COMMONWEALTH OF PUERTO RICO
DEPARTMENT OF HEALTH

4784

"REGULATION OF THE SECRETARY OF HEALTH NO. 79 TO REGULATE THE OPERATION OF ESTABLISHMENTS DEDICATED TO THE MANUFACTURE, PRODUCTION, SALES AND DISTRIBUTION OF DRUGS AND PHARMACEUTICAL PRODUCTS PROMULGATED BY VIRTUE OF THE PROVISIONS OF ACT NO. 282 OF MAY 15, 1945, AS AMENDED, AND THE FEDERAL PROVISIONS ESTABLISHED IN THE "PRESCRIPTION DRUG MARKETING ACT-1987", AND TO REVOKE REGULATIONS NO. 39 APPROVED ON OCTOBER 20, 1975 AND REGULATION NO. 46 OF OCTOBER 23, 1980."

No. 4784
Date: November 10, 1992 11:14 A.M.
Approved: Salvador M. Padilla, Ph. D.
Secretary of State
By: [signature]
Assistant Secretary of State

COMMONWEALTH OF PUERTO RICO
DEPARTMENT OF HEALTH

INDEX

TABLE OF CONTENTS

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ARTICLE I - TITLE

This Regulation shall be known and may be cited as:

"REGULATION OF THE SECRETARY OF HEALTH NO.79 TO REGULATE THE OPERATION OF ESTABLISHMENTS DEDICATED TO THE MANUFACTURE, PRODUCTION, SALES AND DISTRIBUTION OF DRUGS AND PHARMACEUTICAL PRODUCTS PROMULGATED BY VIRTUE OF THE PROVISIONS OF ACT NO. 282 OF MAY 15, 1945, AS AMENDED, AND THE FEDERAL PROVISIONS ESTABLISHED IN THE "PRESCRIPTION DRUG MARKETING ACT -1987", AND TO REVOKE REGULATION NO. 39 APPROVED ON OCTOBER 20, 1975 AND REGULATION NO. 46 OF OCTOBER 23, 1980."

ARTICLE II - LEGAL BASIS

This Regulation is adopted pursuant to the provisions of Act No. 282 of May 15, 1945, as amended, and the federal provisions established in the "Prescription Drug Marketing Act - 1987", Act No. 170 of August 12, 1988, as amended, and to revoke Regulation No. 39 approved on October 20, 1975 and Regulation No. 46 of October 23, 1980.

ARTICLE III - PURPOSE

This Regulation is approved to regulate the operation of establishments dedicated to the manufacture, production, sales and distribution of drugs and pharmaceutical products.

ARTICLE IV - DEFINITIONS:

For purposes of interpreting these regulations, the following terms shall have the following meanings:

(A) Apprentice of pharmacy assistant - Any person authorized by the Puerto Rico Pharmacy Board to start practicing as a pharmacy assistant under the supervision of a registered pharmacist, who has the intention of obtaining a Pharmacy Assistant Certificate, after complying with the corresponding requirements of law specified for said purpose.

(B) Temporary absence - The maximum number of hours that the registered pharmacist may be absent from his daily tasks in a pharmacy, wholesale drug distributor, or pharmaceutical manufacturing firm, when said pharmacist leaves an authorized pharmacy assistant in charge, as provided by the law, and under the conditions that this temporary absence be due to urgent and sporadic needs,

and that it is not prolonged nor that it be repeated for more than the reasonable amount of time necessary to take care of the urgent cause thereof.

(C) Pharmacy Assistant - Any person authorized by the Puerto Rico Pharmacy Board to assist or aid a pharmacist in his duties, as provided by the law.

(CH) Medicine Chest or Dispensary - Any medicine deposit for the use of patients, in hospitals, nursing homes, public health units or similar institutions. It is an indispensable requirement that the medicines be kept in the original containers, which shall indicate in their labels the name and location of the manufacturer.

(D) Department of Health or Department - The Department of Health of the Commonwealth of Puerto Rico.

(E) Wholesale Distributor of Prescription Medicines - Any person, society, corporation or commercial entity that does the wholesale distribution of prescription medicines, including but not limited to, manufacturers, repackers, distributors of own and private brands, druggists, intermediaries, agents, warehouses, including manufacturer and distributor warehouses and warehouses for chain medicine stores and medicine wholesalers, independent wholesale businesses and retail pharmacies that distribute on a wholesale basis.

(F) Wholesale Distribution of Prescription Medicines - Distribution of prescription medicines to persons who are not consumers or patients, excluding:

(1) The intercorporative sales, defined as any transaction or transfer between any division, subsidiary, main office or corporations related or together under the common control of a corporation.

(2) The purchase or other acquisition of medicines or drugs for consumption by a hospital or other health care entity which is a member of

a group purchasing organization, said purchase being made from the group medicine purchasing organization or from other hospitals or health care entities which, in turn, are members of said organizations.

(3) The sales, purchase or marketing of a medicine, or an offer to sell, purchase or market a medicine or drug by a charitable organization to a non-profit affiliate of the organization, within the scope permitted by law.

(4) The sales, purchase or marketing of a medicine or drug, or an offer to sell, purchase or market medicines or drugs between hospitals and other health care entities which are under common control. For purposes of this section, the term "common control" means the power to direct or induce the direction of the administration and policies of a person or an organization, whether through the holding of stock, the right to vote, a contract or other form.

(5) The sales, purchase or marketing of a medicine or drug or offer to sell, purchase or market a medicine or drug for emergency medical reasons. For purposes of this section, the term "emergency medical reasons" includes the transfer of prescription medicines between pharmacies to alleviate a temporary scarcity.

(6) The sales, purchase or marketing of a medicine or drug or the offer to sell, purchase or market a medicine or drug, or the dispatching of a medicine or drug, pursuant to an authorized prescription.

(7) The distribution of medicine samples by

medicine manufacturers representatives, a representative, or distributors representatives.

(8) The sales, purchase or marketing of blood or blood components to be used in transfusions.

(G) Drugs - Substances of animal, vegetable, mineral or synthetic origin used as medicines or in the preparation of a medication.

(H) Wholesale Druggists - A public establishment, registered and authorized by the Department of Health to store, sell or distribute on a wholesale basis to establishments authorized by the Department of Health, drugs and medicines, or wholesale dealing in other articles of legal trade which are customarily sold wholesale to pharmacies in Puerto Rico.

(I) Pharmaceutical Specialties - Shall have the same meaning as patent or propriety medicines.

(J) Commonwealth or States - Shall mean the Commonwealth of Puerto Rico including municipalities, departments, agencies and other instrumentalities.

(K) Pharmaceutical Manufacturing Firm - An establishment registered and authorized by the Department of Health for manufacturing, preparing, mixing, processing, packaging, repackaging, labelling, storing and wholesale selling of drugs and medicines to establishments authorized by the Department of Health.

(L) Pharmacist - A person authorized by the Puerto Rico Pharmacy Board to practice the profession of pharmacist, as determined by law.

(LL) Managing Pharmacist - A pharmacist who is in charge of supervising the dispensing and handling of drugs and the preparation of medical prescriptions in a pharmacy, wholesale drug distributor or pharmaceutical manufacturing firm, and whose name appears as such in the records of the Department of Health; provided, that "in

charge of" shall mean the physical presence of the pharmacist with direct control and direct supervision of the pharmaceutical operations within the establishment. He/she shall likewise be responsible for the faithful compliance of the Laws and Regulations in effect which regulate the manufacturing, warehousing, distributing, dispensing and handling of drugs, and of the preparation of medical prescriptions in the pharmaceutical manufacturing firms, wholesale drug distributors and pharmacies, respectively.

(M) Pharmacy - An establishment registered and authorized by the Department of Health in which drugs, medicines and poisons are kept, packed and dispensed, as well as dealing in other articles of legal trade which are customarily sold in pharmacies in Puerto Rico.

(N) Official formulas - All formulas included in the official compendia: the United States Pharmacopeia and the National Formulary and its supplements.

(Ñ) Drug and Pharmacy Inspector - A pharmacist who is an official of the Department of Health designated to carry out inspections in establishments where drugs, medicines, pharmaceutical products and chemical products used as medicines are manufactured, produced, packed, sold or distributed.

(O) Pharmacy Intern - An aspirant to a pharmacist's license of the Puerto Rico Pharmacy Board, during his period of practical training, as authorized by said Board.

(P) Pharmacy Board or Board - The Puerto Rico Pharmacy Board operating within the Department of Health of the Commonwealth of Puerto Rico.

(Q) License - A permit issued by the Department of Health for operating a pharmacy, wholesale druggist, pharmaceutical manufacturing firm, medicine chest or dispensary, or dealing on a wholesale or retail basis with patent or propriety medicines. (Medicines which do not require a

prescription.)

(R) Medicines - All drugs, chemical products or pharmaceutical preparations, with a simple or compound formula, for internal or external use, that are employed in the diagnosis, cure, prevention, treatment or mitigation of illness in human beings or animals.

(S) Prescription Medicine - A medicine, pharmaceutical preparation or product for human consumption which, by provision of the applicable Commonwealth and Federal laws and regulations, requires a medical prescription to be dispensed, including medications in final doses and active ingredients, subject to the provisions of the applicable Commonwealth and Federal laws.

(T) Patent or Propriety Medicine or Pharmaceutical Specialties (Medicines which do not require a prescription) - A pharmaceutical preparation with a definite commercial name, presented in original packaging, which under Commonwealth and Federal laws and regulations, does not require a medical prescription for dispensing; provided, that there shall be an exclusion form this definition of those products included in the United States Pharmacopeia or in the National Formulary and those products which, in the opinion of the Secretary of Health, should only be dispensed under the supervision of an authorized pharmacist.

(U) Medicine Sample - A unit of medicine whose purpose is to promote the sales of the drug or medicine, not the sales itself.

(V) Medical Prescription - A written order by a person in the legal exercise of medicine, dental surgery or veterinary medicine, so that certain medications be compounded or dispensed by an authorized pharmacist in a duly registered pharmacy.

(W) Secretary of Health or Secretary - The Secretary of Health of the Commonwealth of Puerto Rico.

(X) Non-prescription Medicine Store or Retailer - An establishment registered and authorized by the Department of Health to retail non-prescription or propriety medicines, as determined by law.

(Y) Wholesale Dealer of Non-prescription Drugs - An establishment registered and authorized by the Department of Health to sell or distribute on a wholesale basis to establishments authorized by the Department of Health, non-prescription medicines in their original package, as defined and specified in these Regulations.

ARTICLE V - LICENSES:

(A) Any person, firm or corporation requesting a license from the Department of Health, shall submit a written application on a form supplied by the Department of Health, and shall include all the required information. The Department can determine if the establishment will be operated in accordance with existing Commonwealth and Federal laws and with the regulations issued under those laws. Furthermore, it shall include with said application, a copy of any licenses and permits in effect necessary for the operation of the establishment.

(B) The corresponding license fee shall accompany the license application, according to the following table:

1. Pharmacies.....Three (3) dollars
2. Wholesale druggists.....Thirty (30) dollars
3. Dealers in non-prescription medicines.....Fifteen (15) dollars
4. Pharmaceutical manufacturing firms.....Twenty (20) dollars
5. Dealers in chemical products for technical, agricultural, or industrial purposes.....Fifteen (15) dollars
6. Medicine chests.....Three (3) dollars
7. Dispensaries.....Three (3) dollars

The amount of the license fee in check or money order

shall be made payable to the Secretary of the Treasury.

(C) The information given in the license application shall include: (1) the name, telephone and address of the person, partnership, cooperative, association or corporation requesting the permit; (2) the names under which it does business; (3) the addresses, telephone numbers and names of the responsible persons, related to all of the facilities used by the applicant in the warehousing, handling and distribution of prescription medicines; (4) the name of the owner or operator of the license, including: (i) if it is a natural person, the name of the person; (ii) if it is a partnership, the name of the partnership; the name of each partner; (iii) if it is a corporation, the corporate name, the name, title and address of the officers and directors and the place of incorporation, together with a copy of the certificate of incorporation or authorization to do business in Puerto Rico.

Any change in the aforementioned information must be reported to the Department in writing within the next thirty (30) days. This requirement does not alter in any may the provisions of subparagraph (n) of this Article.

(D) In the case of establishments which are pharmacies, wholesale drug distributors or pharmaceutical manufacturing firms, this application will include the following:

1. Name of the managing pharmacist, names of other authorized pharmacists and of pharmacy aides employed, indicating the license number and annual registration certificate of each.
2. Information demonstrating that adequate technical equipment is maintained in accordance with the operations carried out, together with any other information which the Department of Health deems necessary.

(E) The minimum technical equipment which shall be considered necessary for a pharmacy to fulfill Federal and Commonwealth specifications established regarding safety of operations, and others which may be established in the future, shall include:

1. A balance with its corresponding weighs for weighing small amounts, with a sensitivity of six (6) milligrams; provided, that in those pharmacies where operations require the weighing of large amounts, an appropriate balance shall be provided for said purposes.
2. Volumetric flasks to measure the following amounts: 10cc, 25cc, 120cc, 250cc, 500cc, 1,000cc.
3. Mortars of 16 ounces, 8 ounces and 4 ounces; provided, that at least one shall be a composition mortar.
4. Three stainless steel spatulas, and one spatula of bakelite, rubber or synthetic material.
5. Three glass stirrers.
6. Two glass funnels: one large and one small.
7. A counting tray for pills, tablets and capsules.
8. Adequate packaging material: prescription bottles of 1, 2, 3, 4, 6, 8 and 12 ounces, dropper jars of 1/2, 1, 2 and 4 ounces, salve jars of 1/2, 1. 2 and 4 ounces; containers for capsules, tablets and pills in various sizes, filter paper and weighing paper.
9. A gallon of distilled water with dispenser.
10. The latest edition of the United States Pharmacopeia and the National Formulary, with its corresponding supplements, or in the absence of these, the latest edition of

Remington's Pharmaceutical Science.

11. The latest edition of a reference book on unofficial drugs and two reference works on pharmaceutical specialties.
12. A adequate prescription file.
13. A numbering machine for prescriptions.
14. A table or counter for preparing prescriptions whose surface should be of impermeable material.
15. A refrigerator equipped with thermometer, of adequate construction for maintaining biological products at a temperature no greater than 12.5 degrees Centigrade or 55 degrees Fahrenheit, according to the provisions of Health Regulation No. 75: Conservation and Registration of Biological Products (Puerto Rico Rules and Regulations Chapter 63, Sections 910-1 through 910-9) and in accordance with the temperature specified by the manufacturer.
16. A sink in the prescription preparation area for exclusive use in cleaning pharmaceutical equipment.

(F) Every establishment shall be equipped with toilet and washbasin, supplied with soap, toilet paper and towels at all times, and kept clean and in order; provided, that, in addition, these facilities shall not be used for placing, storing or keeping materials, merchandise or equipment of any kind.

(G) License applications for non-prescription medicine wholesale and retail dealers shall be accompanied by a list of the pharmaceutical products to be sold in said establishments.

(H) All applications for the newly organized establishments shall be submitted no less than thirty (30) days prior to

the date selected for opening to the public. The Department of Health shall carry out this inspection within fifteen (15) days after receiving the application. After carrying out the inspection, the Department of Health will determine acceptance or refusal of the application no later than the following fifteen (15) days.

(I) In order that a newly organized establishment may begin to offer service to the public, it must have previously obtained a license form the Department of Health.

(J) Licenses shall be renewed annually on or before the 10th of July of each year, by means of a written application containing the information required by the Department of Health, accompanied by the corresponding annual license fee, as specified in Part (b) of this Article.

(K) The issuance of a new license for newly organized establishments or renovation shall be subject to having complied with the provisions of law and regulations in force, be these of the Department of Health or whatever other competent agency of the Commonwealth of Puerto Rico, related to the existence and operation of the establishment.

(L) Licenses shall be issued to the name of the owner or corporate name of the establishment and will specify the name and address of the establishment for which it was issued. In the case of a pharmacy, wholesale drug distributor or pharmaceutical manufacturing firm, the license shall also specify the name, pharmacist's license number and annual registration certificate of the managing pharmacist and of the other pharmacists who practice in the establishment, which numbers are issued by the Puerto Rico Pharmacy Board.

(M) Every license shall be non-transferable and shall apply only to the physical location of the business for which it was issued. At all times the license shall be

displayed in a visible and prominent place in the establishment. In the case of a pharmacy, wholesale drug distributor or pharmaceutical manufacturing firm. there shall also be displayed in a visible and prominent place the pharmacist's license, the annual registration certificate and a recent photograph of a size no smaller than 3" x 5" of the managing pharmacist, as well as the certificate of annual registration of the pharmacy assistant or assistants, issued all these licenses and certificates by the Puerto Rico Pharmacy Board.

(N) If an establishment of the type specified in these regulations changes its owner or its physical location, the original license becomes void, and shall be returned to the Department of Health for a new license to be issued. In the case of a change of owner or physical location, the application for a new license shall comply with the provisions of Part (H) of this Article. In the case of a change of owner, the application for a new license, and its acceptance or refusal, will be processed within five (5) days after the transaction has been completed.

(O) Minimum Qualifications Requirements - Upon reviewing the qualifications of the prescription medicine wholesale distributors who request the issuance or renewal of their license, the Department shall consider the following factors, among others:

(1) Whether the applicant has been sentenced under the Commonwealth and Federal laws and statutes regarding the distribution of samples of medicines and drugs, wholesale or retail distribution of drugs or the distribution of controlled substances.

(2) Any sentence of the applicant for a felony under local or Federal laws.

(3) The applicant's prior experience in the

manufacture or distribution of prescription medicines, including controlled substances.

(4) Whether the applicant has submitted false or fraudulent material in any application for the manufacture or distribution of medicines or drugs.

(5) Any suspension or revocation by the local or Federal government of a license obtained by the applicant at present or in the past for the manufacture or distribution of any medicine or drug, including controlled substances.

(6) Compliance with the licensing requirements, in relation to previously issued licenses, if any.

(7) Compliance with the requirements of maintaining and supplying the Department, Commonwealth or Federal officials with the files required under this Section, and

(8) Any other factors or criteria which the Department considers relevant and consistent with the public safety and welfare.

(P) Denial, Suspension, Cancellation and Revocation of Licenses

(1) Denial of Licenses

The Secretary may deny the issuance of licenses, as long as it is proven that the requirements established in this regulation are not complied with or the granting thereof is not in the public interest. Public interest considerations must be based on factors and criteria which are directly related to the protection of the public welfare and health.

(2) Cancellation of Licenses

Licenses may be canceled for the following reasons:

(a) If the commercial operation for which it was issued ceased.

(b) When the business is sold, leased or transferred to another person. In this case, an application for a new license shall be made as provided in Article 5 (h) hereof.

(c) Due to the death of the person in whose name the license was issued. In this case, the new applicant shall initiate the corresponding procedures to acquire a new license within fifteen (15) days following the date of the death of the owner.

(3) Suspension of Licenses

The Secretary may suspend any license for the following reasons:

(a) When a problem is found whose very nature implies a serious threat to the public health.

(b) When the holder of a license has violated any of the requirements established herein.

(c) When the holder of a license interferes with the compliance of the functions and duties of the Secretary or any of his representatives.

(4) Revocation of Licenses

(a) The Secretary may permanently revoke any license issued, in the case of recurring violations of the provisions of this Regulation. Such

revocation shall be preceded by a written notice to the holder of the license and for the holding of an administrative hearing except on those cases where the public health is at risk.

(b) When the license has remained suspended for a period of ninety (90) days and the holder thereof has not complied with the requirements of the Secretary, the license shall be revoked.

(5) Administrative Hearings

A manufacturer, producer, distributor or any other holder of a license issued pursuant to the provisions of these Regulations who has received a notice of intent to suspend or revoke the license or whose license has been suspended, shall be entitled to request an administrative hearing. An administrative hearing procedure shall begin with the filing of a petition with the Office of Legal Affairs of the Department of Health. The plaintiff or petitioner may file the petition for an administrative hearing with the Office of Legal Affairs of the Department of Health on his own or through counsel.

(a) Contents of the petition

The petition must describe the facts upon which the action is based and the remedy sought in a general or specific manner, and it must be signed by the petitioner or by his attorney. Private juridical persons may subscribe the petitions through

a person authorized therefor or through a resolution of said juridical person.

(b) Amendments to the Allegations in the Original Petition

The examining officer in charge of the case may authorize an amendment to the allegations in the interest of justice, if the request for amendment is filed within a reasonable term prior to the hearing. If the party does not appear at the pretrial conference, if any is scheduled, or at the hearing or during any other stage of the proceedings, or if the party fails to comply with any provision or order of the examining officer, default may be entered against said party, eliminating the allegations and the procedure may continue without said party's participation. All of these findings shall be notified to said party to the address on record and the affected party may request the reconsideration of a finding once the Department of Health enters a final resolution in the case.

The examining officers shall be empowered to dispose of all the procedural matters and matters relative to the evidence to be presented in the case, including incidents relative to discovery and

they may issue whatever interlocutory resolutions may be necessary.

All finding so made by the examining officers shall be deemed to be made by the agency and may only be reviewed by motion for reconsideration filed with respect to the final resolution of the case.

(c) Discovery

The applicant shall be entitled to request within a reasonable term prior to the hearing, and to the pretrial, the following information:

(1) All documents in the possession of the Department of Health related to the hearing which the agency proposes to use in the case.

(2) A list of the witnesses who will appear to testify at the hearing, with a brief summary of the contents of their testimony. The examining officer may authorize the use of any discovery mechanism, at his discretion.

(d) Pretrial Conference

The examining officer may schedule motu propio or et the request of a party, a pretrial conference, and he may order the parties to meet prior thereto and to file a report within five (5) working days prior to the date of said hearing.

The contents of the report, as modified and/or approved by the

examining officer, shall govern the subsequent course of the proceeding, except if the examining officer, for just cause and in the interest of justice, authorized any modification.

(e) Notice of Hearing

The notice of hearing shall be made through written notice by certified mail, return receipt requested at least ten (10) working days prior to the holding of the same.

(f) Transfer and Suspension of Hearing

Any party interested in transferring or suspending a hearing must request the same in writing at least five (5) working days prior to the scheduling thereof.

When a request for transfer or suspension is filed by a party other than the agency or an officer who is not from the Commonwealth of Puerto Rico, said request shall constitute a waiver that adjudication of the case shall be made within six (6) months from the filing of the original petition.

(g) Evidence on the Record

The file of the case shall not contain any evidence until the same has been formally submitted by any of the parties and it shall not be considered admitted until determined by the examining officer at the pretrial conference or at the trial

of the case.

Any report or document produced by the agency or by an official of the Commonwealth of Puerto Rico must be duly identified and shall be admissible in evidence if said person is present at the trial to be cross-examined on the document in question unless the parties stipulate to the contents of the report.

(h) Proposed Findings of Facts and Conclusions of Law

The examining officer may order the parties to file a proposed findings of facts and conclusions of law.

(i) Dismissal or Summary Disposition

The examining officer may recommend to the Secretary that he dismiss or summarily dispose of a petition if he deems that the same does not state facts which justify the granting of a remedy, or if there is no real controversy of the facts, as a matter of law to proceed to enter a resolution in favor of the petitioner.

The examining officer to whom a request for dismissal or summary disposition is referred shall refer the same to the Secretary of Health for adjudication.

A finding of dismissal or summary disposition of a petition shall only be revocable through the timely

filing of a motion for reconsideration. If disposition of the case was originally made without the holding of a hearing, the Department of Health shall schedule a hearing to consider the motion for reconsideration.

(j) Reconsideration and Judicial Review Any party adversely affected by a final resolution of the Department of Health, may request reconsideration of the resolution within twenty (20) days from the date of the filing in the record of the notice of resolution or order. The Department must consider the same within fifteen (15) days of the filing of said motion for reconsideration. Should the same be totally denied or not acted upon within those fifteen (15) days, the term to request review to the Court shall commence to run again from the time said denial is notified or from the date on which said fifteen (15) days expire. If a determination is made on the reconsideration, the term to seek review shall commence to count as of the date on which a copy of the notice of the resolution of the agency definitely resolving the motion is filed in the record, which resolution must be issued and filed on the record within ninety (90) days following

the filing of the motion. If the agency fails to take any action regarding the motion for reconsideration within ninety (90) days of having filed the motion for reconsideration, it shall lose jurisdiction over the same as the term to seek judicial review shall commence to count as of the expiration of said ninety (90) days except if the Court, for just cause, authorizes a reasonable extension of time to the agency to resolve the same. The motion for reconsideration shall be jurisdictional in order to request immediate review.

(k) Proceedings for Immediate Action

(1) The Department may use emergency adjudicative proceedings in a situation where there exists imminent risk to the public health, safety and welfare or which requires immediate action by the agency.

(2) The Department may take only whatever action may be necessary within the circumstances described in subparagraph (1) above and which justify the use of an immediate adjudication.

(3) The Department shall issue an order or resolution which includes a concise statement of the findings of fact, conclusions of law and public policy reasons which justify the decision of the agency to take the specific action.

(4) The Department shall give whatever notice it deems most convenient, to the persons who are required to comply with the order or resolution. The order shall become effective upon its issuance.

(5) After an order or resolution for immediate action is issued, the agency must promptly proceed to complete whatever procedures may be required, if no imminent risk exists.

(1) Notices

All notices which are required by the proceedings under this Regulation shall be made by ordinary mail, unless the examining officer provides otherwise. Resolutions or orders for immediate action shall be notified personally to the natural or juridical applicant.

(m) Sanctions and Fines

Any person who during the course of the proceedings or of a hearing shows disrespectful behavior toward the examining officer or toward any of the persons attending the hearing, or who intentionally interrupts or delays the proceedings without just cause, may be sanctioned with an administrative fine which shall not exceed three hundred dollars ($300.00) at the discretion of the examining officer who presides over the proceedings where the forbidden behavior occurs.

(n) Term to File the Request for Review

A petitioner affected by a final order or resolution of the Department and who has exhausted all remedies provided, may file a request for review with the corresponding Superior Court within a term of thirty (30) days from the date of the filing on record of a copy of the notice of the final order or resolution of the agency. The party shall notify the filing of the request for review to the Department and to all parties within the term allowed for requesting said review. Notice must be made by mail.

(Q) Personal

As a condition of the Department of Health for retention of the prescription medicine wholesale distributor

license, the bearer of the license shall required of each person employed i any prescription medicine wholesale distribution activity to have sufficient education, training and experience, or any combination thereof, so that said person can carry out the duties assigned in such a manner that he will ensure that the quality, safety or integrity of the medicines is maintained at all times, as provided by law.

ARTICLE 6 - EMPLOYMENT, SUBSTITUTION AND TERMINATION OF PHARMACIST

(A) Every owner, administrator or person in charge of a pharmacy, wholesale drug distributor or pharmaceutical manufacturing firm shall notify the Department of Health in writing concerning the employment of a pharmacist within three (3) working days of having employed the same, indicating the name, address and pharmacist's license number and annual registration certificate number of said pharmacist, the pharmacist's working hours and the hours that the pharmacy is open for service to the public. The termination of employment of the pharmacist shall also be notified within three (3) working days after the vacancy occurs.

(B) Every pharmacist shall notify the Department of Health in writing of any change in employment within three (3) working days after said change has taken place, indicating the details specified in the preceding Part.

(C) In case the pharmacist of an establishment is temporarily replaced by another pharmacist due to vacation or illness, both pharmacists will notify the Department of Health regarding said replacement, indicating the dates and duration of the replacement. This notification shall be sent within three (3) working days after the replacement takes effect.

(D) At a date after sending said notifications specified above, a Drugs and Pharmacy Inspector, during an

inspection visit to the pharmacy, will make the pertinent entries in the space provided for said purpose in the license, regarding changes related to employment of the pharmacist or the pharmacists.

(E) A pharmacist may act as managing pharmacist of only one pharmacy, wholesale drug distributor or pharmaceutical manufacturing firm at the same time.

ARTICLE VII - TEMPORARY ABSENCES OF THE PHARMACIST

(A) Temporary absences of a pharmacist shall be subject to the norm that they be due to an urgent reason, not of a frequent nature, and that said absences not be prolonged nor repetitive for more than the reasonable required time to take care of the matter which is the cause of the absence.

(B) The temporary absence of a pharmacist in a pharmacy, wholesale drug distributor or pharmaceutical manufacturing firm, when not covered by another substitute pharmacist, shall not exceed six (6) hours in any working day, nor more than thirty (30) hours in a week. The term working day shall be understood as the number of hours in the day when the establishment is open to the public, or carrying out pharmaceutical operations.

(C) If the pharmacist is not substituted by another pharmacist during his temporary absence, then a pharmacist assistant shall be in charge of the establishment; provided, that during this temporary absence, medical prescriptions will not be dispensed. During this temporary absence, the pharmacy aide shall be responsible for compliance with the provisions of the law and the corresponding provisions of these regulations in this respect.

(D) Every pharmacy, wholesale drug distributor and pharmaceutical manufacturing firm shall maintain a register or record of the temporary absences of the pharmacist, according to the model form to be supplied by

the Department of Health. The record shall indicate the day, month and year, number of hours absent from the establishment, and a description of the reasons or motives for the temporary absence. The record shall be kept in a bound book, with consecutively numbered pages. Entries shall be made in clear and legible writing in ink or with indelible pencil. At no time will entries be made in graphite pencil or any other type of pencil. Any corrections will be made by crossing out the original material and writing the correct entry or words next to the crossed-out material. No corrections will be made by erasing or scratching out the original material.

(E) Entries in the temporary absence records shall be made by the pharmacist at the time of initiating his temporary absence, and upon returning to the establishment; provided, that, if he does not do so, it shall be understood that he is not rendering services in the establishment, action which will constitute a violation of Section 23 of Act No. 282 of May 15, 1945, as amended.

(F) The temporary absence record shall be present at all times in the establishment and shall be made available to the Drugs and Pharmacy Inspector, who may write notes in the record and must sign said additional entries, and also make photostatic copies of the entries when he deems necessary.

(G) The temporary absence record shall be considered as prima facie evidence of the contents of its entries.

(H) During an absence of the pharmacist not covered by another pharmacist, a sign or card shall be placed in a visible and conspicuous location, which will contain, in letters no less than four (4) inches high and one and a half (1 1/2) inches wide, in the place where prescriptions are dispensed, the following information: Pharmacist not on duty from _____ A.M. _____ P.M. to ___ A.M. _____ P.M.

(I) The lunch hour stipulated in the license application submitted and approved shall be considered to be a temporary absence.

(J) All pharmacies must have a medicine preparation area designed in such a manner that it can be completely closed when the pharmacist is not present.

ARTICLE VIII - CLOSING ORDER

(A) In the case of a pharmacy, wholesale drug distributor or pharmaceutical manufacturing firm which, in violation of the provisions of Section 23 of Act No. 282 of May 15, 1945, as amended, continues operations or remains open to the public without the presence of a pharmacist or pharmacy assistant during the temporary absences of the pharmacist permitted under the law and these regulations, or in those cases where the absence of the pharmacist exceeds the period of temporary absence permitted by law without being covered by another pharmacist, the Secretary of Health shall exercise those powers conferred by Law and shall proceed to notify the owner of the establishment of his intention to order the closing of said establishment, granting the owner a period of no less than ten (10) days to appear before the Secretary and show cause why such order of closing should not be sustained.

(B) After holding this hearing, the Secretary shall then analyze the evidence submitted and act in the manner which he considers just and reasonable within three (3) days after said hearing. If the Secretary should decide to close the establishment, the corresponding closing order shall become effective immediately upon receipt of the written notice by the owner of the establishment.

(C) If the owner does not comply with said closing order, the Secretary shall proceed to submit the record of the case to the Department of Justice, for the purpose of initiating and Order to Cease and Desist (Injunction) to

secure an immediate closing of the establishment and compliance with the law.

ARTICLE IX - MEDICAL PRESCRIPTIONS

(A) It shall be illegal to prepare or dispense, or allow the preparation or dispensing of a medical prescription by a person who is not an authorized pharmacist; provided, that a pharmacy assistant, a pharmacy aide trainee or a pharmacy intern may dispense and prepare prescriptions under the immediate supervision of an authorized pharmacist. Immediate supervision shall be understood as the physical presence of the pharmacist in the area of preparation and the review of the work done.

(B) Medical prescriptions shall only be prepared and dispensed in authorized pharmacies.

(C) The pharmacist shall sign every medical prescription at the time when he dispenses the prescription.

ARTICLE X - MEDICINE CHEST OR DISPENSARY

(A) No medical prescriptions will be prepared or dispensed from medicine chests or in dispensaries, nor will any class of medicine be repacked or relabelled.

(B) Medicine held in medicine chests or dispensaries will be kept in their original containers, duly labelled, and with indications on the label of the name and location of the manufacturer.

(C) Medicine chests or dispensaries shall contain or maintain a limited stock of medicine for treatment of patients cared for in those institutions authorized to operate said medicine chests or dispensaries.

ARTICLE XI - WHOLESALE DISTRIBUTION

(A) Wholesale drug distributors, pharmaceutical manufacturing firms, and wholesale distributors or dealers in non-prescription medicines or pharmaceutical specialties shall only sell drugs and medicines to those establishments authorized by the Department of Health for dispensing on a retail basis said drugs and medicines;

and it shall be understood that wholesale drug distributors, pharmaceutical manufacturing firms and wholesale dealers in non-prescription medicines or pharmaceutical specialties may not retail drugs and medicines directly to the public.

(B) Wholesale drug distributors and pharmaceutical manufacturing firms may not sell to establishments authorized as non-prescription wholesale or retail dealers or dealers of pharmaceutical specialties, medicines not classified as non-prescription medicines or pharmaceutical specialties, as provided by the law and these regulations.

(C) Pharmacies and non-prescription medicine stores shall not sell drugs and medicines on a wholesale basis unless a license is provided to conduct such activities.

ARTICLE XII - NON-PRESCRIPTION MEDICINE OR PHARMACEUTICAL SPECIALTIES

(A) Products considered as non-prescription medicines or pharmaceutical specialties, according to the definitions in these regulations, may be sold without the intervention of a pharmacist in those establishments registered and authorized by the Department of Health as pharmacies, wholesale drug distributors, wholesale dealers in non-prescription medicines or pharmaceutical specialties and retail dealers in non-prescription medicines or pharmaceutical specialties.

(B) Any pharmaceutical product which contains any of the following types of drugs: antibiotics, amphetamines, narcotics, sulfa, barbiturates, biological products, antihelminthics, poisonous medications and whatever other product having hypnotic or somniferous properties or effects are not to be considered as non-prescription medicines or pharmaceutical specialties and they shall be sold only in establishments authorized as pharmacies or druggist shops.

(C) No substance included in the United States Pharmacopoeia and the National Formulary and its supplements shall be considered as a non-prescription medicine or pharmaceutical specialties, with the exception of those substances included in Part (E) of this Article.

(D) Any pharmaceutical product, the label of which establishes that a medical prescription is required for dispensing, shall not be considered as a non-prescription medicine or pharmaceutical specialty.

(E) The following medicines will be considered as non-prescription medicines or pharmaceutical specialties:

1. Antitussives - those which contain ammonium chloride, white pine syrup, wild cherry, chloroform, thymol, Guaiacol, potassium sulfonate, quinine and dextromethorphan. Products containing opium derivatives shall not be included.
2. Products for diabetics such as Sucaryl, Sweeta, saccharine, Benedict's solution, clinitest.
3. Analgesics - those containing aspirin and its derivatives.
4. Antacids - those containing sodium bicarbonates, kaolin, magnesium carbonate of hydroxide, bismuth salts. Those containing derivatives or alkaloids shall not be included.
5. Antiseptics - for mouthwash and external use.
6. Ointments - those used for burns and which contain tannic acid, phenol, zinc salts and picric acid derivatives, and those used to alleviate nose, throat and chest discomfort due to a cold.
7. Nasal inhalers - those containing menthol or camphor or their derivatives. Products containing ephedrine or their derivatives shall not be included.
8. Laxatives - those containing phenolphthalein, mineral oil, senna, holy seed, effervescent saline salts in liquid or tablet form, or dioctyl sodium sulfosuccinate.

9. Antidiarrheals - those containing kaolin, pectin, aluminum salt or aluminum gel.
10. Eye drops or lotion - those used for refreshing the eyes which contain boric acid, camphor, sodium borate and zinc salts.
11. Vitamins - those multiple vitamins used as nutritional supplements. Neither therapeutic vitamins nor specific vitamins nor pediatric vitamins shall be included.
12. Rehabilitative tonics.
13. Powdered milks.
14. Other products considered as household remedies, such as: alcohol, boric acid ointment, calamine lotion, castor oil, corn removers, epsom salts, cod liver oil, glycerine suppositories, cotton, witch hazel, gauze, milk of magnesia, mineral oil, bay rum, grains of Paradise ("malagueta"), medicinal adhesive plasters, adhesive tape, peroxide, liniment.

(F) In establishments authorized to wholesale and retail non-prescriptions medicines or pharmaceutical specialties, medicines shall be kept and dispensed in their original containers duly labelled, with indications on the label of the name of the manufacturer, and kept in an adequate environment so as to avoid deterioration of their quality, purity and potency.

(G) The Secretary of Health is authorized, at any time, to request from establishments authorized as wholesale or retail distributors of non-prescription medicines or pharmaceutical specialties, the list of the products offered for sale.

ARTICLE XIII - SIGNS

(A) No one may display a sign outside an establishment, nor advertise in newspapers, on the radio, on television, through printed flyers or other promotional means, or in any other manner advertise said establishment with a name which includes the words in Spanish "farmacias", "droguería", "botica", "apotecario", or the words in English: "drug store",

"pharmacy", "wholesale druggist", or a combination of these, or whatever related word or phrase; or display any insignia or emblem which might indicate or imply to the public that the establishment is a pharmacy or wholesale drug distributor, unless the establishment is actually an authorized pharmacy or wholesale drug distributor currently licensed through the Department of Health.

ARTICLE XIV - MANUFACTURER, REPACKAGING AND IMPORTATION OF PHARMACEUTICAL PRODUCTS

(A) It shall be the duty of every person or legal entity dedicated to the preparation or manufacture, repackaging or importation of medicinal formula or pharmaceutical products or medicines not previously registered in the Department of Health, and prior to placing such medicines on public sale through wholesaler drug distributors, or in pharmacies or in whatever other establishment authorized by the Department of Health, or distributing these medicines as free samples in Puerto Rico, to submit the formulas of said preparation for registry in the Department of Health before commencing said activities.

(B) It shall also be the duty of every salesman or agent of non-prescription or proprietary medicines, to register his name and address with the Department of Health.

(C) The provisions of this Article shall not apply to any medicine or medicinal compound prepared by means of a medical prescription when, in all circumstances, the prescription has been written specifically for a particular person and not for general use, and that the medicine prepared be for the exclusive use of the person for whom the prescription was prepared. Neither will these provisions apply to official formulas prepared in a pharmacy for consumption in the same establishment.

(D) Upon submitting a formula for registry, the petitioner shall present to the Secretary of Health a registration application, in which the following will be stated:

1. Name of the preparation.

2. Name of the applicant - If the applicant is a corporation, information must be provided on the complete name of the corporation, where and when it was incorporated, names of the corporate officers and business address. If the applicant is a partnership, information must be provided about the names of the partners and home addresses. In the case of a trademark, information must be submitted on the complete trademark name, the signature of the applicant, as well as the names of the persons conducting business under this trademark.
3. Place where the medication is prepared or manufactured.
4. Form and size in which the medication is dispensed (specifying if in solid or liquid state).
5. Complete formula making up the preparation.
6. Therapeutic effects attributed to the preparation.
7. Exact text of all advertising, labels and printed material which is affixed to, or accompanies the original container or packaging.

(E) In the case of official formulas submitted for registration purposes, the applicant will not be required to submit the information required in Parts (D)-(5) and (D)-(6) of Article 11.

(F) The Secretary of Health shall not reveal the ingredients of registered formulas, except as may be required by order of a court with jurisdiction.

(G) Documents concerning each registered formula shall be filed in the offices of the Department of Health in an appropriate location, identified by correlative numbers.

(H) Reference shall not be made in any sign or advertisement or in any other form, that the Department of Health accepts any responsibility in relation to the therapeutic purpose of said medications.

(I) The Secretary of Health shall deny the registration of any medicinal formula for the following reasons:

1. If such formula contains alcohol in excess of the amount needed as a solvent or preservative, or if such were not sufficiently medicated so as to be appropriate as an intoxicating beverage.
2. If such formula were to be offered or used directly or indirectly for any immoral or illegal purpose.
3. If such formula is claimed by means of advertisements or recommendations, to be a specific remedy for any illness, condition or physical deformity.
4. If such formula were to be given to children less than one year of age and contains any substance, the dosage of which would be considered dangerous for said children.
5. If such formula contains opium or any of its derivatives and such information is not specified on the label in larger type and distinctive colors, from the remaining text.
6. If such formula contains cocaine or its salts, or any mixture, compound or product of eucaine or its salts.

(J) The Secretary of Health shall approve the registration of all medicinal formula that have been investigated and accepted by the Federal Food and Drug Administration and comply with other Federal Laws, through the presentation of the indispensable documentary evidence which demonstrates that the medicinal preparation conforms to the conditions established in this Article.

(K) The Secretary of Health is authorized to revoke the registration of a pharmaceutical product if he finds that said product is being sold, distributed or supplied as a free sample, in violation of the provisions of this Article.

(L) The Drugs and Pharmacy Inspectors shall collect from time to time, as provided by the Secretary of Health, samples of the preparations whose formulas have been registered in the Department of Health; PROVIDED, that if the chemical analysis demonstrates that the composition of the preparation should turn out to be different from that of the previously

registered formula, or if the labels or bibliography which accompany the containers have been modified without authorization of the Department and of the Federal Food and Drug Administration, the Secretary of Health shall then seize or destroy, as deemed necessary, said preparation or the same may be ordered to be done by the representative authorized to sell the medication.

(M) The sale of pharmaceutical products which have not been registered as provided in these regulations, shall not be permitted in Puerto Rico and seizure and destruction of the same will be accomplished.

ARTICLE XV - MINIMUM REQUIREMENTS FOR THE STORAGE AND HANDLING OF PRESCRIPTION MEDICINES AND THE ESTABLISHMENT AND MAINTENANCE OF REGISTRIES FOR THE DISTRIBUTION OF PRESCRIPTION MEDICINES

All wholesale prescription distributors, their officers, agents, representatives and employees must comply with the following minimum requirements for storing and handling prescription medicines and for the establishment and maintenance of registries for the distribution of prescription medicines:

(A) Facilities - All facilities used for the storage, handling, maintenance, offering, marketing or presentation of prescription medicines, must:

(1) be of the proper size and construction to facilitate proper cleaning, maintenance and functioning.

(2) have storage areas designed to provide adequate illumination, ventilation, temperature, sanitary measures, humidity, space, equipment and safety conditions.

(3) have a quarantine area for the storage of prescription medicines which have expired, become damaged, deteriorated, are incorrectly marked, adulterated or which are in sealed containers which have been opened.

(4) be kept in clean and orderly condition.

(5) be free from any infestation of insects, rodents, birds or pests of any kind.

(B) Safety

(1) All facilities used for the wholesale distribution of prescription medicines must be insured against unauthorized entry.

(i) The exterior access to the premises must be properly controlled and maintained at a minimum.

(ii) The exterior perimeter of the premises must be well lit.

(iii) The entrance to areas where prescription medicines are kept must be limited to authorized personnel.

(2) All facilities must be equipped with an alarm system which detects entries outside of working hours.

(3) All facilities must be equipped with a safety system which provides proper protection against burglary and theft. When appropriate, the safety system must provide protection against burglaries or thefts which are facilitated or concealed through the alteration of computer or electronic filing systems.

(C) Storage - All prescription medicine must be stored at proper temperatures under proper conditions, in accordance with the specifications, if any, on the label of the medicine or with the requirements of the latest edition of a critical compendium, such as for example the National Formulary and the United States Pharmacopoeia.

(1) If storage requirements have not been established for a prescription medicine, the medicine must be kept in a temperature-controlled room, as the term is defined in the official compendium, to help ensure that its identity, potency, quality and purity are not adversely affected.

(2) In order to document the proper storage of prescription medicines, proper equipment, artifacts or registers, whether manual, electromechanical or electronic, should

be used for recording the temperature and humidity.

(3) The registry maintenance requirements provided in paragraph (f) of this section must be followed with respect to all of the stored medicines.

(D) Inspection of materials

(1) Upon receipt, every package must be visually examined for identification and to prevent the acceptance of contaminated prescription medicines, or that, in some manner, they are not appropriate for distribution. This inspection must be adequate enough to reveal damages to the packaging which may suggest possible contamination or other damage to the contents.

(2) All shipments to be dispatched must be carefully inspected for purposes of identifying the prescription medicines and to ensure that prescription medicines that have been damages in the warehouse or have been kept under inadequate conditions are not delivered.

(3) The bookkeeping requirements contained in paragraph (f) of this section must be followed in relation to all of the prescription medicines which are received or dispensed.

(E) Prescription Medicines Returned, Damages or Expired

(1) Prescription medicines which have expired, have become damages, deteriorated, labelled incorrectly, or adulterated must be placed in quarantine and physically separated from other prescription medicines until they are destroyed or returned to their suppliers.

(2) All prescription medicines whose sealed or immediate exterior packaging, or whose secondary sealed packaging have been opened or used, must be identified as such and must be placed in quarantine and physically separated from other prescription medicines until they are destroyed or returned to their suppliers.

(3) If the conditions under which a prescription medicine has been returned creates doubts as to its safety, identify,

potency, quality or purity, then the medicine must be destroyed or returned to its supplier, unless an inspection, examination or other investigation shows that the medicine satisfies proper standards of safety, identity, potency, quality and purity. Upon determining whether the conditions under which a medicine has been returned causes doubts as to its safety, identity, potency, quality or purity, the wholesale distributor must consider, among other things, the conditions under which the medicine has been stored, warehoused, or shipped before or during its return and the condition of the medicine and its package, box or label as a result of the storage or shipment.

(4) The bookkeeping requirements contained in paragraph (f) of this section must be followed for all prescription medicines which have expired, have become damaged, deteriorated, labelled incorrectly or adulterated.

(F) Bookkeeping or Registries

(1) Wholesale distributors must establish and keep inventories and registries of all transactions related with the receipt and distribution and other disposition of prescription medicines. Said registries must contain the following information:

(i) The source of the medicines, including the principal name and address of the seller or assignor and the address of the place where the medicine was sent.

(ii) The identity and amount of the medicines received distributed or sold; and

(iii) The dates of receipt and distribution or other disposition of the medicines.

(2) Inventories and registries must be available for inspection and photocopy by authorized officials of Federal or local agencies in charge of compliance of the laws, for a period of two (2) years, from disposition of

the medicines.

(3) The registries described in this section, which are kept in the place of inspection or which may be located immediately by computer and other electronic means, must be available immediately for authorized inspection during the retention period. Registries which are kept in a central location separate from the place of inspection and which cannot be located electronically must be made available for inspection within the period of two (2) working days from the date they are requested by a Commonwealth or Federal official.

(G) Written Norms and Procedures. Prescription medicine wholesalers must establish, maintain and comply with the written policies and procedures which shall be followed in relation to the receipt, safety, storage, inventory and distribution of prescription medicines, including policies and procedures for identification, registry and reporting of losses and thefts, and correction of all errors and inaccuracies in inventories. Wholesale dealers must include in their written policies and procedures the following:

(1) A procedure whereby the oldest inventory of prescription medicine is distributed first. The procedure may allow for deviations of this requirement if said deviations are temporary and adequate.

(2) A procedure for handling withdrawals and removal of prescription medicines which adequate for dealing with withdrawals and removals caused by reason of:

(i) any action initiated at the request of the Food and Drug Administration and other Federal or local government agency, including the Department.

(ii) any voluntary action of the manufacturer initiated with the purpose of withdrawing from the market defective or potentially defective medicines, or

(iii) any action carried out to promote public health and safety through the replacement of existing

merchandise with an improved product or with a new package design.

(3) A procedure to ensure that wholesale dealers are prepared for, protected against, and handled any crisis which affects the safety or operation of any facilities in the event of a strike, fire, flooding and other natural disaster or local or national emergency situations.

(4) A procedure to ensure that prescription medicines which have expired are segregated from other medicines and returned to the manufacturer, or destroyed. This procedure must include written documentation on the disposition of prescription medicine which has expired. This document must be kept for a period of two (2) years after disposition of the medicines which have already expired.

(H) Responsible Persons. Wholesale dealers of prescription medicines must establish and maintain lists of officials, directors, managers and other persons in charge of the wholesale distribution, storage and handling of medicines, including a description of their duties and a summary of their qualifications.

(I) Compliance with Federal and Local Laws. Wholesale dealers must operate in compliance with the applicable Federal and Local Laws and Regulations.

(1) Wholesale dealers must allow authorized personnel from the Department, and authorized Federal Officials to enter and inspect their facilities and delivery vehicles and to audit their registries and written operational procedures, in reasonable hours and in reasonable manner, up to the extent authorized by law. These officials must be required to show their proper identification prior to permitting their access to delivery vehicles, as well as to the wholesale distributor facilities.

(2) Wholesale dealers who work with controlled substances

must register with the local government entities in charge of controlled substances and with the Federal Controlled Substance Administration, and they must comply with all of the applicable local regulations and the applicable regulations of the Federal Controlled Substances Administration.

(J) Salvaging and Reprocessing. Wholesale dealers are subject to the provisions of the applicable Federal and local laws and regulations related to salvaging or reprocessing of prescription medicines, including the pertinent sections of these regulations.

ARTICLE XVI - PENALTIES

(A) Violations of these regulations shall be considered as violations of Act No. 282 of May 15, 1945, as amended, "Puerto Rico Pharmacy Act" and those incurring in said violations shall be penalized with the penalties appearing in Sections 386, 403 and 406 of said Act (24 LPRA SS 386, 403 and 406). Furthermore, the penalties provided by Law No. 170 of August 12, 1988, as amended, the "Uniform Procedure Act", Section 7.1 shall be applicable.

ARTICLE XVII - SEPARABILITY OF PROVISIONS

The nullification or unconstitutionality of a paragraph, part or Article of these regulations shall not affect the validity of the remaining provisions of the regulations.

ARTICLE XIX - REPEAL CLAUSE

All other regulations in conflict with these regulations are hereby repealed.

ARTICLE XX - EFFECTIVE DATE

These regulations, issued in accordance with the provisions of Law No. 282 of April 15, 1945, as amended, known as the "Puerto Rico Pharmacy Law", the Federal provisions established in the "Prescription Drug Marketing Act 1987", shall enter into effect immediately after being approved by the Honorable Governor of Puerto Rico and after having complied with the provisions of Law No. 170 of August 12, 1988, as amended.