

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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DEPARTMENT OF AGRICULTURE

Administrative Order No. 138
Series of 1990

DEPARTMENT OF HEALTH

Administrative Order No. 100
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**SUBJECT: REGULATIONS FOR THE LICENSING OF VETERINARY DRUG AND
PRODUCT ESTABLISHMENT AND OUTLETS.**

Pursuant to R.A. No. 3720, as amended by Executive Order No. 175, otherwise known as the Food, Drugs and Devices and Cosmetics Act” R.A. 6675 otherwise known as the “Generics Act” of 1988, R.A. 1556, otherwise known as the “Livestock and Poultry Feeds Act”, R.A. 1071, an act to regulate the sale of veterinary biologics ad medicinal preparation and R.A. 3101, an act authorizing the Director of the Bureau of Animal Industry, subject to the approval of the Secretary of Agriculture and Natural Resources to promulgate regulations for the preparation, sale, traffic in, shipment, and importation of viruses, sera toxins of analogous products used for the treatment of domestic animals, the following requirements for the licensing of veterinary drug and product establishments and outlets are hereby promulgated for the information, guidance and compliance of all concerned.

In accordance with the above laws, any organization company or business establishments in the veterinary drugs and products industry shall fall under the following general classification:

- I. Veterinary Drug and Product Establishment refers to any organization or company involved in the manufacture importation, repacking, labeling, advertising and / or distribution of veterinary drugs and products. This is covered by Chapter 1 below.
- II. Veterinary Drug Outlet refers to drugstore, pharmacy, livestock and poultry supply store and other business establishments selling veterinary drugs and products. This is covered by Chapter II below.

CHAPTER I – VETERINARY DRUG AND PRODUCT ESTABLISHMENTS.

1. Definition of Different Types of Veterinary Drug and Product Establishments

- 1.1 Veterinary Drug and Product Manufacturer refers to any establishment engaged in operations involved in the production of a drug including propagation, processing, compounding, finishing, filing, repacking, labeling, advertising, storage, distribution or sale of the veterinary drug products proving that for the purpose of this regulation

the compounding and filling of prescription by drugstores shall not be considered as production operations.

- 1.2 Veterinary Drug and Product Traders refers to any establishment which is a registered owner of the drug product, procures the raw materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such veterinary drug and product to a licensed manufacturer. In addition a trader may also engage in distribution, and/or marketing of its veterinary drugs and products.
- 1.3 Veterinary Drug and Product Distributor / Importer refers to any veterinary drug and product establishment that imports raw materials, active ingredients and / or finished products, for its own use or for wholesale or distribution to other drug establishments or outlets.
- 1.4 Veterinary Drug and Product Distributor / Exporter refers to any veterinary drug and product establishment that exports raw materials, active ingredients and / or finished products to another country.
- 1.5 Veterinary Drug and Product Distributor, Wholesaler refers to any veterinary drug and product establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

2. Standards and Requirements for License To Operate (LTO)

2.1 General Requirements

- 2.1.1 Application – any person desiring to operate or establish, a veterinary drug and product establishment shall file with the BFAD/BAI an application supported by the following documents:

- 2.1.1.1 A standard petition form containing among others the name, age, citizenship and a passport size picture (5 x 5 cm), of the petitioner and other pertinent circumstances pertaining to the proposed veterinary drug and product establishment including the place where it is to be established.

- 2.1.1.2 Proof of registration as an establishment, ie.:

- a) For single proprietorship an authenticated photocopy of the certificate of Business Name Registration issued by the Bureau of Domestic Trade (BDT) of the Department of Trade and Industry.
 - b) For partnerships, corporations and other judicial persons authenticated photocopies of the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and the Articles of Incorporation or Partnership.

- 2.1.1.3 A valid Certificate of Registration of the establishment's Filipino Veterinarian issued by the Professional Regulation Commission (PRC).

2.1.1.4 A valid Certificate of Registration of the establishment's Filipino Pharmacist issued by the Professional Regulation Commission (PRC).

2.1.1.5 A valid credential of the establishment's Filipino Microbiologist in case of veterinary biological manufacturer and trader.

2.1.1.6 A certificate of attendance to a BFAD/BAI sponsored / accredited Seminar on Licensing of Veterinary Drug and Product Establishments:

2.1.1.7 An Affidavit of Undertaking providing that the applicant shall;

- a) change the establishment's name if there is already a validly registered name similar to it.
- b) Display the duly approved LTO in conspicuous place within the establishment.
- c) Notify BFAD/BAI in case of any change in the circumstances described in the application, among others; change of location, change of veterinarian, change of pharmacist, change in veterinary drugs and products.

2.1.1.8 An authenticated photocopy of Contract of Lease for the space to be occupied if the applicant does not own it.

2.1.2 A Certificate of continuing compliances with specific technical requirements (to be specified by BFAD/BAI according to section 2.2 below).

2.1.3 A Batch Distribution Record Book duly registered with BFAD/BAI.

2.1.4 A contingency plan procedure for a systematic, effective and prompt recall in case any of its products is found violative and ordered recalled from the market by BFAD/BAI.

2.1.5 An orderly and secure system of filing up to date invoices from suppliers and buyers identifying lot numbers or batch numbers of manufacturers stock pursuant to BFAD Memo Circular No. 001 s. 1983.

2.2 Specific Requirements:

An entity applying for a LTO as a veterinary drug and product manufacturer or veterinary drug and product trader or veterinary drug and product distributor shall be required to demonstrate its capacity to perform adequately as such in a manner that satisfactorily assumes the safety, efficacy and quality of its veterinary drugs and product. It should be required to conform with the following relevant standards and requirements specific for each category in addition to the above general requirements.

2.2.1 Veterinary Drug Manufacturers

2.2.1.1 Guidelines on Current Good Manufacturing Practices (GMP) provided for under A.O. No. 220 s. 1974, as amended including location, building and floor plans, and additional guidelines issued by BFAD.

2.2.1.2 Minimum standards for pharmaceutical manufacturing equipment / machines owned by the manufacturer described in Annex A.

2.2.1.3 Minimum standards for quality control facilities owned by the manufacturers described in Annex B.

2.2.1.4 If importing raw materials active ingredients and / or finished products for use in manufacture of veterinary drug and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturers by BFAD/BAI is necessary, the cost of inspections shall be borne by the applicant establishment. However, in lieu of the above a Certification Scheme from WHO or from an acceptable equivalent drug regulatory agency or organization.

2.2.2 Veterinary Biological Manufacturers

2.2.2.1 Guidelines on Current “Good Manufacturing Practices (GMP)” provided for under A.O. No. 220 s. 1974, as amended including location, building and floor plans, and any additional guidelines issued by BFAD, administrative Order No. 9 issued by BAI and other guidelines as required by NDC and other agencies.

2.2.2.2 Minimum standards for veterinary biological manufacturing equipment / machine described in Annex C.

2.2.2.3 Minimum standards for quality control facilities described in Annex D.

2.2.2.4 If importing raw materials, active ingredients and / or finished products for use in manufacture of veterinary drug and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment.

2.2.3 Veterinary Medicated Feeds, Medicated Feed Premix, Medicated Feed Supplement, Medicated Feed Additive and Medicated Water Additive Manufacturer.

Medicated feed refers to any feed which contains drug ingredients intended or represented for the cure, mitigation, treatment or prevention of diseases of animal other than man or which intended to affect certain drug ingredients the structure or any function of the body of animal other than man.

2.2.3.1 Relevant guidelines on Current Good Manufacturing Practices (GMP) provided for under A.O. No. 220 s. 1974, as amended including location, building

and floor plans, and any additional guidelines issued by BFAD and Administrative Order No. 35 issued by BAI.

2.2.3.2 Minimum standards for Veterinary Medicated Feed manufacturing equipment / machine described in Annex E.

2.2.3.3 Minimum standards for quality control facilities described in Annex F whether owned or contracted by the manufacturer provided the contracted quality control facility is accredited by BAI.

2.2.3.4 If importing raw materials, active ingredients and/or finished products for use in manufacture of veterinary drugs and products, a certificate that the manufacturer is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate any equivalent governments regulatory agency and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspections of the foreign manufacturers by BFAD/BAI is necessary, the cost of inspection shall be done by the applicant establishment.

2.2.4 Veterinary Drug and Product Traders.

2.2.4.1 A valid contract of agreements with a BFAD/BAI licensed manufacturers containing a stipulated authentications that both the veterinary drug trader and the manufacturer are jointly responsible for the quality of the veterinary drug and products;

2.2.4.2 If importing raw materials, active ingredients and/or finished products for use in the manufacturer of veterinary drug and product, a certificate that the manufacturer is registered with the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the consulate, any equivalent regulatory government agency and evidence that the manufacturer meets BFAD/BAI standards for local manufacturers. If inspection of the foreign manufacturer by the BFAD/BAI is necessary, the cost of inspection shall be borne by the applicant establishment.

2.2.4.3 A description of the production process and quality control procedures to be followed by the contracted manufacturer, jointly certified by the owner and the pharmacist of the veterinary drug and product establishment.

2.2.5 Veterinary Drug and Product Distributors

2.2.5.1 Importers

2.2.5.1.1 Foreign Agency Agreement between the Philippine Importer and foreign supplier duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate, any equivalent regulatory government agency.

2.2.5.1.2 A certificate that the manufacturer of the raw material, active ingredient and/or finished product is registered in the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate, any equivalent regulatory government agency and evidence that the manufacturer

meets BFAD/BAI standard for local manufacturers. If inspection of the foreign manufacturers of the BFAD/BAI is needed the cost of inspection shall be borne by the applicant establishments.

2.2.5.1.3 In case of finished products Certificate of Free Sale of the product in the country of origin, duly authenticated by the territorial Philippine Consulate, in the absence of the Consulate, any equivalent regulatory government, agency and evidence that such certificates is issued in substantial compliance with BFAD/BAI standards.

2.2.5.2 Exporters

2.2.5.2.1 A valid contract with a BFAD/BAI licensed manufacturer in addition to other requirements set by other competent authorities.

2.2.5.3 Wholesalers

2.2.5.3.1 A valid contract with BFAD/BAI licensed veterinary drug and product manufacturer, trader or distributor.

2.2.5.3.2 A certification that the products it sells are registered with BFAD/BAI.

2.3 Other Additional Requirements:

In addition to the above standards and requirements, BFAD/BAI in the course of evaluating an application may require other additional documentation or evidence to satisfactorily ascertain the capability of the veterinary drug and product establishment.

3. Renewal of License to Operate (LTO)

3.1 The License to Operate shall have the following validities for all categories of veterinary drug and product establishments:

3.1.1 Initial Period (Initial Application) 1 year.

3.1.2. Subsequent, Period (Renewal Application) 2 years

3.2 At least one month prior to the expiration of the LTO, veterinary drug and product establishment shall apply to renew their license.

3.3 In considering the renewal applications, BFAD/BAI shall ascertain the continued compliance by the veterinary drug and product establishment with the standards and requirements stipulated in section 2.1 and 2.2

4. Administrative Sanctions

4.1 Grounds for Revocation of LTO.

4.1.1 Misrepresentation of any material fact in the application for LTO and in any documentation used as a basis for issuing the LTO.

4.1.2 For manufacturers and traders any deficiency in GMP that is likely to result in adulterated, misbranded, substandard or unsafe products as determined by BFAD/BAI. This included, among others, grossly inadequate premises, lack of key technical and professional personnel, lack of key equipment in production or quality control, inadequate or improper documentation of the production process.

4.1.3 For distributors; distribution of fake, substandard, misbranded, adulterated or unsafe veterinary drugs and products.

4.1.4 Violation of BFAD/BAI standards of quality, efficacy, purity and safety of veterinary drugs and products.

4.1.5 Sale and distribution of therapeutic antibiotic and biological products without batch certification by BFAD/BAI.

4.1.6 Failure to take adequate remedial or corrective measures for deficiencies identified in accordance with requirements of BFAD/BAI.

4.1.7 Failure to keep up to date, secure, orderly, and easily inspected records that would indicate continued compliance with standards.

4.2 Grounds for Suspension of LTO.

4.2.1 Minor deficiencies in GMP or material management that need to be corrected but are not immediately or likely to result in adulterated, misbranded, substandard or unsafe veterinary drugs and products as determined by BFAD/BAI. These include, among others, poor housekeeping inadequate storage facilities, non-functional equipment, and failure to comply with laboratory safety standards.

4.2.2 Lapses in record keeping of invoices, receipts or distribution records.

4.3 Lapses in record keeping of invoices, receipts or distribution records.

No establishment whose LTO was revoked may apply for LTO within 5 years after the revocation of its license.

5. Schedule of Fees

5.1 Upon application for a license to operate of a veterinary drug and product establishment, the following non-refundable fees shall be charged for each application:

Veterinary Drug and Product Manufacturer (Code VDAPM)

Veterinary Drug and Product Trader (Code VDAPT)

Veterinary Drug and Product Distributor (Code VDAPDW/VDAPDE/VDAPDI)

Code	Initial	Renewal (good for 2 years)
VDAPM	P 5,000	P 10,000

VDAPT	P 3,000	P 6,000
VDAPDW/VDAPDE/VDAPDI	P 2,000	P 4,000

5.2 If a veterinary drug and product establishment engaged in activities belonging to more than one of the above categories, applicant must apply for LTO for each of the category and pay the corresponding fees.

5.3 Only upon payment of application fees may the application be processed. A surcharge of fifty percent (50%) of the above fees shall be imposed on applications for renewal filed after the validity of the license has lapsed. Any change in the category of veterinary drug and product establishment or change in ownership shall require a new application.

CHAPTER II – VETERINARY DRUG AND PRODUCT OUTLETS

1. Definitions of Different Types of Veterinary Drug and Product Outlets.

1.1 Drugstore, Pharmacy and Botica and drug outlets where registered veterinary drugs and products, chemical products, active pharmaceutical, proprietary medicines or pharmaceutical specifications are compounded and/or dispensed and hold executive veterinary hospitals, clinic and Farm storage store where drugs and products are stored for their exclusive use.

1.2 Veterinary and agricultural supply store, livestock and poultry supply and any other outlets selling prescription veterinary drugs and products.

1.3 Retail outlet for non-prescription drugs including the traditional outlets such as supermarkets and stores means a drug outlet where registered non-prescription or over-the-counter (OTC) or self-service (SS) Veterinary drugs and products are sold in their original packages, bottle or containers or in mail quantities nor in their original containers.

2. Standards and Requirements for License to Operate (LTO)

2.1 General Requirements

2.1.1 Application of person desiring to operate or establish a veterinary drug and product outlet shall file with the BFAD/BAI application supported by the following documents:

2.1.1.1 A standard petition form containing among others the name, age, citizenship and a passport size picture (5x5cm) or the petitioner and other pertinent circumstances pertaining to the proposed veterinary drug and product outlet including the place where it is to be established.

2.1.1.2 Proof of registration as an establishment, i.e.:

- a) For single proprietorship; an authenticated photocopy of the Certificate of Business Name Registration issued by the

Bureau of Domestic Trade (BDT) of the Department of Trade and Industry.

- b) For partnership, corporation and other judicial persons; authenticated photocopy of the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and the Articles of Incorporations or partnership.

2.1.1.3 A valid Certificate of Registration of the establishment's Filipino Pharmacy/Veterinarian issued by the Professional Registration Commission (PRC)

2.1.1.4 A certificate of attendance to a BFAD/BAI accredited Seminar for Licensing of veterinary drug and product outlet.

2.1.1.5 An Affidavit of undertaking providing that the applicant shall;

- a) change the establishment's name if there is already a validly registered name similar to it.
- b) display the duly approved LTO in a conspicuous place within the establishment.
- c) notify BFAD/BAI in case of any change in the circumstances described in the application such as: change of location, change of pharmacist, etc.

2.1.1.6 Tentative list of veterinary drugs and products intended to be sold using generic names with brand names when applicable.

2.1.1.7 An authenticated photocopy of Contract of Lease for the space to be occupied if the applicant does not own it.

2.1.2 For drugstore, pharmacy or botica, see Specific Requirements 2.2.1

2.2 Specific Requirements:

Any entity applying for a license to operate drugstore, pharmacy or botica or retail outlet shall be required to demonstrate its capacity to perform adequately its functions to inform its clientele in accordance with Section 6 (d) of R.A. 6675 and sell veterinary drugs and products, which are safe, effective and of good quality to the public. It shall be required to conform with relevant standards and requirements specific for each, category, in addition to the foregoing general requirements.

- 2.2.1 Drugstore, Pharmacy or Botica requirements are provided for in A.O. No. 56 s. 1989 and therefore shall secure the license to operate from the BFAD. However, they shall secure a license to operate from the BAI if they shall sell veterinary drugs and products. Such LTO shall be automatically granted by the BAI upon presentation of LTO from BFAD, payment of corresponding fees and tentative list of veterinary drugs and products intended to be sold using generic names with brand names when applicable.

2.2.2 Veterinary and agricultural supply store livestock and poultry supply store are outlets selling prescription veterinary drugs and products.

2.2.2.1 Premises

2.2.2.1.1 A signboard in front at the place of business bearing the registered name of the veterinary drugstore, but veterinary drugs and product outlet selling exclusively non-prescription or over-the-counter (OTC) or self-service veterinary drug and product, the signboard should indicate so by putting the symbol non –Rx or equivalent.

2.2.2.1.2 A well-ventilated area not less than 12 sqm. in floor area with concrete, tile or wooden flooring.

2.2.2.1.3 A suitable and proper place (e.g. refrigerator) for the adequate storage of veterinary drugs and products as specified on the label.

2.2.2.1.4 A suitable cabinet for keeping poisons and/or dangerous drugs when applicable.

2.2.2.1.5 An adequate water and electrical supply.

2.2.2.1.6 Other additional requirements of BA and FPA.

2.2.2.2 Reference Books and Documents

2.2.2.2.1 Philippine National Veterinary Drug Formulary.

2.2.2.2.2 Philippine Veterinary Drug Codex.

2.2.2.2.3 R.A. 3720, otherwise known as the Foods, Drugs and Devices and Cosmetics Act as amended and relevant implementing rules and regulations.

2.2.2.2.4 R.A. 6675, Generics Act of 1988 and relevant implementing rules and regulations.

2.2.2.2.5 R.A. 5921 Pharmacy Law, as amended and relevant implementing rules and regulations.

2.2.2.2.6 R.A. 3101, An Act authorizing the Director of Animal Industry to promulgate regulation for the preparation sale, traffic in, and shipment, and importation of viruses, serum, toxins, or analogue products used for the treatment of domestic animals and relevant implementing guidelines.

2.2.2.2.7 R.A. 1071, An Act to regulate the sale of veterinary biologics and medicinal preparation and relevant implementing guidelines.

2.2.2.2.8 R.A. 1556 Livestock and Poultry Feeds Act, and relevant implementing guidelines.

2.2.2.3 Record Books Duly Registered with BFAD/BAI.

2.2.2.3.1 Prescription Book

2.2.2.3.2 Dangerous Drugs Book, when applicable.

2.2.2.3.3 Poisons Book, when applicable.

2.2.2.4 A duly BFAD/BAI Registered pharmacist or veterinarian.

2.2.2.5 Other Additional Requirements:

2.2.2.5.1 Invoices indicating the lot number or batch number of the manufacturer's stock pursuant to BFAD Memo. Circular No. 001 s. 1983.

2.2.2.5.2 File of prescriptions filled, consecutively numbered.

2.2.2.5.3 Dry Seal or Rubber Stamp containing the name and address of the veterinary drug and product outlet.

2.2.3 Requirements for a Retail Outlet for Non-Prescription, Over-the-Counter and Self-Service Veterinary Drugs and Products.

2.2.3.1 Premises

2.2.3.1.1 A signboard in front at the place of business bearing the registered name of the retail outlet and the symbol product or equivalent.

2.2.3.1.2 An adequate, well ventilated area with concrete, tile or wooden flooring.

2.2.3.1.3 A suitable and proper place for the adequate storage of non-prescription drugs when where are products sold other than drugs, area exclusively for veterinary drugs and shall be allocated within the premises.

2.2.3.2 Reference Books and Documents

2.2.3.2.1 Philippine National Veterinary Drug Formulary.

2.2.3.2.2 Philippine Veterinary Drug Index.

2.2.3.2.3 R.A. 5921, Pharmacy Law and its implementing rules and regulations.

2.2.3.2.4 R.A. 6675 the Generics Act of 1988 and relevant implementing rules and regulations;

2.2.3.2.5 R.A. 3720 as amended or Foods, Drugs and Devices and Cosmetics Act.

2.2.3.2.6 R.A. 3101, An Act authorizing the Director of Animal Industry to promulgate regulation for the preparation, sale, traffic in and shipment, and importation of viruses, serum, toxins, or analogue products used for the treatment of domestic animals and relevant implementing guidelines.

2.2.3.2.7 R.A. 1071, An Act to regulate the sale of veterinary biologics and medicinal preparation and relevant implementing guidelines.

2.2.3.2.8 R.A. 1556 Livestock and Poultry Feeds Act and relevant implementing guidelines.

2.2.3.3 Other Additional Requirements

2.2.3.3.1 Invoices indicating the Act number or batch number of the manufacturer's stock pursuant to BFAD Memo. Circular Law 001 s. 1983.

2.2.3.3.2 Dry Seal or Rubber Stamp containing the name and address of the veterinary drug and product outlet.

3. Renewal of License to Operate (LTO)

In case of renewal of LTO THE Veterinary drug and product outlet must have all categories of performance, consistent with BFAD/BAI standard and requirements, without any cases of serious violation of existing laws, rules and regulations.

4. Administrative Sanctions

4.1 Temporary Closure

Failure to comply with the standards and requirements for LTO as stated above.

4.2 Suspension of License to Operate

4.2.1 Failure to product invoices and receipts together with lot number, expiry dates for the veterinary drugs and products in stock.

4.2.2 Failure to properly record and keep a file of all prescriptions filled in the last two years.

4.2.3 Refusal to allow entry of BFAD/BAI inspectors.

4.3 Revocation of License to Operate

4.3.1 Sale or offer for sale of adulterated, misbranded, sub-standard, unregistered, expired and/or unsafe veterinary drugs and products marked "Not for Sale".

4.3.2 Failure to properly record dangerous drugs as determined by DDB.

4.3.3 Lack of pharmacist / veterinarian.

4.3.4 Failure to take necessary remedial or corrective measures within the prescribed period as directed by BFAD/BAI.

5. Validity

The license to operate shall have the following validities:

Initial Period of validity

1 year

Validity of Subsequent Renewal

2 years

6. Schedule of Fees

Upon application for a license to operate, the following non-refundable fees shall be charged for each application:

Initial

P 200.00

Renewal (Good for two years)

P 400.00

Only upon payment of application fees may the application be processed. A surcharge of fifty percent (50%) of the above fees shall be imposed on applications for renewal filed after the validity of the license has lapsed.

SEPARABILITY CLAUSE

In case any provision of this rules and regulations is declared contrary to law or unconstitutional other provisions which are not affected thereby shall continue to be in force in effect.

REPEALING CLAUSE

All administrative orders, rules and regulations and other administrative issuance or parts thereof inconsistent with the provisions of this Regulations are hereby repealed or modified accordingly.

EFFECTIVITY

This Regulation shall take effect fifteen (15) days after its publication in a newspaper of general circulation.

(Sgd.) SENEN C. BACANI .M.D.
Secretary of Department of Agriculture

(Sgd.) ALFREDO R.A.BENGZON, M.D.
Secretary of Health