting from failure to observe this Law, its regulations and other complementary standards.

TITLE X – Labeling and Publicity

Article 57. The Executive Branch shall issue regulations on labeling, product inserts, brochures, labels and leaflets that regard the products herein addressed.

Sole Paragraph. In addition to the commercial name or trademark, medications shall compulsorily display their Brazilian Common Denomination or, if applicable, their International Common Denomination in the materials addressed in the **caput** of this Article, in packaging and in sales promotion materials, in font sizes never smaller than the half font size of their commercial name or trademark. (phrasing established by Provisional Measure no. 2,190-34, of 2001)

Article 58. Advertisements of the products regulated herein shall only be released after the authorization of the Ministry of Health and in accordance with the provisions of regulations, regardless of the used media for their disclosure and communication.

Paragraph 1. In the case of drugs, medications, and any other product that require medical or dental prescriptions to be sold, their advertisements shall exclusively target doctors, dental surgeons, and pharmacists.

Paragraph 2. The advertisement of over-the-counter drugs, dietary products, household cleaning products, cosmetics, and hygiene products shall be the scope of specific standards in regulations.

Article 59. Labeling and advertising materials of the products herein addressed shall not contain designations, geographic names, symbols, figures, drawings, or any indication that provide intended uses or characteristics different from those the product truly has and that may lead to misinterpretations, mistakes, or confusion as to the product origin, nature, composition, or quality.

TITLE XI – Packaging

Article 60. Packaging, equipment and devices internally elaborated or coated with substances that have contact with the product and may change its effects or may cause harm to health shall require the Ministry of Health's approval, according to the regulations.

Paragraph 1. Packaging of drugs, medications, pharmaceutical supplies, hygiene products, cosmetics, perfumes, and other similar products that do not contain internal substances able to change the product's purity and efficacy conditions are hereby exempt from the aforementioned approval.

Paragraph 2. The use of packaging that may cause direct or indirect harm to health for the packaging of drugs, medications or pharmaceutical supplies shall not be authorized.

Paragraph 3. The approval of the kind of packaging to be used shall be granted after previous analysis, as appropriate.

TITLE XII – Means of Transportation

Article 61. Should products require special storage and handling conditions, the vehicles used for transportation shall have equipment that enable storage and preservation conditions that ensure product purity, safety, and efficacy.

Sole Paragraph. The vehicles used for transportation of drugs, medications, pharmaceutical supplies, healthcare products, dietary products, hygiene products, perfumes, and others similar, shall ensure the required disinfecting and hygiene conditions to preserve human health.

TITLE XIII – Violations and Penalties

Article 62. Medications, drugs, and pharmaceutical supplies that undergo the following situations shall be considered changed, falsified, or improper for use:

I – the product has been mixed or packaged with substances that modify its therapeutic value or intended use;

II - when an element part of the normal composition has been partially or entirely eliminated, falsified or replaced by another of lower quality, when the dose is modified, or when a foreign substance

is added to the composition and changes the formula indicated in the registration application;

III – when the product volume does not correspond to that approved;

IV – when the conditions of product purity, quality, and authenticity do not meet the requirements contained in the Brazilian Pharmacopeia or in another Code adopted by the Ministry of Health.

Sole Paragraph. Should there be any change in the product due to environmental conditions or to actions unrelated to the technical manager or company, the latter is hereby obliged to immediately withdraw the product from the market for correction or replacement, under the penalty of committing sanitary violation.

Article 63. Hygiene products, cosmetics, perfumes, or others similar, shall be considered forged, falsified, or adulterated when:

I – they have indications that lead to errors, mistakes or confusion as to the product origin, composition, or intended use;

II – they do not observe the specifications contained in the registration application or patterns and paradigms established herein and in regulations;

III – they have changed the nature, composition, properties or characteristics that constituted the conditions for their registration by the addition, reduction, or elimination of raw materials or components.

Sole Paragraph. Supplies constituted by active, additive or complementary raw materials of chemical, biological or biochemical nature, whether natural or synthetic, or any other material intended for the manufacture, handling and improvement of hygiene products, cosmetics, perfumes, and others similar are hereby also enclosed by this Article.

Article 64. It is hereby forbidden to reuse containers previously used for food, beverage, sodas, dietary products, medications, drugs, chemical products, hygiene products, cosmetics, and perfumes for the packaging of sanitizers and other similar products.

Article 65. It is hereby forbidden to adopt new dates or to repackage expired products using new packaging, except therapeutic serums that may be dosed or filtered again.

Article 66. Failure to observe the provisions of this Law, of regulations and complementary standards, shall consist of sanitary violation, being the offender hereby subject to the proceedings and penalties set forth in Decree-Law no. 785, of August 25th, 1969, notwithstanding other applicable civil and criminal penalties.

Sole Paragraph. The proceedings addressed in this Article may be initiated and judged by the Ministry of Health or by State, Territory, or Federal District health surveillance authorities, as appropriate.

Article 67. Regardless of the provisions of Decree Law no. 785, of August 25th, 1969, the following practices punishable with the penalties indicated thereof shall constitute serious or very serious violations under the terms hereof:

I – to label the products within the scope of this Law or to advertise them without observing the provisions set forth herein or in regulations and contradicting the terms and conditions of their respective registration application or authorizations;

II – to change the product manufacturing process without previous authorization of the Ministry of Health;

III – to sell or exhibit expired products for sale;

IV – to adopt new dates for expired products or to repackage them using new packaging, except for therapeutic serums that may be dosed or filtered again;

V – to industrialize products without the assistance of a legally licensed technical manager;

VI – to use, in hormone preparations, organs of sick, exhausted or skinny animals, or of animals that are not sane or present signs of decompositions when manipulated;

VII – to resell biological products not stored in refrigerators according to the criteria established by the manufacturer and approved by the Ministry of Health;

VIII – to apply raticides, whose action is manifested by gas or vapor, in galleries, manholes, basements, or locations with possible connections with residences or spaces visited by human beings or domestic animals.

TITLE XIV – Law-Enforcement Inspections

Article 68. Health surveillance measures shall enclose any product herein addressed, including those exempt from registration, as well as healthcare products, establishments of manufacture, distribution, storage, sales, and vehicles for product transportation.

Sole Paragraph. The labeling, publicity, and advertisements of any product and trademark by any communication media are hereby equally subject to health surveillance measures.

Article 69. Law-enforcement inspections are responsibility of:

I – the federal health authority:

when the product is in transit from one state to another through rivers, lakes, ocean or air controlled by federal bodies;

in the case of imported or exported products;

in the case of sample collection for previous control and fiscal analysis;

II – the State, Territory, or Federal District health authority:

in the case of products industrialized or shipped for use within their respective jurisdiction;

in the case of industrial or commercial establishments, facilities, and equipment;

in the case of transportation through roads, rivers or lakes within their jurisdiction;

in the case of sample collection for fiscal analysis.

Sole Paragraph. The competences addressed in this Article may be delegated by the Federal, State and Federal District Government through mutual agreement, except in cases of powers clearly established in law as not delegable.

Article 70. Health surveillance actions shall be continuous, constituting a daily activity of health authorities.

Article 71. The duties and prerogatives of inspectors shall be established in the regulation of this Law.

Article 72. The investigation of violations shall be carried out, under the terms hereof, by the collection of samples and interdiction of the product and establishment, according to the provisions of regulations.

Paragraph 1. The proof of violation shall be the grounds, depending on the case, for product arrest and product destruction in the entire national territory, for product registration cancellation, and for annulment of the establishment license, which shall only be imposed after the publication on the Brazilian Official Gazette of unappealable conviction.

Paragraph 2. Changes resulting from natural or unforeseeable causes, circumstances and events that damage, deteriorate or contaminate products, making them ineffective or harmful to health, shall also be grounds for product arrest, interdiction and destruction.

Article 73. For the purposes of health surveillance inspection, the tests intended to verify the efficiency of the formula shall be performed according to the standards established by the Ministry of Health.

Article 74. Public servants who are business partners, shareholders or stakeholders, in any way, of companies that perform activities subject to this Law or who provide them services, with or without employment contract, may not serve health surveillance inspecting bodies or controlling laboratories.

TITLE XV - Drug Quality Control

Article 75. The Ministry of Health shall establish standards and shall improve the mechanisms intended to assure costumers of drug quality, taking into account product identity, activity, purity, efficacy and innocuity and enclosing the specifications for product inspection and quality.

Sole Paragraph. The standards addressed in this Article shall determine the quality specifications for raw materials and in-process

products used in the manufacture of medications, and for medications themselves, and shall precisely describe their acceptance criteria.

Article 76. No raw materials or in-process products may be used in the manufacture of medications without having had their quality verified and accepted according to the evidence that shall be object of the Ministry of Health's standards.

Article 77. Inspections of production of medications shall target, at first, the following aspects:

I – the manufacturing process, taking into account the unfavorable intrinsic and extrinsic factors, including the possibility of raw material, in-process product, and finished product contaminations;

II – finished products, in order to verify compliance with the requirements pertinent to technical managers responsible for product production and inspections, to facilities and equipment, environmental cleaning, raw materials, inspection and self-inspection systems, and medication registration.

Article 78. Notwithstanding the Public Authorities' control and inspections, all establishments that manufacture medications shall have a technical department for quality inspection, which shall have independent competence to verify the quality of raw materials or substances, to monitor the quantitative operational aspects of the manufactured medications, and to perform other required tests.

Sole Paragraph. Industrial pharmaceutical laboratories may exercise the controls addressed in this Article in official institutes or laboratories by means of a contract or agreement.

Article 79. All reports on accidents or harmful reactions caused by medications shall be delivered to the competent health surveillance authority.

Sole Paragraph. Changes made in the quality of medications and any alteration in their physical characteristics shall be investigated in a detailed manner and, after proven, they shall be object of the applicable corrective measures.

TITLE XVI – Health Surveillance Bodies

Article 80. The health surveillance activities herein addressed shall be conducted by the following:

I – in the federal sphere, by the Ministry of Health, according to the legislation and regulations;

II – in States, Territories, and Federal District, by their own health surveillance bodies, according to the pertinent federal standards and to the supplementary local legislation.

TITLE XVII – Final and Temporary Provisions

Article 81. Companies that already explore the activities herein addressed in this Law shall have the period of 12 months to make the necessary changes and adaptations in order to comply with the provisions hereof.

Article 83. Drugs, chemical products and magistral formulations shall be sold in their original packaging and may only be fractioned in commercial establishments for reselling, under the direct responsibility of their respective technical manager.

Article 84. The provisions hereof shall not preclude the application of other standards to which the activities herein addressed may be subject, as to the aspects of specific legislation.

Article 85. The previsions hereof are hereby applicable, as appropriate, to the products addressed in Article 1 hereof that are regulated by special standards.

Article 86. Phytosanitary and zoosanitary products, products for exclusive veterinary use and those intended for prevention of rats and other rodents in agriculture are hereby exempt from the requirements hereof if they are intended and applicable for different purposes from those herein established.

Article 87. The Executive Branch shall pass the necessary acts and regulations for proper compliance with this Law.

Sole Paragraph. While the regulations and acts addressed in this Article have not been passed, the current legal instruments shall continue in force if not conflicting with the provisions hereof.

Article 88. This Law shall come into force 95 days after its publication and all provisions to the contrary are hereby revoked.

Brasília, September 23rd, 1976; 155th year of Independence and 88th year of Republic.

ERNESTO GEISEL
Paulo de Almeida Machado