Presidency of the Republic
Office of Civil Affairs
Sub Office for Legal Affairs

PROVISIONAL MEASURE Nº 2.190-34, OF AUGUST 23, 2001.

Amends provisions of Law nº 9.782, of January 26, 1999, that defines the National Agency for Sanitary Oversight and creates a National Agency for Sanitary Oversight, and of Law nº 6.437, of August 20, 1977, that delineates infractions of federal sanitary legislation and establishes the respective sanctions, as well as setting forth other arrangements.

THE PRESIDENT OF THE REPUBLIC, in the exercise of the powers vested in him by Article 62 of the Constitution, has hereby adopted the following Provisional Measure, with the force of law:

Art. 1 The following provisions set forth in Law nº 9.782, of January 26, 1999, are hereby to take effect with the following amendments::

"Art. 3 The National Agency for Sanitary Oversight – ANVISA is hereby created, a government agency subject to a special regime, associated with the Ministry of Health, with its headquarters and jurisdiction in the Federal District, with an indefinite period of duration and to conduct its activities throughout the entire national territory.

....**." (New Rendering - NR)**

"Art. 7 .....

.....

VII – to authorize the operation of companies engaged in manufacturing, distributing and importing the products mentioned in Article 8 of this Law and the sale of medications;

.....

XXV – to monitor the evolution of prices for medications, equipment, components, inputs and health services, and to such end it is authorized:

a) to requisition, when it may deem it necessary, information concerning production, inputs, raw materials, sales and any other data, in the possession of people in a public or private capacity who are engaged in activities of production, distribution and sale of goods and services covered by this sub-paragraph, maintaining legal confidentiality, when applicable;

b) to undertake the examination of inventories, papers and documents of any countries or persons in a public or private capacity who are engaged in activities of production, distribution and sale of the goods and services covered by this sub-paragraph, maintaining legal confidentiality, when applicable;

c) when existence is verified of evidence of the infractions that are mentioned in sub-paragraphs III or IV of Article 20 of Law nº 8.884, of June 11, 1994, having taken place due to an unjustified increase in prices or the charging of excessive prices for the goods and services referred to in these sub-paragraphs, to summon those responsible to justify the conduct in question within a period not greater than ten business days;

d) to apply the penalty set forth in Article 26 of Law nº 8.884, of 1994;

XXVI – to control, inspect and monitor advertising and publicity for products subject to the regime of sanitary oversight in the light of health legislation;

XXVII – to determine in a ruling places for entry into and departure from the country for narcotics, psychotropics and precursors, having consulted with the Department of Federal Police and the Secretary of Federal Revenue.

.....

§ 4 The Agency can delegate to an organ of the Ministry of Health the execution of the duties set forth in this article relating to doctor, outpatient and hospital services indicated in §§ 2 and 3 of Article 8, observing the prohibitions set forth in § 1 of this article.

§ 5 The Agency must undertake its activities always in observance of the guidelines established by Law nº 8.080, of September 19, 1990, to follow up on the process of decentralization of the execution of activities for the States, the Federal District and Municipalities, observing the prohibitions set forth in § 1 of this article.

§ 6 The decentralization mentioned in § 5 is to be put into effect only after approval by the respective State, District and Municipal Councils of Health."(NR)

"Art. 8 .....

.....

§ 5 The Agency may dispense with the registration of immunobiological products, insecticides, medications and other strategic inputs when they are acquired through multilateral international agencies for use in public health programs by the Ministry of Health and its associated institutions.

§ 6 The Minister of State for Health can require performance of actions that fall within the competencies of the National Agency for Sanitary Oversight in specific cases involving a risk to public health.

§ 7 The enactment mentioned in § 6 must be published in the Official Diary of the Union (DOU)

§ 8 The Services and facilities subject to control and health inspection are those involved in port, airport and border activities, as well as immigration stations and customs terminals, and water, land and air transportation services." (NR)

"Art. 9 .....

Sole paragraph. The Agency shall also have a Consulting Council which is to include at a minimum representatives of the National Government, the States, the Federal District, the

Municipalities, producers, businesses, the scientific community and users as indicated in the regulation.” (NR)

"Art. 15. The following things fall within the competency of the Collegiate Directorate:

I – to define the strategic guidelines of the Agency;

II – to propose to the Minister of State for Health the governmental policies and guidelines intended to enable the Agency to achieve its objectives;

III – to publish standards that fall within the competency of the Agency;

IV – to comply with and enforce compliance with standards concerning sanitary oversight;

V – to prepare and disseminate periodic reports on its activities;

VI – to consider appeals of decisions by the Agency, upon petition of the interested parties;

VII – to forward the financial statements of the Agency to the competent authorities.

§ 1 The Directorate shall be required to convene with the presence of at least three Directors, among them the Director-President or his legal substitute, and they shall arrive at decisions based on a simple majority.

§ 2 The decisions enacted by the Agency shall be subject to appeal to the Collegiate Directorate, with a suspensive effect, as the last administrative instance.” (NR)

"Art. 16. The following things fall within the competency of the Director-President:

I – to represent the Agency in or out of court;

II – to preside over meetings of the Collegiate Directorate;

III – to decide urgent matters provisionally, subject to approval by the Collegiate Directorate;

IV – to cast the deciding vote in cases of tied votes of the Collegiate Directorate;

V – to appoint and dismiss employees, filling staff positions either with career civil servants or naming trusted associates, and to exercise disciplinary authority pursuant to the terms of the legislation in force;

VI – to forward to the Consulting Council periodic reports prepared by the Collegiate Directorate;

VII – to sign contracts and agreements and to order expenditures;

VIII – to draft, approve and promulgate internal regulations, define the scope of activity of organizational units and the executive structure of the Agency;

IX – to conduct the operational management of the Agency." (NR)

"Art. 19. The Administration of the Agency shall be governed by a management contract negotiated between its Director-President and the Minister of State for Health, in consultation with the Ministers of State for the Treasury and Planning, Budget and Management, within a period of no more than one hundred and twenty days following the appointment of the Director-President of the agency.

....." (NR)

"Art. 22. .....

.....

X – the earnings taken in through applications in the financial market from revenues mentioned in sub-paragraphs I to IV and VI to IX of this article.

....." (NR)

"Art. 23. .....

.....

§ 4 The fee should be collected pursuant to the terms specified in a ruling enacted by ANVISA.

.....

§ 6 Laboratories established or controlled by the Government, producers of medications and inputs subject to Law nº 6.360, of September 23, 1976, in the interest of public health, are exempt from payment of the Enforcement Tax for Sanitary Oversight..

§ 7 Renewals of registrations, permits and certificates are subject to the periods of expiration and the fees stipulated for the initial applications, as set forth in the Annex.

§ 8 The provision of § 7 is applicable to what is set forth in §§ 1 to 8 of Article 12 and the sole paragraph of Article 50 of Law nº 6.360, of 1976, in § 2 of Article 3 of Decree-Law nº 986, of October 21, 1969, and § 3 of Article 41 of this Law." (NR)

"Art. 30. As soon as the National Agency for Sanitary Oversight is established with the publication of its internal regimen by the Collegiate Directorate, the Institution shall automatically be invested with the exercise of its duties and the Secretary of Sanitary Oversight will be terminated." (NR)

"Art. 41. .....

§ 1 The Agency shall be authorized to grant operating permits to companies and registration for products that are applicable only to manufacturing facilities and merchandise intended for foreign markets, as long as they do not pose any risks to public health.

§ 2 The regulation referred to in the **heading** of this article is also applicable to exemptions from registration.

§ 3 Companies subject to Decree-Law nº 986, of 1969, are also obliged to comply with Article 2 of Law nº 6.360, of 1976, with regard to authorization for operation by the Ministry of Health and licensing by the health agencies of the States where they are located." (NR)

Art. 2 Law nº 9.782, of 1999, is to take effect with the following articles appended:

"Art. 41-A. The registration of medications with exclusively generic names shall have priority over others, pursuant to what is set forth in a ruling enacted by the Collegiate Directorate of the National Agency for Sanitary Oversight." (NR)

"Art. 41-B. When the sale of products subject to sanitary oversight that are inappropriate for consumption is ascertained, the company responsible shall be obliged to publish an advertisement containing an alert to the public, within the period and pursuant to the terms indicated by the health authority, and it shall be subject to payment of the fee for the test and prior approval of the informational content by the National Agency for Sanitary Oversight." (NR)

Art. 3 The National Institute for Quality Control in Health shall be subordinate in technical matters to the National Agency for Sanitary Oversight, and in administrative matters to the Oswaldo Cruz Foundation.

Sole paragraph. Assignments to positions for career civil servants as well appointments for remunerated posts filled by outside individuals at the National Institute for Quality Control in Health shall fall within the competence of the Minister of State for Health, by nomination of the Director-President of the National Agency for Sanitary Oversight, in consultation with the President of the Oswaldo Cruz Foundation.

Art. 4 Food products imported in their original packaging shall have March 1st, 2000 as the cutoff date for the regularization of their registration status with the National Agency for Sanitary Oversight.

Art. 5 Staff members on the personnel rosters of the Ministry of Health and the National Health Foundation employed as of December 31, 1998, at the Secretary of Health Oversight and at the Airport, Port and Border Units shall be reassigned to the National Agency for Sanitary Oversight.

§ 1 The staff members of the National Health Foundation, reassigned in accordance with what is set forth in the **heading**, shall be incorporated into the same organizational structure as staff members from the Ministry of Health.

§ 2 If the job reclassification noted in § 1 provides lower salaries than those previously received, the difference will be paid as a distribution specified on the payroll, applying thereto the same percentages as the general salary increase for public servants, or through payment in advance of the salary adjustment

Art. 6 Annex II of Law nº 9.782, of 1999, is to take effect in accordance with the Annex to this Provisional Measure.

Art. 7 Articles 2 and 3 of Law nº 9.294, of July 15, 1996, are to take effect with the following text:

"Art. 2 .....

.....

§ 2 It is forbidden to use the products mentioned in the **heading** in aircraft and vehicles of public transportation." (NR)

"Art. 3 .....

.....

§ 2 Advertising in the media shall contain, depending on its characteristics, a warning, whenever possible both spoken and written, on the harmful effects of smoking, alcoholic beverages, medications, therapies and pesticides, using sentences established by the, Ministry of Health, presented sequentially, either simultaneously or on a rotating basis.

§ 3 Packaging and packs of smoking products, with the exception of those intended for export, and the material of the advertising referred to in the heading of this article shall contain the warning mentioned in § 2 accompanied by images or figures that illustrate the meaning of the message.

....." (NR)

Art. 8 Article 7 of Law nº 9.294, of 1996, is to take effect with the following § 4 appended, renumbering the current § 4 to § 5:

"§ 4 Advertising is allowed for generic medications in publicity campaigns sponsored by the Ministry of Health and in places within establishments that are authorized to dispense them, with due indication of the reference medication." (NR)

Art. 9 Articles 3, 18 and 57 of Law nº 6.360, of September 23, 1976, are to take effect with the following amendments:

"Art. 3 .....

.....

XX - Similar Medication – those medications that contain the same active ingredient(s), present the same concentration, pharmaceutical form, method of administration, posology and therapeutic indication, and that are equivalent to the medication registered with the federal agency responsible for sanitary oversight, can only differ in characteristics relating to size and shape of the product, expiration date, packaging, labeling, excipients and vehicles, and must always be identified by commercial name or brand;

.....

Sole paragraph. In the case of generic imported medications whose bioequivalence tests were performed outside the country, the comparative dissolution tests must be presented involving the test medication, the international reference medication used in the bioequivalence study and the national reference medication." (NR)

"Art. 18. .....

§ 1º If it is not possible to comply with what is set forth in the **heading** of this article, proof of the registration in effect must be presented, issued by the health authority of the country in which it is sold or by an international health authority, and approved in a ruling enacted by the National Agency for Sanitary Oversight of the Ministry of Health.

§ 2º In the registration application for the medication of foreign origin, the manufacturing company must submit proof of compliance with Good Manufacturing Practices recognized in this country." (NR)

"Art. 57. .....

Sole paragraph. In addition to the commercial name or brand, in the pieces mentioned in the **heading** of this article medications must display on packages and promotional materials the Common Brazilian Name, or, when appropriate, the Common International Name, in letters and characters never smaller than half the size of the letters and characters of the commercial name or brand." (NR)

Art. 10. The **heading** of Article 2 of Law nº 9.787, of February 10, 1999, is to take effect with the following text:

"Art. 2 The federal agency responsible for sanitary oversight shall issue regulations within a period of one hundred and eighty days, counting from February 11, 1999:" (NR)

Art. 11. Distributors of medications shall be subject to the provisions of Article 15 of Law nº 5.991, of December 17, 1973.

Art. 12. Articles 2 and 10 of Law nº 6.437, August 20, 1977, are to take effect with the following text:

"Art. 2 .....

.....

XII – requirement of a message of correction;

XIII – suspension of advertising and publicity.

§ 1º The penalty of a fine shall entail payment of the following amounts:

I – for small infractions, from R$ 2,000.00 (two thousand reals) to R$ 75,000.00 (seventy five thousand reals);

II – for serious infractions, from R$ 75,000.00 (seventy five thousand reals) to R$ 200,000.00 (two hundred thousand reals);

III – for extremely serious infractions, from R$ 200,000.00 (two hundred thousand reals) to R$ 1,500,000.00 (one million five hundred thousand reals).

§ 2 The fines set forth in this article shall be doubled in the event of repeat offenses.

§ 3 Without impairment to what is set forth in Articles 4 and 6 of this Law, in the application of the penalty of a fine the competent health authority shall take into consideration the economic capacity of the offender." (NR)

"Art. 10. .....

.....

V - .....

penalty - warning, prohibition of advertising, suspension of sales, requirement of corrective message, suspension of advertising and publicity, and a fine." (NR)

.....

XVIII – to import or export, display for sale or deliver for consumption health-related products whose period of validity has expired, or to write in new dates after the period has expired;

.....

XXVIII - .....

penalty - warning, seizure, rendering the product unusable and/or banning it; suspension of sales and/or manufacture of the product, cancellation of product registration, partial or total banning of the establishment, cancellation of the company's federal operating permit, cancellation of the establishment's state operating license and/or fine;

XXIX - .....

penalty - warning, seizure, rendering the product unusable and/or banning it; suspension of sales and/or manufacture of the product, cancellation of product registration, partial or total banning of the establishment, cancellation of the company's federal operating permit, cancellation of the establishment's state operating license, prohibition of advertising, and/or fine;

XXX - .....

penalty - warning, seizure and or banning of the product, suspension of sales and/or manufacture of the product, cancellation of product registration, partial or total banning of the establishment, cancellation of the company's federal operating permit, cancellation of the establishment's state operating license, and/or fine;

XXXI - .....

penalty - warning, seizure, rendering the product unusable and/or banning it; suspension of sales and/or manufacture of the product, cancellation of product registration, partial or total banning of the establishment, cancellation of the company's federal operating permit, cancellation of the establishment's state operating license, prohibition of advertising , and/or fine;

XXXII – non-compliance with legal and regulatory provisions, measures, formal requirements, other health requirements, by natural or juridical persons who provide services relating to public health on ships, aircraft, land vehicles, customs terminals, airport or port terminals, border stations and crossings and facilities for servicing land vehicles:

penalty- warning, banning, cancellation of operating permit and/or fine;

XXXIII - non-compliance with legal and regulatory provisions, measures, formal requirements, other health requirements, by companies administering customs terminals, airport or port terminals, border stations and crossings and facilities for servicing land vehicles:

penalty- warning, banning, cancellation of federal operating permit and/or fine;

XXXIV - non-compliance with legal and regulatory provisions, measures, formal requirements, other health requirements relating to importation or exportation, by natural or juridical persons, of raw materials or products subject to sanitary oversight:

penalty- warning, seizure, rendering unusable, banning, cancellation of federal operating permit, cancellation of product registration and/or fine;

XXXV - non-compliance with legal and regulatory provisions, measures, formal requirements, other health requirements concerning establishments and good manufacturing practices for raw materials and products subject to sanitary oversight:

penalty- warning, seizure, rendering unusable, banning, cancellation of federal operating permit, cancellation of product registration and/or fine;

XXXVI – undertaking to change the establishment for the storage of the imported product subject to a ban, without authorization of the competent health agency:

penalty- warning, seizure, rendering unusable, banning, cancellation of federal operating permit, cancellation of product registration and/or fine;

XXXVII - undertaking sale of an imported product subject to a ban:

penalty- warning, seizure, rendering unusable, banning, cancellation of federal operating permit, cancellation of product registration and/or fine;

XXXVIII – in establishments intended for the storage and/or distribution of products subject to sanitary oversight, failure to ensure the maintenance of standards of identity and quality of imported products subject to a ban or awaiting physical inspection:

penalty- warning, seizure, rendering unusable, banning, cancellation of federal operating permit, cancellation of product registration and/or fine;

XXXIX – interrupting, suspending or reducing without just cause the production or distribution of red label low-risk prescription medications that are for continuous use or essential to the health of an individual, or of black label high-risk prescription medications, bringing about a market shortage:

penalty- warning, total or partial banning of the establishment, cancellation of product registration, cancellation of company's federal operating permit, cancellation of the establishment's state operating license and/or fine;

XL – failure to communicate to the agency of sanitary oversight of the Ministry of Health the interruption, suspension or reduction of manufacturing or distribution of medications referred to in sub-paragraph XXXIX:

penalty- warning, total or partial banning of the establishment, cancellation of product registration, cancellation of the company's federal operating permit, cancellation of the establishment's state operating license and/or fine;

XLI - non-compliance with legal and regulatory provisions, measures, formal requirements, other health requirements, by natural or juridical persons, engaged in providing services relating to public health on ships, aircraft, land vehicles, customs terminals, airport or port terminals, border stations and crossings and facilities for servicing land vehicles:

penalty- warning, total or partial banning of the establishment, cancellation of product registration, cancellation of the company's federal operating permit, cancellation of the establishment's state operating license and/or fine.

....." (NR)

Art. 13. Rulings enacted on the basis of Provisional Measure nº 2.190-33, of July 26, 2001. are hereby validated.

Art. 14. This Provisional Measure enters into force on the date of its publication.

Art. 15. Articles 9 and 10 of Decree-Law nº 891, of November 25, 1938, Article 4 of Decree-Law nº 986, of October 21, 1969, Article 82 of Law nº 6.360, of September 23, 1976, Article 3 of Law nº 9.005, of March 16, 1995, the sole paragraph of Article 5, the sub-paragraphs XI, XII and XIII of Article 7, Articles 32 and 39 and their paragraphs and Annex I of Law nº 9.782, of January 26, 1999 are hereby rescinded.

Brasília, August 23, 2001; 180th year of Independence, and 113th year of the Republic.

FERNANDO HENRIQUE CARDOSO
José Serra
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This text does not replace the text published in the D.O.U. bulletin on August 24, 2001

ANNEX

ENFORCEMENT OF TAX FOR SANITARY OVERSIGHT

Items	OCCASIONS FOR COLLECTION	Amounts in R$	Period for Renewal
1			
1.1	Registration of foodstuffs, food additives, beverages, bottled water and recycled packaging	6,000	Five years
1.2	Alteration, inclusion or exemption of registration of foodstuffs	1,800	---
1.3	Revalidation or renewal of registration of foodstuffs	6,000	Five years
1.4	Certification of Good Manufacturing Practices for each establishment or manufacturing unit, by product line of foodstuffs		
1.4.1	In Brazil and MERCOSUL countries		
1.4.1.1	Certification of Good Manufacturing Practices and Control for each establishment or manufacturing unit, by type of activity and product	15.000	Annual

	line or sale line for industries of foodstuffs		
1.4.2	Other countries	37.000	Annual
2			
2.1	Registration of cosmetics	2.500	Five years
2.2	Alteration, inclusion or exemption of registration of cosmetics	1,800	---
2.3	Revalidation or renewal of registration of cosmetics	2.500	Five years
2.4	Certification of Good Manufacturing Practices for each establishment or manufacturing unit, by product line of cosmetics		
2.4.1	In Brazil and MERCOSUL countries		
2.4.1.1	Certification of Good Manufacturing Practices for each establishment or manufacturing unit by product line of cosmetics, hygiene products and perfumes	15.000	Annual
2.4.2	Other countries	37.000	Annual
3			
3.1	**Operating permits and special operating permits for companies, as well as their respective renewals**	---	---
3.1.1	Medication industry	20.000	---
3.1.2	Pharmaceutical inputs industry	20.000	---
3.1.3	Distributor, importer, exporter, transporter, warehouse operator, packager and repackager and others provided for in specific legislation on medications and pharmaceutical inputs	15.000	Annual
3.1.4	Fractionation of pharmaceutical inputs	15.000	Annual
3.1.5	Drugstores and pharmacies	500	Annual
3.1.6	Industry of cosmetics, hygiene products and perfumes	6,000	---
3.1.7	Distributor, importer, exporter, transporter, warehouse operator, packager, and repackager and others provided for in specific legislation regarding cosmetics, hygiene products and perfumes	6,000	---
3.1.8	Cleaning products industry	6,000	---
3.1.9	**Distributor, importer, exporter, transporter, warehouse operator, packager, and repackager and others provided for in specific legislation regarding cleaning products**	6,000	---
3.2	Operating permit and special operating permit for prescription pharmacies	5.000	Annual
4			
4.1	Registration, revalidation and renewal of registration of medications		
4.1.1	New products	80.000	Five years
4.1.2	Similar products	21.000	Five years
4.1.3	Generic medications	6,000	Five years
4.1.4	A new association in Brazil	21.000	---
4.1.5	A monodrug approved for association	21.000	---
4.1.6	New way of administering medication in Brazil.	21.000	---
4.1.7	New concentration in Brazil	21.000	---
4.1.8	New pharmaceutical form in Brazil	21.000	---
4.1.9	Phytotherapeutic medications		
4.1.9.1	New products	6,000	Five years
4.1.9.2	Similar products	6,000	Five years
4.1.9.3	Traditional products	6,000	Five years
4.1.10	Homeopathic medications		

4.1.10.1	New products	6,000	Five years
4.1.10.2	Similar products	6,000	Five years
4.1.11	New processing in Brazil	1,800	---
4.2	Alteration, inclusion or exemption of registration of medications	1,800	---
4.3	Certification of Good Manufacturing Practices for each establishment or manufacturing unit, by product line of medications		
4.3.1	In Brazil and MERCOSUL countries		
4.3.2	Certification of Good Manufacturing Practices of medications and pharmaceutical inputs	15.000	Annual
4.3.3	Other countries	37.000	Annual
4.3.4	Certification of Good Distribution and Storage Practices of medications and pharmaceutical inputs by establishment	15.000	Annual
5			
5.1	Operating Permits		
5.1.1	Operating permit for companies providing storage and distribution services for medications, raw materials and pharmaceutical inputs in customs terminals open to the public	15.000	Annual
5.1.2	Operating permit for companies providing storage and distribution services for substances and medications subject to special control in customs terminals open to the public	15.000	Annual
5.1.3	Operating permit for companies providing storage and distribution services for cosmetics, hygiene products or perfumes and raw materials in customs terminals open to the public	6,000	Annual
5.1.4	Operating permit for companies providing storage and distribution services for household cleaning products and raw materials in customs terminals open to the public	6,000	Annual
5.1.5	Operating permit for companies providing storage and distribution services for medical-hospital materials and equipment and “in vitro” diagnostic products (correlatives) in customs terminals open to the public	6,000	Annual
5.1.6	Operating permit for companies providing storage and distribution services for foodstuffs in customs terminals open to the public	6,000	Annual
5.1.7	Operating permit for companies providing alternative services for provision of drinking water for human consumption on board aircraft, ships and land vehicles providing international passenger service	6,000	Annual
5.1.8	Operating permit for companies providing services of insect or rat extermination on ships, land vehicles in transit through border stations and crossings, aircraft, port and airport terminals for freight and passengers, customs terminals open to the public and border stations and crossings	6,000	Annual
5.1.9	Operating permit for companies providing cleaning, disinfection and decontamination services of surfaces of aircraft, land vehicles in transit through border stations and crossings, ships, port and airport terminals for freight and passengers, customs terminals open to the public and border stations and crossings	6,000	Annual
5.1.10	Operating permit for companies providing cleaning services and removal of wastes from treatment of used water and discharges in port and airport terminals for freight and passengers, customs terminals open to the public and border stations and crossings	6,000	Annual
5.1.11	Operating permit for companies providing sewage and sewage treatment services for aircraft, ships and land vehicles in transit through border stations and crossings in airport and port terminals, as well as border stations and crossings	6,000	Annual
5.1.12	Operating permit for companies providing services for the separation, retrieval, processing, storage, transport, treatment and final disposal of solid waste from aircraft, land vehicles in transit through border stations and crossings, ships, port and airport terminals for freight and passengers, customs terminals open to the	6,000	Annual

	public and border stations and crossings		
5.1.13	Operating permit for companies providing services in port and airport areas, border stations and crossings, for laundry, medical care, lodging, drugs, pharmacies and herbal products, sale of hospital materials and equipment, barbers and hair dressers, manicures, beauty salons and the like	500	Annual
5.1.14	Operating permit for surrogate companies to manage, represent or administer transactions on behalf of a shipping company, making the necessary arrangements in port for shipment of freight (a shipping agency)	6,000	Annual
5.2	Approval in process for the import of products subject to sanitary oversight		
5.2.1	Approval for import by a juridical person of goods, products, raw materials and inputs subject to sanitary oversight, for purposes of sale or industrial processing		
5.2.1.1	Import of up to ten items of goods, products, raw materials or inputs	100	---
5.2.1.2	Import of from eleven to twenty items of goods, products, raw materials or inputs	200	---
5.2.1.3	Import of from twenty one to thirty items of goods, products, raw materials or inputs	300	---
5.2.1.4	Import of from thirty one to fifty items of goods, products, raw materials or inputs	1.000	---
5.2.1.5	Import of from fifty one to one hundred items of goods, products, raw materials or inputs	2.000	---
5.3	Approval for import by a natural person of medical-hospital materials and equipment and “in vitro” diagnostic products subject to sanitary oversight for purposes of provision and sale of services to third parties.	100	---
5.4	Approval for import by hospitals and private health institutions of medical-hospital materials and equipment “in vitro” diagnostic products subject to sanitary oversight, provision and sale of services to third parties	100	---
5.5	Approval for import and export by natural persons of products or raw materials subject to sanitary oversight for purposes of individual or own use	EXEMPT	---
5.6	Approval for import by a juridical person of samples of products or raw materials subject to sanitary oversight for analysis and experimentation, with the aim of product registration	100	---
5.7	Approval for import by a juridical person of samples of products or raw materials subject to sanitary oversight for purposes of demonstration at trade fairs and public events	100	---
5.8	Approval for import by a juridical person of samples of products subject to sanitary oversight for purposes of demonstration for specialized professionals	100	---
5.9	Approval in process for export of products subject to sanitary oversight	---	---
5.9.1	Approval for export by juridical person of goods, products, raw materials and inputs subject to sanitary oversight for purposes of sale or industrial processing	EXEMPT	---
5.9.2	Approval for export by juridical person of samples of goods, products, raw materials or inputs subject to sanitary oversight for analysis and experimentation with the aim of product registration	EXEMPT	---
5.9.3	Approval for export by juridical person of samples of products or raw materials subject to sanitary oversight for purposes of demonstration at trade fairs or public events	EXEMPT	---
5.9.4	Approval for export by juridical person of product samples subject to sanitary oversight for purposes of demonstration to specialized professionals	EXEMPT	---
5.9.5	Approval for export and import by juridical person of human		

	biological samples for purposes of conducting laboratory tests and experiments		
5.9.5.1	Export and import of a maximum of twenty samples	100	---
5.9.5.2	Export and import of from twenty one to fifty samples	200	---
5.9.6	Approval of export by public research institutions of human biological samples for purposes of conducting laboratory tests and experiments	EXEMPT	---
5.9.7	Approval of substitute import license involving processes for the import of products and raw materials subject to sanitary oversight	50	---
5.10	Harvest and transport of samples for laboratory analysis of imported products subject to control analysis		
5.10.1	Within the Municipality	150	---
5.10.2	To another Municipality in the same State	300	---
5.10.3	Another State	600	---
5.11	Inspection for verification of compliance with sanitary requirements relating to lifting the ban on imported products stored in an area external to the customs terminal of public use		
5.11.1	Within the Municipality	150	---
5.11.2	To another Municipality in the same State	300	---
5.11.3	Another State	600	---
5.12	Inspection every six months to verify compliance with sanitary requirements concerning sanitary-hygienic conditions of platforms comprising facilities or structures, fixed or mobile, located in waters under national jurisdiction, intended for direct or indirect activities of surveying and extraction of mineral resources coming from the bottom of inland waterways or their subsoil, or the seabed, the continental shelf or the marine subsoil.	6,000	---
5.13	Approval for exemption from tax on the process of import or export of products subject to sanitary oversight	EXEMPT	---
5.14	Sanitary control of activities in ports		
5.14.1	Issue of international certificate of rat extermination and exemption from rat extermination for vessels that conduct the following kinds of navigation:		
5.14.1.1	Long distance high seas international transit, with maritime, river-maritime or maritime-lake navigation, engaged in activities or services of freight or passenger transport	1000	---
5.14.1.2	Long distance high seas international transit, with maritime, river-maritime or maritime-lake navigation, engaged in fishing activities	1000	---
5.14.1.3	Long distance high seas international transit, with maritime, river-maritime or maritime-lake navigation, engaged in sporting and recreational activities not for commercial purposes	EXEMPT	---
5.14.1.4	Inland waterways international transit, with river navigation, and engaged in activities or services of freight or passenger transport	1000	---
5.14.1.5	Inland waterways international transit, with river navigation, and engaged in fishing activities	1000	---
5.14.1.6	Inland waterways international transit, with river navigation, and engaged in sporting and recreational activities not for commercial purposes	EXEMPT	---
5.14.2	Issue of national certificate of rat extermination and exemption from rat extermination for vessels that conduct the following kinds of navigation:		
5.14.2.1	High seas coastal piloting in exclusively national transit, with maritime, river-maritime or maritime-lake navigation, and engaged in activities or services of freight or passenger transport	500	---
5.14.2.2	High seas platform support, in exclusively national transit and with maritime, river-maritime or maritime-lake navigation	500	---

5.14.2.3	High seas, engaged in other activity or service, in exclusively national transit and with maritime, river-maritime or maritime-lake navigation	500	---
5.14.2.4	Inland waterways exclusively national transit with maritime or maritime-lake navigation and engaged in activities or services of freight or passenger transport	500	---
5.14.2.5	Inland waterways exclusively national transit with maritime-river, river, or river-lake navigation and engaged in activities or services of freight or passenger transport	500	---
5.14.2.6	Inland waterways for port support, in exclusively national transit and with maritime or maritime-lake navigation.	500	---
5.14.2.7	Inland waterways for port support in exclusively national transit and with maritime-river, river or river-lake navigation	500	---
5.14.2.8	Inland waterways, involving other activities or services, in exclusively national transit and with maritime or maritime-lake navigation	500	---
5.14.2.9	Inland waterways involving other activities or services, in exclusively national transit and with maritime-river, river or river-lake navigation.	500	---
5.14.2.10	High seas or inland waterways, involving fishing activities, with departure from and entry into different ports in the national territory	500	---
5.14.2.11	High seas or inland waterways, involving fishing activities, with departure from and entry into the same port in the national territory and without intermediate stopovers	EXEMPT	---
5.14.2.12	Inland waterways involving sport and recreational activities for non-commercial purposes, in municipal, inter-city or interstate transit, with maritime-river, river or river-lake navigation	EXEMPT	---
5.14.2.13	Inland waterways involving sport and recreational activities for non-commercial purposes, in municipal, inter-city or interstate transit, with maritime or maritime-lake navigation	EXEMPT	---
5.14.3	Issuance of guide for disembarkation of passengers and crews of ships, aircraft or land vehicles for international transit.	500	---
5.14.4	Issuance of port clearance certificate for ships engaged in the following kinds of navigation:		
5.14.4.1	Long distance international transit, with maritime, maritime-river or maritime-lake navigation, and engaged in activities or services of freight or passenger transport.	600	---
5.14.4.2	Long distance international transit, with maritime, maritime-river or maritime-lake and engaged in fishing activities	600	---
5.14.4.3	Long distance international transit, with maritime, maritime-river or maritime-lake navigation, and engaged in sports and recreational activities for non-commercial purposes.	EXEMPT	---
5.14.4.4	Long distance international transit, with maritime, maritime-river or maritime-lake navigation, and engaged in sports and recreational activities for commercial purposes	600	---
5.14.4.5	Inland waterways international transit, with river navigation, and engaged in sports and recreational activities for non-commercial purposes	EXEMPT	---
5.14.4.6	Inland waterways international transit, with river navigation, and engaged in sports and recreational activities for commercial purposes	600	---
5.14.4.7	Inland waterways international transit, with river navigation, and engaged in fishing activities	600	---
5.14.4.8	High seas coastal piloting in exclusively national transit, with maritime, maritime-river or maritime-lake navigation, and engaged in activities or services of freight or passenger transport	600	---
5.14.4.9	High seas for platform support, in exclusively national transit and with maritime, maritime-river or maritime-lake navigation	600	---
5.14.4.10	High seas involving other activities or services, in exclusively	600	---

	national transit and with maritime, maritime-river or maritime-lake navigation		
5.14.4.11	Inland waterways, in exclusively national transit, with maritime or maritime-lake navigation, and engaged in activities or services of freight or passenger transport	600	---
5.14.4.12	Inland waterways, in exclusively national transit, with maritime-river, river or river-lake navigation, and engaged in activities or services of freight or passenger transport	600	---
5.14.4.13	Inland waterways for port support, in exclusively national transit and with maritime or maritime-lake navigation	600	---
5.14.4.14	Inland waterways for port support, in exclusively national transit and with maritime-river, river or river-lake navigation	600	---
5.14.4.15	Inland waterways, engaged in other activities or services, in exclusively national transit and with maritime or maritime-lake navigation	600	---
5.14.4.16	Inland waterways, engaged in other activities or services, in exclusively national transit and with maritime-river, river or river-lake navigation	600	---
5.14.4.17	High seas or inland waterways, engaged in fishing activities, with departure from and entry into different ports in the national territory	600	---
5.14.4.18	High seas or inland waterways, engaged in fishing activities, with departure from and entry into the same port in the national territory and without intermediate stopovers	EXEMPT	---
5.14.4.19	Inland waterways, engaged in sports and recreational activities for non-commercial purposes, in municipal, inter-city or interstate transit, with maritime or maritime-lake navigation	EXEMPT	---
5.14.4.20	Inland waterways engaged in sports and recreational activities for non-commercial purposes municipal, inter-city or interstate transit, with maritime-lake, maritime-river, river or river-lake navigation	EXEMPT	---
5.14.4.21	Any vessel of the Brazilian Navy, or vessel operating at the Navy's invitation, used for non commercial purposes	EXEMPT	---
6			
6.1	Registration of cleaning products		
6.1.1	Product of Risk Level II	8.000	Five years
6.2	Alteration, inclusion or exemption of registration of cleaning products	1,800	---
6.3	Revalidation or renewal of registration of cleaning products		
6.3.1	Product of Risk Level II	8.000	Five years
6.4	Certification of Good Manufacturing Practices for each establishment or manufacturing unit by product line of cleaning products		
6.4.1	In Brazil and MERCOSUL countries		
6.4.1.1	Certification of Good Manufacturing Practices by establishment or manufacturing unit by product line for industries of domestic cleaning products	15.000	Annual
6.4.2	Other countries	37.000	Annual
7			
7.1	Operating permit for companies and renewal of permits by establishment or manufacturing unit for each type of activity	---	---
7.1.1	By manufacturing establishment for one or more lines of health products (equipment, materials and "in vitro" diagnostic products)	10,000	---
7.1.2	Distributor, importer, exporter, transporter, warehouse operator, packager, repackager and others provided for in specific health product legislation	8.000	---
7.1.3	By retail establishment for health products	5.000	---
7.2	Certification of Good Manufacturing Practices of health products, for	---	---

	each establishment or manufacturing unit by product line		
7.2.1	In Brazil and MERCOSUL countries	---	---
7.2.1.1	Certification of Good Manufacturing Practices of health products	15.000	Annual
7.2.2	Other countries	37.000	Annual
7.3	Certification of Good Practices of Distribution and Storage of health products by establishment	15.000	Annual
7.4	Modification or addition to certification by inclusion of a new type of product line (equipment, materials and “in vitro” diagnostic products)	5.000	---
7.5	Registration, revalidation or renewal of registration of health products		
7.5.1	Large-scale diagnostic or therapeutic equipment such as for nuclear medicine, computerized tomography, magnetic resonance and coronary angiography.	20.000	Five years
7.5.2	Other medium- and small-scale diagnostic or therapeutic equipment, articles, materials, "in-vitro" diagnosis products and other health products	8.000	Five years
7.5.3	Family of large-scale diagnostic or therapeutic equipment	28.000	Five years
7.5.4	Family of medium- and small-scale diagnostic or therapeutic equipment, articles, materials, diagnostic reagents for "in vitro" use and other health products	12.000	Five years
7.6	Alteration, inclusion or exemption in the registration of health products	1,800	---
7.7	Issuance of certificate for export	EXEMPT	---
8			
8.1	Toxicological evaluation for purposes of product registration		
8.1.1	Technical product with active ingredient not registered in Brazil	1,800	---
8.1.2	Technical product with active ingredient already registered in Brazil	1,800	---
8.1.3	Formulated product	1,800	---
8.2	Toxicological evaluation for registration of component	1,800	---
8.3	Toxicological evaluation for purposes of Special Temporary Registration	1,800	---
8.4	Toxicological reclassification	1,800	---
8.5	Re-evaluation of product registration, pursuant to Decree nº 991/93	1,800	---
8.6	Toxicological evaluation for purposes of inclusion of culture	1,800	---
8.7	Alteration of dose		
8.7.1	Alteration of dose, increased in the application	1,800	---
8.8	Alteration of dose, increased in the application	EXEMPT	---
9			
9.1	Registration, revalidation or renewal of registration of smoking products	100.000	Annual
10	Approval to disseminate advertising containing alert to the public within the period and pursuant to the conditions indicated by the health authority	10,000	---
11	Approval in process for clinical research	10,000	---
12	Alteration or addition to operating permit	4,000	---
13	Substitution of legal representative, responsible technician or cancellation of permit	EXEMPT	---
14	Certificates, attestations and other official statements	1,800	---
15	Re-opening of process and second copy of document	1,800	**---**

Notes:

1. The fees in the Table are reduced by:

a) fifteen per cent, in the case of companies with annual billing less than or equal to R$ 50,000,000.00 (fifty million reals) and greater than R$ 20,000,000.00 (twenty million reals);

b) thirty per cent, in the case of companies with annual billing less than or equal to R$ 20,000,000.00 (twenty million reals) and greater than R$ 6,000,000.00 (six million reals);

c) sixty per cent, in the case of companies with annual billing less than or equal to R$ 6,000,000.00 (six million reals);

d) ninety per cent, in the case of small companies;

e) ninety five per cent, in the case of micro-enterprises, except for item 3.1, whose values in the case of a micro-enterprise are reduced by ninety per cent.

2. In items 3.1.1, 3.1.2, 3.1.6, 3.1.8 and 7.1.1, the manufacturing process includes all activities necessary for obtaining the products mentioned in those items.

3. In items 3.1.3, 3.1.7, 3.1.9 and 7.1.2, the distribution of medications, cosmetics, hygiene products, perfume and domestic cleaning products includes activities of storage and shipping.

4. For small companies and micro-enterprises, the fee for the granting of the Certification of Good Manufacturing Practices and Control will be charged for each establishment or manufacturing unit.

5. Until December 31, 2001, micro-enterprises will remain exempt from the fee for the granting of the Certification of Good Manufacturing Practices and Control, Registration or Renewal of Registration of Products or Groups of Products, as well as fees involved for the instances noted in items 5.2.1 and 5.10.1, and this exemption can be extended until December 31, 2003, by decision of the Collegiate Directorate of ANVISA.

6. For purposes of Registration or Renewal of Registration, medications will be considered new that contain a new molecule and have patent protection.

7. The fee for Registration or Renewal of Registration of medications or groups of phytotherapeutic, homeopathic, Large Volume Parenteral Solutions and Small Volume Parenteral Solution will be the same as the fee for item 4.1.3, Generic medications.

8. The fees in the Table for Renewal of Registration of Product or Group of Products will be reduced by ten per cent upon renewal.

9. Classification as a small company or micro-enterprise for the purposes set forth in item 1, is to be granted in conformity with what is established by Law nº 9.841, of October 5,1999.

10. When concerned with export-related activities, the issuance of certificates, attestations and other official statements, the re-opening of processes and providing a second copy of documents, are exempt from collection of fees.

11. Alterations or additions to registrations shall be exempt from collection of fees for texts of instructions on use, indications and labels, change of phone number, change of CGC/CNPJ number or other legal information, pursuant to the terms of a ruling enacted by the Collegiate Directorate of ANVISA.

12. The reductions in fees indicated in item 1 do not apply to items 3.1.5 and 5.1.13 of the Table, or to companies located in countries that are not members of MERCOSUL.

13. Companies engaged in express delivery activities (courier), and that are classified under letters "a", "b" or "c" of item 1 in the Notes, are subject, independent of billing, to a single fee for approval of importation of the merchandise indicated in items 5.3, 5.4, 5.6, 5.7 and 5.8 of this Annex, for the amount of R$ 40.00.

14. Companies engaged in express delivery activities (courier) and that are classified under letters "a", "b" or "c" of item 1 in the Notes, are subject, independent of billing, to a fee for approval of export of the merchandise indicated in items 5.9.5.1 and 5.9.5.2 of this Annex, for the following amounts:

a) R$ 40.00, when a maximum of 20 samples is involved for delivery to an individual recipient, with each item checked by the health authority through verification of the bill of lading;

b) R$ 80.00, when 21 to 50 samples are involved for delivery to an individual recipient, with each item checked by the health authority through verification of the bill of lading;

15. The Collegiate Directorate of ANVISA shall adjust what is set forth in item 5.14 and its deductions based on the size of the vessels by net register tonnage and class, types of navigation, waterways and voyages undertaken.

16. For purposes of what is set forth in the foregoing item, the following definitions apply:

16.1. Net register tonnage – (NRT): expression of the working capacity of a vessel, determined in accordance with the prescriptions of these rules, as a function of the volume of the enclosed spaces intended for transport of freight, the number of passengers transported, the place to which passengers are to be transported, and the draught/depth ratio and gross tonnage, with net register tonnage understood as an adimensional size.

16.2. Class of vessel: sport recreation, fishing, passenger, freight, mixed and others

16.3. Type of navigation:

16.3.1. Navigation on the High Seas: performed in maritime waters considered unsheltered, and may be:

16.3.1.1. Long Distance: navigation between Brazilian and foreign ports;

16.3.1.2. Piloting: navigation between ports or points of Brazilian territory using coastal waterways or coastal and inland waterways; and

16.3.1.3. Platform Support: activities performed for the logistical support of vessels and facilities in national territorial waters and in the exclusive economic zone, that involve activities relating to fishing, mineral extraction and hydrocarbons.

16.3.2. Inland Navigation: conducted in what are considered inland waterways, rivers, lakes, canals, bays, coves, inlets, and maritime areas considered sheltered.

16.3.3. Navigation of Port Support Vessels: carried out exclusively in ports and around shipping terminals for the upkeep of ships and port facilities.

16.4. Navigable waterways: maritime, rivers and lakes.

16.5. Navigation: municipal, inter-city, interstate and international.