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RULES AND PROCEDURES GOVERNING THE IMPORTATION, DISTRIBUTION, MANUFACTURE, PRESCRIPTION, DISPENSING AND SALE OF DANGEROUS DRUGS AND EXEMPT DANGEROUS DRUG PREPARATIONS

DDB BOARD REGULATION NO. 4, February 28, 1991

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Pursuant to the powers vested in the Dangerous Drugs Board under paragraphs (a) and (1), Section 36, Article VIII of Republic Act No. 6425, as amended, Revenue Regulations 16-67 are hereby amended to read as follows:

Article I
Definition of Terms

SECTION 1. Definitions — As used in this Regulation, the term:

a. Law or This Law refers to the Act approved on March 30, 1972, Republic Act No. 6425, otherwise known as "The Dangerous Drugs Act of 1972," as amended.

b. Narcotic Drug refers to any drug which produces insensibility, stupor, melancholy or dullness of mind with delusions and which may be habit-forming and shall include opium, opium derivatives and synthetic opiates.

c. Dangerous Drug refers to either:

1. Prohibited Drug, which includes opium and its active components and derivatives, such as heroin and morphine; coca leaf and its derivatives, principally cocaine; alpha and beta cocaine; hallucinogenic drugs, such as mescaline, lysergic acid diethylamide (LSD) and other substances producing similar effects; indian hemp and its derivatives; all preparations made from any of the foregoing; and other drugs and chemical preparations, whether natural or synthetic, with the physiological effects of a narcotic or a hallucinogenic drug; or

2. Regulated Drug, which includes self-inducing sedatives, such as secobarbital, phenobarbital, pentobarbital, barbital, amobarbital and any other drug which contains a salt or a a derivative of a salt of barbituric acid; any salt, isomer or salt of isomer, of amphetamine, such as benzedrine or dexedrine, or any drug which produces physiological action similar to amphetamine; and hypnotic drugs, such as methaqualone, nitrazepam or any other compound producing similar physiological effects.

d. Exempt Dangerous Drug Preparation” refers to any preparation which as determined by the Board, (a) is a useful and much needed medicine required to be easily available to the public in medical need thereof; (b) presents no or negligible risk of abuse; and (c) is so compounded, mixed or prepared as to render its dangerous drug content impossible to recover with readily applicable means in a quantity liable to abuse and therefore, does not give rise to a public health and social problem.

e. Opium refers to the coagulated juice of the opium poppy (Papaver Somniferum L.) and embraces every kind, character and class of opium, whether crude or prepared, the ashes or refuse of the same; narcotic preparations thereof or therefrom; morphine or any alkaloid of opium; preparations in which opium morphine, or any alkaloid

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of opium enter as an ingredient; opium poppy; opium seeds; opium poppy straw; and leaves or wrappings of opium leaves, whether prepared for use or not.

f. Cannabis Sativa L., otherwise known as marihuana or indian hemp refers to every kind, class, genus or species of the plant cannabis sativa l., including cannabis americana, hashish, bhang, guaza, churrus and ganjab, and embraces every kind, class and character thereof, whether dried or fresh and flowering or fruiting tops or any portions of the plant, seeds thereof, and all its geographic varieties, whether as a reefer, resin, extract or tincture or in any form whatsoever.

g. Hallucinogens are chemical substances which when administered in pharmacological doses, create gross distortions in perception without significantly blunting or dulling consciousness. Such substances have a profound effect on mood, thought and behavior, with rapid development of tolerance, as well as development of physical and psychological dependence.

h. Depressants are chemical substances which produce dose-dependent and complex actions in the central nervous system resulting in decreased function leading to psychological and physical dependence with symptoms of abstinence upon withdrawal of the chemical substances. These include sedatives, hypnotic and anti-anxiety agents.

(i. Stimulants are chemical substances which act on the central nervous system by producing euphoria, depression of appetite (anorexia), and hyperthemia. Chronic use results in the development of tolerance except as regards the toxic psychosis syndrome. Cross toleration to the substances of the same group occurs with varying degrees of withdrawal reactions upon discontinuation of the chemical substances.

(j. Board refers to the Dangerous Drugs Board.

k. Exempt Officials include officials of the national, provincial, city, or municipal governments as well as official, of government owned or controlled corporation.

l. Person includes natural or judicial persons; also drugstore, hospital, college of pharmacy, medical or dental clinic, sanatorium, or other similar institution or entity.

m. Physician includes all persons duly authorized to practice medicine.

n. Dentist includes all persons duly authorized to practice dental medicine.

o. Veterinarians include all persons duly authorized to practice veterinary medicine.

p. Pharmacists include all persons duly authorized to practice pharmacy.

Words importing the singular may include the plural; words importing the masculine gender may be applied to the feminine gender or the neuter.

The definitions contained herein shall not be deemed exclusive.

Article II
Registration and Fees

SECTION 2. Registration — All applications for registration and for the issuance of a license to deal in dangerous drugs and exempt dangerous drug preparations shall be filed with the Dangerous Drugs Board, or with the Board’s authorized representatives, if outside of the Metro Manila area. Persons or entities situated outside of the Metro Manila shall file their applications with the Special processing officers deputized as such by the Board.

The requirements for registration are as follows:

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A. Requirements for S-1, S-3, S-4, S-5-C and S-5-I (License Holders)

- Renewal — License to Operate for 19 __ from BFAD

- Certificate of Compliance from BFAD

- Business Permit — 19 __ (Current)

- Mayor's Permit — 19 __ (Current)

- PRC — Pharmacist (Unexpired/Updated)

- PTR — 19 __ (Current)

- Letter from Pharmacist authorizing the representative to apply and secure S-License.

- Letter authorizing Pharmacist to deal with Dangerous Drugs.

- SEC Registration

B. Requirements for S-2 (License Holders)

- Privilege Tax Receipt (PTR) 19 __ (Current)

- PRC — Physician (Unexpired/Updated)

- Letter from Physician authorizing the representative to apply and secure S-License.

SECTION 3. Deputation of Drug Regulation Officers in the Regional Offices of the Department of Health as Special Processing Officers of the Board — Drug Regulation Officers of the Department of Health are hereby deputized as Special Processing Officers of the Board. As so designated, these Regional Drug Regulation Officers shall (a) receive, process and approve applications for registration and licensing to deal in dangerous drugs and exempt dangerous drug preparations submitted by qualified applicants situated in their respective regions, (b) issue S-Licenses and (c) submit monthly reports to the Dangerous Drugs Board which shall include information on all persons or entities registered and licensed to deal in dangerous drugs and exempt dangerous drug preparations during the month.

When problems which cannot be resolved by the deputized special processing officers arise in connection with the processing and approval of the applicants, the applications together with other papers pertinent thereto shall be forwarded to the Dangerous Drugs Board in Manila for processing and approval.

When two or more Regional Drug Regulation officers are employed in the regional office, the higher ranking Regional Drug Regulation Officer as determined by the Department of Health shall be considered as hereby deputized.

SECTION 4. Custody of Records — Custody of all records pertinent to registration and license to deal in dangerous drugs and exempt dangerous drug preparations shall repose on the Dangerous Drugs Board. Those in the health regional offices shall be transferred to the custody of the Regional Drug Regulation Officers deputized as special Processing Officers of the Board.

SECTION 5. Inspection of Persons or Entities Authorized to Import, Export, Manufacture, Distribute, Prescribe, Dispense, Deal In or Sell Dangerous Drugs or Exempt Dangerous Drug Preparations.

A. Who undertakes inspection. For the purpose of R.A. 6425, as amended, all inspections shall be in accordance with Board Regulation No. 1, series of 1980 and shall be undertaken by the Dangerous Drugs Board’s Executive

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Director; the Chief, Control, Regulation and Intelligence Division; Drug Regulation Officers and such other officers as may be deputized in writing as Drug Regulation Officers by the Chairman of the Board.

B. Purpose of inspection. The Board shall inspect the drug establishment of an applicant or registrant to determine if the applicant or registrant complies with the record-keeping system (Section 68) and the security requirements (Section 77) of these regulations.

C. Denial of registration or revocation or suspension of license. An application for registration may be denied or a license may be revoked or suspended on the following grounds:

- Conviction of the applicant or licensee of an offense under the provisions of R.A. 6425, as amended, or these regulations; or other existing laws and regulations of the country.

- Unfitness of the person to hold such license or

- The premises of the establishment are deemed by the Board to be unfit for the purpose for which such license is granted.

SECTION 6. Administrative Designation — The registration of the persons embraced in this regulation and the collection of fees shall be done in the following manner:

> Schedule S, Paragraph 1: Amount of fee, P30.00 per annum or a fractional part thereof for persons dealing in exempt dangerous drug preparations.
>
> Schedule S, Paragraph 2: Amount of fee, P50.00 per annum for physicians, dentists, veterinarians, and other professionals lawfully entitled to distribute, dispense, give away or administer any dangerous drugs. This license shall be renewable every three (3) calendar years.
>
> Schedule S, Paragraph 3: Amount of fee, P60.00 per annum for retail dealers.
>
> Schedule S, Paragraph 4: Amount of fee, P180.00 per annum for wholesale dealers.
>
> Schedule S, Paragraph 5-I for importers: Amount of fee, P360.00 per annum for raw materials; P500.00 per annum for finished products.
>
> Schedule S, Paragraph 5-C for compounders, producers and manufacturers: Amount of fee P360.00 per annum.
>
> Schedule S, Paragraph 6: Amount of fee, P30.00 per annum for persons not registered as importer, manufacturer, producer or compounder but lawfully entitled to obtain and use in a laboratory dangerous drugs for the purpose of research, instruction or analysis.
>
> Schedule S, Paragraph 7: For persons paying a fee of One Peso and Fifty Centavos (P1.50) per 100 grams of finished products in accordance with the following:
> "The fee at the rate of One Peso and Fifty Centavos (P1.50) per 100 grams or any fractional part thereof in a package shall be paid by the importer, manufacturer, producer, or compounder of dangerous drugs in any form, their salts, isomers, any material, compound, mixture or preparation which contains any quantity of dangerous drugs, and exempt preparations imported into or produced in the Philippines and sold or removed for consumption or sale, which shall be in addition to any import duty on such dangerous drugs and exempt dangerous drug preparation and shall be paid immediately before removal from the place of production, if produced in the Philippines, or if imported, before the release of such drugs or preparations from the customs house.

A. Amount of Fee. The fee is One Peso and Fifty Centavos (P1.50) per 100 grams or a fraction thereof in each package. For instance, the fee on a package containing less than One Hundred (100) grams will be P1.50. The fee is measured by the entire content of a package or container, not by the weight of the dangerous drug or exempt

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dangerous drug preparations contained therein.

B. Unit of Fee. With the exception noted in the succeeding paragraph, the unit subject to fee is the smallest individual package or container. Thus, if a manufacturer sells a preparation in packages containing 100 grams each and put such packages into a larger container, the fee is not One Peso and Fifty Centavos (P1.50) per 100 grams on the outer container, but on each of the inner packages.

C. Ampules. When Ampules or other hermetically sealed units, each containing only a single dose, are placed in a package holding not more than twelve (12) units, the fee may be paid on the joint contents of the entire number of units at the rate of P1.50 per 100 grams or a fraction thereof. A new fee will attach whenever a new derivative, compound, or preparation is produced, whether or not the fee has been paid on the component ingredients or parts thereof. Thus, imported opium is subject to one fee, morphine produced in this country from such imported opium is subject to another fee, a preparation manufactured by the use of such morphine also will be subject to fee and so on. Preparations and remedies coming within the provisions of Section 11 of the law are not subject to the fee, manufactured dangerous drugs and exempt dangerous drug preparations which are subsequently exported are subject to fee whether manufactured for export or not."

D. Tablets. In the case of tablets contained in one pack of 100 tablets or less, the fee shall be P1.50 per 100 grams or a fraction thereof.

E. Capsules. In the case of capsules where 100 capsules or less are contained in one pack, the fee shall be P1.50 per 100 grams or a fraction thereof.

When business is done during the month of January, the fee shall be paid for the whole year. The fee on S-1 is P30.00 a year, or any fraction thereof, regardless of the commencement of the business.

Renewal of Schedule S license must be made not later than January 31st of each year.

Failure to secure the S-license within the prescribed period shall be penalized with a surcharge amounting to 10% of the required fee but not less than P10.00, except in the case of S-2 license which shall be P50.00.

Prescription Compounding — Persons who have paid the fee as retail dealers do not incur liability as manufacturers or compounders on account of compounding dangerous drugs and exempt dangerous drug preparations to fill legitimate prescriptions of registered practitioners.

The S-1 license should be issued only to those persons who do not possess any other Schedule S-license. Hence, if one is already in possession of an S-3 license as a retail dealer in dangerous drugs and exempt dangerous drug preparations or any other license under Schedule S issued under these regulations, he need not secure an S-1 license. If the dealer or pharmacist himself makes his medicines containing dangerous drugs and exempt dangerous drug preparations in pursuance of prescriptions, he should secure an S-3 license although the amount of dangerous drugs and exempt dangerous drug preparations mixed with said medicine does not exceed the amount fixed in Section 11.

SECTION 7. Display and Retirement of License — The person to whom a license has been issued shall at all times keep it conspicuously displayed in this office or place of business during the period for which the license was paid.

Holders of Schedule S licenses who desire to retire from business on or before the expiration date of the period covered by the license shall present their license to the processing officer. The processing officer shall note on the body of the privilege license the fact of retirement and return the same to the payer who shall retain it and the said official should promptly mail a certification of retirement to the DDB or to the special processing officer in the

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region, as the case may be.

SECTION 8. Reports of Processing Officers — Immediately after the issuance of each Schedule S license, the processing officer shall submit a report to the Executive Director of the Board.

The Report shall contain the following:

- Name or style of the person or firm to whom the license was issued,

- Date of issue,

- Paragraph and assessment number of the license issued,

- Amount of fee paid,

- Period for which such license is paid,

- Kind of business, occupation, or profession,

- Place of business, (street, number, municipality and province), and

- The number and date of the certificate of registration issued by the Board of Medical Examiners, the Board of Dental Examiners, the Board of Veterinary Examiners or the Board of Pharmaceutical Examiners, as the case may be, authorizing the payer to engage in the business or follow the occupation or profession for which the license has been issued. If he has no such certificate issued by the said Board, such fact shall be so stated.

SECTION 9. Producers — Every person who produces dangerous drugs or exempt dangerous drug preparations to be sold on order forms not by mixing or compounding but by merely transferring the contents of one package or of a number of packages of the same or of greater or smaller size is liable to license as a producer at the rate of P360.00 per annum.

SECTION 10. Wholesale Dealers — Every person who sells or offers for sale dangerous drugs or exempt dangerous drug preparations in original packages is subject to license as a wholesale dealer at the rate of P180.00 per annum. A wholesale dealer is not allowed to import, manufacture, produce, compound, or mix up in any manner, any dangerous drugs or exempt dangerous drug preparations. His business consists in buying and selling dangerous drugs or exempt dangerous drug preparations in the original packages or containers. He cannot open the original packages or containers and dispose of a portion only or any of their contents without providing himself with an S-3 license.

SECTION 11. Retail Dealers — Every person who sells dangerous drugs or exempt dangerous drug preparations from original stamped packages with or without compounding, pursuant to prescriptions written by registered physicians, dentists, and veterinarians in the course of professional practice only is liable to license as a retail dealer at the rate of P60.00 per annum. Holders of S-3 license, when engaged in the business of compounding medicines containing dangerous drugs for the purpose of keeping them in stock for sale or for disposition at wholesale should secure the S-5 license as compounders of dangerous drugs. However, such holders of S-3 license need not secure the S-5 license if they are engaged in the business of manufacture, sale, distribution, giving away, dispensing, or possession of preparations and remedies, which do not contain, more than two grains (0.1296 gram) of opium, or more than one-fourth of a grain (0.0162 gram) of morphine, or more than one-eight of a grain (0.0081 gram) of heroin, or more than one grain (0.0648) of codeine or any salt or derivative or any of them in one fluid ounce (29.57 cubic centimeters) or, of a solid or semisolid preparation, in one avoirdupois ounce (28.3495 grams) or preparations and remedies of Indian Hemp for external use only, provided that such preparations and remedies are manufactured for retail trade as medicines and not for the purpose of evading the

intentions and provisions of the law. When a pharmacist in charge of prohibited drugs in a drugstore transfers such drugs to his successor, in case of retirement or resignation, he shall not be considered with respect to such transfer, as wholesale dealer, in dangerous drugs.

SECTION 12. Importers, Manufacturers and Compounders — The S-5-I should be issued only to importers, and the S-5-C to compounders, manufacturers or producers. An importer, as such, cannot manufacture, produce, or compound any dangerous drugs and exempt dangerous drug preparations or medicine containing them and neither can a manufacturer, compounder, or producer, as such, import dangerous drugs and exempt dangerous drug preparations. An importer, under an importer's license only, cannot purchase dangerous drugs and exempt dangerous drug preparations from local firms for sale or distribution at wholesale without first securing an S-4 license as wholesale dealer. Importers, manufacturers, producers, or compounders of dangerous drugs will not be required to secure privilege licenses as wholesale dealers for the disposal of the drugs imported, manufactured, produced, or compounded by them. But those desiring to dispose of said drugs at retail should secure retail dealers' license. A person holding an S-3 license as a retail dealer in dangerous drugs and who fills prescriptions of registered physicians, in the preparation of which he uses a portion of dangerous drugs from the original packages or containers, is not required to secure an S-5 license as a compounder.

SECTION 13. Laboratory Use — Chemists occupying an independent status and not that of an employee, who, being thereunto lawfully entitled, make analysis of dangerous drugs or exempt dangerous drug preparations or use such drugs in analyzing other substances in a laboratory and other lawfully entitled persons who obtain and use in a laboratory dangerous drugs or exempt dangerous drug preparations for the purpose of research, instruction, or analysis, if not registered as a compounder, importer or manufacturer and not manufacturing or compounding dangerous drugs or exempt dangerous drug preparations for sale or removal for consumption of sale, are liable to license at the rate of P30.00 per annum.

SECTION 14. International Movements — Exports and Imports — Exports and imports of dangerous drugs or exempt dangerous drug preparations shall be made only after a permit is obtained from the Board.

In transit shipments — Dangerous drugs merchandise arriving in a port of the Philippines, shown by the shipping papers, i.e. either the bill of lading, manifest or invoice, to be intended for transportation to another country must have prior authority of the Board.

SECTION 15. Repacking — Repacking dangerous drugs or exempt dangerous drug preparations is production within the intent of the law and as such it must have prior authority of the Board.

SECTION 16. Dual Liabilities — Any person conducting two or more types of business at the same location must secure from the Board a license for each type of business.

SECTION 17. A person must secure from the Board as many licenses as he has places of business. Thus, if a concern has one or more separate branches where of the various types of business is carried on, the license must be paid for each branch separately, however, a manufacturer, compounder, or producer who has paid the license fee as such, and who has a principal office or place of business separate and apart from the place where the actual manufacturing, compounding or producing is done, is not required to pay an additional license with respect to such office or place of business provided that no merchandise except samples is kept thereat, on account of orders taken at such office or place of business for dangerous drugs and exempt dangerous drug preparations to be delivered from the place of manufacture, compounding or production. If sales are from the place of manufacture, compounding or production, from stock kept at such office or place of business, the license as wholesale or retail dealer, or both, as the case may be, must be paid with respect to such office of place of business.

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An S-3 license holder, in case of the absence or leave of the pharmacist in charge of the drugstore, shall notify the Board of such absence or leave. The owner of the drugstore or the chief of hospital in case of hospital pharmacies, shall also authorize a person who will temporarily take the place of the pharmacist who is absent or on leave. Such authority shall be in writing and submitted to the Board.

No person is permitted to dispense or deal in dangerous drugs or exempt dangerous drug preparations except upon orders received or engagements made at, with respect, or by reason of, a fixed address.

SECTION 18. Warehouse — The license does not attach with respect to a warehouse where dangerous drugs or exempt dangerous drug preparations are stored, provided that no sales are made at such a place.

SECTION 19. Partnerships — A partnership is subject to the same license liability as an individual. Should either of the partners also individually engage in any drug-related activity, he will incur additional liability with respect to such activity.

SECTION 20. Institutions — Hospitals, colleges, medical and dental clinics, sanitaria, and other institutions not expressly exempted from the license are subject to the same special license liability as other persons dealing in or handling dangerous drugs or exempt dangerous drug preparations.

SECTION 21. Principals — Principals and not their agents, are liable to the license imposed. Employers and other principals will be regarded as responsible for the acts of the employees and other agents within the scope of their employments.

SECTION 22. Employees — an employee or a person who has registered and paid the license will not himself incur liability to license as long as he acts solely within the scope of his employment. However, an employee who, within or without the scope of his employment, does any unlawful act, will be held personally liable.

SECTION 23. Nurses — Nurses are regarded as agents of practitioners or institutions under whose direction or supervision, their duties are performed and they are neither permitted to register, nor be in possession of dangerous drug and exempt dangerous drug preparations, except as such agents, or as patients. Any unused dangerous drug or exempt dangerous drug left by a practitioner with a nurse, to be administered during his absence, upon discharge of the nurse must be returned to the practitioner, who will account for the drugs in his records. Any dangerous drug or exempt dangerous drug preparation found in the possession of a nurse not at the time under the supervision of a practitioner shall be forfeited to the government.

SECTION 24. Traveling Salesmen — Traveling Salesmen who merely solicit orders and forward them to their respective principals are not required to register or pay any license.

SECTION 25. Display of Registration — The person to whom a certificate of registration has been issued shall at all times keep it conspicuously displayed in his office or place of business during the period for which the license was paid.

SECTION 26. Termination of Registration — The registration of any person shall terminate if and when such person dies, ceases legal existence or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Board promptly of such fact.

Article III
Order Forms

SECTION 27. Written Order Required — Except as otherwise provided, order forms are required for all transactions in dangerous drugs and for the importation, exportation and manufacture of exempt dangerous drug preparations. Dangerous Drug Order Forms (DDB Form No. 8-72), Import Certificate Forms (DDB Form No.

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10-72), Order Forms for Importation of Exempt Dangerous Drug Preparations (DDB Form No. 9-72) and Order Forms for Exportation of Exempt Dangerous Drug Preparations (DDB Form No. 11-72) may be secured from the Dangerous Drugs Board.

A. Restriction on the sale of dangerous drug order forms, import certificate forms, and order forms for importation of exempt dangerous drug preparations. Blank Order Forms may be obtained only by persons who are duly qualified under R.A. 6425, as amended, and have legitimate use therefor. Dangerous Drug Order Forms shall be sold only to persons holding current Schedule S license except S-1, and Import Certificate Forms (DDB Form No. 10-72) only to persons holding current Schedule S-5-I license, as importers.

B. Order forms not transferable. A person to whom a Dangerous Drug Order Form Booklet, a Dangerous Drug Import Certificate Booklet (DDB Form No. 10-72) and Booklet for Importation of Exempt Dangerous Drug Preparations has been issued cannot transfer it to another except when no part of the booklet has been used, in which case the authority of the Board must be secured before effecting the transfer.

C. Order form to be used consecutively. Dangerous Drug Order Forms, Order Forms for Importation and Order Forms for Exportation of Exempt Dangerous Drug Preparations shall be used consecutively. Each set of numbers shall be accounted for. If an order is cancelled or spoiled, all the copies thereof shall be forwarded to the Dangerous Drugs Board, or if it is lost or destroyed, an affidavit setting forth the circumstances of such loss or destruction shall be submitted to the Board.

The order form bearing the serial number next following the cancelled, spoiled or missing order form shall not be acted upon by the Board unless the foregoing requirements are complied with.

D. Lost or stolen order forms. Lost or Stolen Order Forms shall be immediately reported to the Control, Regulation and Intelligence Division (CRID) of the Board. An Affidavit stating the circumstances of such loss and a copy of the police blotter shall be submitted to the Board. These documents shall be forwarded by the Executive Director to the Chairman of the Board. If the order form reported stolen or lost is subsequently recovered or found, the Board shall also be notified about it.

SECTION 28. Requirements for the Purchase of Order Forms —

a. Current Privilege Tax Receipt (PTR)

b. Current S-License (Narcotic License)

c. Current Professional Regulation Commission (PRC) registration card

d. A duly accomplished form (Blank Forms can be obtained from the Control, Regulation and Intelligence Division, DDB)

e. An I.D. size picture taken not earlier than a month from the time of the intended purchase (required only when a first purchase is made)

f. Three (3) specimen signatures of the person for whom the order forms are purchased

g. Permit to operate issued by the Bureau of Food and Drugs (BFAD)

h. Letter of the owner of the establishment authorizing the representative to purchase order forms.

SECTION 29. Disposition of Dangerous Drugs and Exempt Dangerous Drug Preparations — It shall be unlawful for any person to sell, barter, exchange, or give away any dangerous drugs and exempt dangerous drug preparations except in pursuance of a dangerous drug order and a permit from the Board. This requirement shall

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also apply to transfer of dangerous drugs from wholesale to retail within the same establishment. No manufacturing or compounding or any preparation shall be done without a permit duly approved by the Board. Nothing contained in this section shall apply to:

1. A dealer selling, dispensing, or distributing any dangerous drugs and exempt dangerous drug preparations to a consumer under and in pursuance of an original prescription of a registered physician, dentist, veterinarian registered under these regulations or of a government official authorized to prescribe dangerous drugs and exempt dangerous drug preparations.

2. Physicians, dentists, veterinarians registered under these regulations, who, in the course of professional practice, administer such drugs to other patients upon whom they personally attend for legitimate medical purposes.

3. Lawful exportations

4. Duly registered persons with a current Schedule S license who dispose of dangerous drugs on personal written emergency orders in accordance with and under the circumstances outlined in Section 34 of these regulations.

SECTION 30. Local Purchase of Dangerous Drugs and Exempt Dangerous Drug Preparations — Upon receipt by the Board of order forms, the signature on such order form shall be compared with the signature appearing on the application for registration. Unless the Board is satisfied that the order is authentic it will not be honored.

A. Execution of forms. Order forms are issued and shall be accomplished in sextuplicate. The attachment of extra sheets to order forms is not permitted. If one order form is not sufficient to include all the items of an order, a second form shall be used. The order forms are intended solely to cover disposition of dangerous drugs to registered persons. A separate order booklet should be used for the compounding, wholesaling and retailing business. They shall not in any case be used in prescriptions.

B. Manner of preparation. The order forms shall become a part of the permanent records of the registrant filling them, and are required by law to be kept available for inspection for a period of five (5) years. The importer, manufacturer or wholesaler should insist for his own protection that the order forms be prepared in such a manner as to render their subsequent alteration both difficult of accomplishment and easy of detection. Purchasers should also be careful to protect order forms signed by them against subsequent alteration. Official Order Forms (DDB Form No. 8-72) for the purchase of dangerous drugs should be prepared with the use of a typewriter or ink, and manufacturers and wholesale dealers should return unfilled any order form executed in a less permanent manner. The date when the order form is prepared, the name and address and current S-License number of the purchaser shall be entered in the space provided therefor. Only one item should be entered on each line and not more than six items shall be entered on a single form. An item shall consist of one or more packages or bottles of the same kind and size; two or more such packages or bottles shall always be regarded as a single item and shall never be counted on the form as two or more items. A separate item shall be made for each article of different description or size. The purchaser shall show with respect to each item the number of packages, in terms of kilos, grams, ounces, grains, pills or tablets (indicating the size in case of pills or tablets), if in a solid form, or in terms of liters, gallons, pints or ounces, if in liquid form; the name of the article desired, and the name and the quantity of the dangerous drugs contained in the article if it is not itself a pure dangerous drug.

D. (sic) Qualification of purchaser. The purchaser shall at the time the order form is submitted be registered and shall have paid the fees necessary to qualify him up to the end of the calendar year. The purchaser shall likewise be qualified for the year within which the merchandise is received. Any person executing and presenting an order form who, at the time of such presentation is not duly registered and has not paid the necessary fees, will not be

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issued the order form being purchased.

SECTION 31. Manner of Approval — Upon receipt of DDB Form No. 8-72 in sextuplicate, the approving officers shall analyze, process and enter the same in the record book. It shall also be numbered consecutively, the number appearing in the permit shall be the same as the one appearing in the record book.

Approved order forms are signed by the Executive Director or his duly authorized representative. The purchaser or his authorized representative shall sign the file copies (copies 5th and 6th) in order to get the first four copies. An approved order form shall bear the corresponding format stamped on each copy according to its disposition:

Copy 1 —
"Copy for seller" (File)

Copy 2 — Front page — "Copy for endorsement by seller to

DDB upon completion of transaction."

Back page — "Returned to DDB. Transactions
complete as indicated"

"Purchased/Sold the following dangerous drugs on (Date)

Signature of licensee

Return to DDB by mail

Copy 3 — "Copy for purchaser" (File)

Copy 4 — Front page — "copy for endorsement by purchaser
to the DDB upon completion of transaction"
Back page — (Same as format to be found in back of No. 2)

Copy 5 — "File — Dangerous Drugs Board"

Copy 6 — "File — Dangerous Drugs Board"

SECTION 32. Alterations — No alteration, erasure, or change in any description may be made in any order form by any person, after approval by the Board. If for any reason, a dealer could not fill an order form for dangerous drugs duly approved by the Board, the dealer shall return both copies of the order form to the Board within thirty (30) days from the date of approval of the said order form with a statement of the reason for such failure. This obligation, however, shall, devolve upon the purchaser in case the dangerous drugs order form duly approved by

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this office is presented personally by him or through his representative to the dealer who is unable to fill the same. Should the person on whom an order form for dangerous drugs is made, be unable to supply the quantity ordered, he shall notify this office in writing of the amount available which in no case should be more than the original quantity approved, and return both copies to this office for the necessary corrections. Upon receipt, the changes should be noted in all six copies of the order form.

SECTION 33. Procedure in Case of Loss: — A. Of dangerous drugs and exempt dangerous drug preparations:

- Where the dangerous drugs or exempt dangerous drug preparations are lost by theft or robbery or through breakage of the container or other accidents, the person in whom possession and responsibility for the drugs or preparations repose at that time shall inform the Dangerous Drugs Board, by telephone or other possible means, of such loss within twenty-four (24) hours from the time the breakage or accident occurred or from the time the theft, or robbery was discovered. He shall also immediately execute an affidavit in quadruplicate indicating the kinds and quantities of the dangerous drugs and exempt dangerous drug preparations lost or destroyed and the circumstances involved, which affidavit together with a copy of the invoice covering the purchase of drugs or preparations, shall be forwarded to the Dangerous Drugs Board within seventy-two (72) hours from the date of occurrence or discovery of the breakage or other accidents, theft or robbery.

- Documentary evidence that the local police authorities were notified shall accompany the affidavit in case of loss due to theft or robbery.

- Upon receipt of the information made thru the telephone or other possible means, drug regulation officers of the Board shall immediately undertake an initial ocular inspection and investigation at the site where the loss occurred to verify the reported circumstances. The results of such inspection and investigation together with the affidavit and other documentary evidences shall be referred to the National Bureau of Investigation for investigation as to the veracity of the statements and the liability, if any, of the person involved in the loss.

- In case the loss occurs outside Metro Manila, the provisions of paragraphs 1 to 3 hereof shall apply except that the required report by telephone or other means shall be made directly to the Regional Drug Regulation Officer of the Department of Health deputized as such by the Dangerous Drugs Board under Board Order No. 2, Series of 1983, and having jurisdiction in the region. The required referral for investigation shall be made by the said Drug Regulation Officer to the Head of the nearest branch of the National Bureau of Investigation. Said NBI official shall thereafter cause the conduct of the necessary investigation and submit his recommendations to the Dangerous Drugs Board.

- Copies of the affidavit and the documentary evidence shall be retained and filed with the records of the Board on the person, establishment, agency or institution involved.

B. Of order forms. Whenever any used or unused order forms are stolen from, or lost by, any person registered under R.A. 6425, as amended, he shall immediately upon discovery of such theft or loss, report the same to the Board stating the serial number of the forms stolen or lost.

If an entire booklet or order forms is stolen or lost and the licensee is unable to state the serial number thereof, he shall report the theft or loss to the Board, in lieu of the numbers of the forms contained in such booklet, the name and address of the licensee, and the approximate date of purchase thereof. If the unused order form reported stolen or lost is subsequently recovered or found, the Board shall be notified thereof.

C. Of prescription forms for dangerous drugs (DDB Form No. 1-72). It shall be the duty of every physician, veterinarian, dentist or other practitioner to whom prescription form (DDB Form No. 1-72) for dangerous drugs has been issued, to report any loss thereof to the Dangerous Drugs Board within twenty-four (24) hours from the

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discovery of such loss, indicating the circumstances surrounding the loss. Upon receipt of said report, the Board shall cause the publication of the loss in a newspaper of general circulation.

Every loss of prescription forms for dangerous drugs shall be referred for investigation to any police or investigative agency as the Board shall determine. Whenever necessary the police or investigative agency may take possession of the prescription forms remaining in the possession of the physician, veterinarian, dentist, or other practitioner. Should the findings of the police or investigative agency show negligence on the part of the physician, veterinarian, dentist or practitioner, the cost of the publication of the loss shall be reimbursed to the Board by the negligent physician, veterinarian, dentist or practitioner, and he may be barred from further purchasing prescription forms.

SECTION 34. Filling of an Emergency Order —

A. In cases of emergency where life or health is endangered, an order in any form duly signed by the purchaser may be sent to the dealer who may supply the kind and quantity of the dangerous drugs ordered. The dealer shall then prepare a signed statement fully explaining the circumstances of the case and submit said statement, together with the regular dangerous drugs order (DDB Form No. 8-72) in sextuplicate properly accomplished by the purchaser immediately after receiving the drugs, to the Board not later than the business day following the day the order was filled, if within Metro Manila area, or within a reasonable time, if in the provinces, the disposition of the copies of the dangerous drugs order is the same as that outlined in Section 31 hereof, except that one copy will be sent to the purchaser and another copy to the dealer who filled the order. Should such an explanation be unsatisfactory or should there be an indication of an abuse of this privilege, the corresponding action will be taken by the Board.

B. The following are specified as falling within the category of emergency cases:

- Where the prescription has to be issued to a patient whose need for dangerous drugs is immediate and urgent and had been brought about by the effects, or during the course of natural and other calamities, such as typhoons, earthquakes, conflagrations, etc., of such a magnitude as to preclude prompt access to the official prescription forms for dangerous drugs;

- Where the need for prescribing the dangerous drugs has arisen as a result of a serious accident necessitating the administration of the drugs at the scene or in the vicinity of the accident and the required prescription forms are not readily available;

- Where the need for the dangerous drugs is urgent and its ready availability may, in the opinion of the prescribing physician, spell the difference between the life and death of the patient, and for unavoidable and justifiable reasons the prescribed prescription form is not within access.

C. In every case where the exempting provision of Section 25(B) of R.A. 6425, as amended, is availed of, the prescribing physician shall certify, at the back of the ordinary prescription form utilized, as to the nature, time and place of the emergency conditions and the name and address of the patient, and shall see to it that his (physician's) full name and address is indicated in printed form beneath his signature. He shall also strictly comply with the requirement in said Section 25(B) that the prescribing physician shall, within three (3) days from issuing such prescription, inform the Board of the same in writing.

SECTION 35. Returned Goods — A person registered in any class may return dangerous drugs to the person from whom they have obtained on an order form of the latter addressed to the former, who shall not be considered a wholesale dealer by reason thereof, and approved by the Board. The order form should, however, contain a notation that the drugs therein described are merely returned goods.

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SECTION 36. Importation of Dangerous Drugs and Exempt Dangerous Drug Preparations — Dangerous drugs and exempt dangerous drug preparations may only be imported under a permit issued by the Board pursuant to an application therefor, and after determination by the Board that the quantity requested in the application is necessary to provide for, and will be applied to, medical and legitimate uses only. An exception to this rule may be made in the case of an emergency which, in the judgment of the Board, so affects the welfare of all or a large proportion of the population as to justify such extraordinary action. No importation by mail shall be permitted.

SECTION 37. Who May Import — In exercising the powers and discharging the duties conferred and imposed upon it by law with respect to the importation of dangerous drugs and exempt dangerous drug preparations, the Board shall take such action as in its opinion will effectuate the intent and purpose of the law. In determining whether any applicant shall be permitted to import dangerous drugs and exempt dangerous drug preparations, the board shall consider the character and standing of the applicant, his production facilities and trade connections whether there is reasonable probability that he will apply the dangerous drugs and exempt dangerous drug preparations imported by him to medical and other legitimate purposes, whether better quality of dangerous drugs and exempt dangerous drug preparations, or any other factors which the Board deems appropriate to consider in carrying out the policy mentioned. In the case of new applicants, the Board shall also consider whether the allotments to them of shares in the amount of dangerous drugs and exempt dangerous drug preparations determined by it to be necessary for medical and other legitimate uses would probably have the effect of reducing or rendering uncertain the supply of dangerous drugs and exempt dangerous drug preparations as to endanger the efficient administration of R.A. 6425, as amended.

Application for importation of dangerous drugs or exempt dangerous drug preparations:

A person who wishes to import dangerous drugs or exempt dangerous drug preparations shall present to the Dangerous Drugs Board DDB Form 10-72 (Import Certificate) or DDB form 9-72 (Special Permit) respectively, in sextuplicate, serially numbered with all six (6) copies bearing the same serial number, accompanied by a letter of application for importation and other documentary evidence deemed adequate by the Dangerous Drugs Board, showing that the dangerous drugs or exempt dangerous drug preparations are consigned to an authorized importer and that they shall be applied exclusively to medical and other legitimate uses within the country.

Application for importation of dangerous drugs or exempt dangerous drug preparations are reviewed as received, and are only approved for duly authorized and registered importers. Each application must be filed fifteen (15) days prior to importation. Application for importation shall be made in writing and shall show the following:

- Date of application

- Name and address of the consignor

- Kind and quantity to be imported

- Stock on hand of the item being imported

- Kind and quantity of drugs or preparations to be manufactured from the requested importation.

- Dangerous drug content per preparation or net quantity per unit in grams of the preparation to be manufactured from the requested importation.

- Statement regarding any pending importation of dangerous drug/exempt dangerous drug preparations.

- Purpose of importation/exportation

- Name and address of the importer

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- Current S-5 (I) license of the importer

An application for importation of dangerous drugs (DDB Form No. 10-72) and exempt dangerous drug preparations (DDB Form No. 9-72) shall be in writing stating the name and address of the exporter, the kind and quantity to be imported, the stock on hand of the items sought to be imported (if importation is being renewed), the name and address of the importer, his current S-5-I license number. Only upon receipt of a reply from the Board shall the importer accomplish the appropriate form.

Estimated quota requirements as well as projected importation and production schedules shall be submitted to the Board by importers, manufacturers and compounders not later than January 10th of each calendar year.

SECTION 38. Preparation of Import Certificate — The import certificate (DDB Form No. 10-72) shall be prepared in sextuplicate. Such certificate shall not be valid unless signed by the Board or its duly authorized representative. Import certificates shall be serially numbered, the six copies of a given import certificate to bear the same serial number. Each copy of the certificate shall have printed thereon the disposition to be made thereof thus: the original (pink) — "copy for the exporter through the importer"; duplicate (blue) — "copy for the importer to be presented to the Bureau of Customs"; triplicate (yellow) — "copy for the competent authority of the exporting country"; quadruplicate (green) — "copy for the Philippine consulate"; Quintuplicate (orange) —"copy for the Bureau of Customs"; sextuplicate (white) — "file copy".

Each copy of the certificate shall bear a notation to the effect that the Board is satisfied that the consignment proposed to be imported is required for legitimate and medical or scientific purposes. Each copy of the certificate shall also be dated and shall certify that the importer named therein is permitted under the provisions of R.A. 6425, as amended, to import, thru the port named, one shipment not to exceed the specified quantity of dangerous drugs and exempt dangerous drug preparations. All import certificates issued shall be entered in a register kept by the Board for that purpose. No import certificate shall be altered or changed by any person after being duly signed by the Executive Director of the Board, and any change or alteration upon the face of the import certificate after it shall have been signed shall render it void and of no effect. Import certificates are not transferable.

SECTION 39. Manner of Approval — upon receipt of DDB Form No. 10-72 and/or DDB Form No. 9-72 accompanied by the letter mentioned in Section 36 the same if correctly accomplished, shall be approved by the Board by executing the certificate portion of all the copies of the form. The six copies shall be signed by the Executive Director of the Board or his duly authorized representative and facsimiles or signatures shall not be used.

SECTION 40. Disposition of Copies of Import Certificates — The original copy, together with the duplicate, shall be transmitted to the importer who will retain the duplicate copy on file as his record of authority for the importation and transmit the original copy of the permit to the foreigner exporter. The foreign exporter will submit the original copy of the import certificate to the proper governmental authority in the exporting country (if required as a pre-requisite to the issuance of a export authorization). The triplicate copy shall be forwarded to the Philippine Consulate nearest the state or country of exportation. The quintuplicate shall be forwarded to the Commissioner of Customs. the sextuplicate copy of the import certificate shall be retained on file in the Dangerous Drugs Board. A copy (xeroxed copy) of the import certificate shall be forwarded to the Central Bank of the Philippines).

SECTION 41. Effect of Permit to Import — An import certificate or special permit duly signed and issued shall be authority to import, by the importer named therein, one shipment only not to exceed the maximum quantities of the dangerous drugs and exempt dangerous drug preparations specified in the import certificate or special permit from a specified foreign exporter, said shipment to be made and received in the country on or before the date

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indicated in the import certificate or special permit unless for good cause shown, the Board allows a longer period within which the shipment is to be made. Partial shipments will not be allowed.

When the importation has been effected or when the period fixed for importation has expired, the copy of the export authorization sent by the competent authority of the exporting country should be returned specifying the amount of dangerous drugs and exempt dangerous drug preparations actually received or that no import has taken place.

If the shipment made under the import certificate or special permit is greater than the maximum amount of dangerous drugs and exempt dangerous drug preparations authorized to be imported under the import certificate or special permit as determined by the Processing Customs Officer, such difference shall be seized and forfeited to the government. If the shipment is less than the amount authorized to be imported under the import certificate or special permit as determined by the processing officer, the balance of the allotment will remain available to the importer pursuant to a new import certificate or special permit as may be requested and issued during the remainder of the calendar year to which the allotment is applicable.

SECTION 42. Cancellation of Import Certificate and Special Permit — If on the date an import certificate or special permit expires the dangerous drugs and exempt dangerous drug preparations listed therein have not been received in the Bureau of Customs, the import certificate or special permit is automatically cancelled and no subsequent importation of dangerous drugs and exempt preparations by virtue of the said cancelled import certificate or special permit shall be allowed. Any dangerous drugs and exempt dangerous drug preparations received in the Bureau of Customs after the date of expiration of the import certificate or special permit previously authorizing its importation into the Philippines shall be returned immediately to the exporter at the expense of the importer. An import certificate or special permit may be cancelled after being issued, at the written request of the importer, stating the reasons for such cancellation.

SECTION 43. Forfeiture of a Shipment of Dangerous Drugs and Exempt Dangerous Drug Preparations — A shipment of dangerous drugs and exempt dangerous drug preparations shall be forfeited under any of the following grounds:

1. Failure of the importer to obtain an import certificate or special permit from the Board before sending his order for the said dangerous drugs and exempt dangerous drug preparations.

2. Unauthorized alteration or erasure on the import certificate or special permit or failure of the shipment to correspond with the terms and conditions embodied in the said certificate or permit.

3. Importation of dangerous drugs and exempt dangerous drug preparations in excess of the quantity authorized in the import certificate or special permit, pursuant to Section 36 hereof, in which case, only the excess shall be subject to forfeiture.

SECTION 44. Duties of Importers —

1. When any importation of dangerous drugs and/or exempt dangerous drug preparations reaches a port of entry under Philippine Customs Control, it shall be the duty of the importer to:

- Notify the Dangerous Drugs Board of such arrival within three (3) working days from receipt of the notice of arrival thereof issued by Philippine Customs Authorities;

- Furnish the Customs Narcotics Office with a copy of the said notice of arrival, a duplicate copy of the certificate of importation covering the shipment, a copy of the export permit issued by the government of the country of origin, and proof of payment of the S-7 fee required by law.

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2. Upon clearance of the importation by the customs authorities and upon completion of the transfer of the drugs or preparations to the importer's laboratory, office of warehouse, the importer shall accordingly notify the Dangerous Drugs Board by telephone within 24 hours. The telephone notification should be confirmed immediately thereafter by letter accompanied by a photo copy of the export permit issued by the government of the country of origin if no such copy was submitted as required in paragraph 1 hereof. When the Board is so notified, Drug Regulation Officers of the said body shall proceed with the checking and verification of the shipment.

3. The importer shall take all precautionary measures for the safe transportation of the dangerous drugs from the customs house to the importer's premises.

4. For the purposes of paragraphs 1 and 2 hereof, the importer shall utilize DDB Form No. 1-83.

SECTION 45. Exportation of Dangerous Drugs and Exempt Dangerous Drug Preparations — No person shall in any manner export or take out of the Philippines any dangerous drugs and exempt dangerous drug preparations, nor shall any carrier receive for exportation, or export or carry out of the Philippines any dangerous drugs and exempt dangerous drug preparations unless and until a permit in due form to export the dangerous drugs and exempt dangerous drug preparations in each instance shall have been issued by the Board.

A dealer desiring to export dangerous drugs and exempt dangerous drug preparations shall present to the Board an import certificate or permit (and a translation thereof if in a foreign language) or a certified copy of such license or permit issued by competent authorities in the country of destination, or other documentary evidence deemed adequate by the Board showing that the merchandise is consigned to an authorized permittee, that it is to be applied exclusively to medical and legitimate uses within the country of destination, that it will not be re-exported from such country, and that there is an actual shortage and a demand for the merchandise for medical and legitimate uses within such country. Verification by Philippine Consular Officials of signatures on foreign license will be necessary in case of doubt.

Each application to export shall show the exporter's registry number and current number and shall show the name and detailed description of the dangerous drugs and exempt dangerous drug preparations, desired to be exported, the net quantity thereof, the number and size of packages or containers, the name and quantity of the dangerous drugs and exempt dangerous drug preparations. The application shall include the name, address, and business of the consignee, the foreign port of entry, the port of exportation, the approximate date of exportation, the name of the exporting carrier, or vessel (if known, or if unknown it should be stated how shipment will be made, exports of dangerous drugs and exempt dangerous drug preparations by mail being prohibited). The application shall be signed by the exporter, or by his duly authorized representative, and shall contain the address from which the drugs will be shipped for exportation. The exportation, however, of heroin is hereby prohibited.

SECTION 46. Disposition of Copies of Export Permit — If, from the facts presented in the application, the Board finds it proper to permit the requested exportation, an export permit shall be prepared in sextuplicate in the Office of the Executive Director of the Board, each of which shall be marked as to disposition and distributed in accordance with the following purposes; the original, together with the duplicate copies, shall be transmitted to the exporter, the original to accompany the shipment and the duplicate to be retained by him as his record of authority for the exportation; the triplicate to be forwarded to the office in the country of destination which issued the import certificate or other documentary evidence upon which the export permit is founded; the quadruplicate to be forwarded to the Philippine Consulate nearest the state or country of importation; the quintuplicate to be forwarded to the Commissioner of Customs; and the sextuplicate to be retained on file in the Office of the Executive Director of the Board; and a copy (xeroxed copy) to be forwarded to the Central Bank of the

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Philippines.

SECTION 47. Special Conditions Relative to Export Permits — Each export permit shall be serially numbered and predicated upon a separate import certificate or documentary evidence, and not more than one shipment shall be made thereon. All export permits shall be entered in a register kept for the purpose. Export permits are non-transferable.

An export permit shall not be valid after the date specified therein, which date shall conform to the expiration date specified in the supporting import certificate or other documentary evidence upon which the export permit is founded, but in no event shall the expiry date be subsequent to six (6) months after the date the permit is issued. Any unused export permit shall be returned by the permittee to the Office of the Executive Director of the Board for cancellation.

No export permit shall be issued for the exportation of dangerous drugs or exempt dangerous drug preparations to any country when the Board has information to show that the estimates submitted with respect to that country for the current period, under Article 19 of the 1961 single convention on narcotic drugs, as amended, have been, or considering the quantities to be imported, will be exceeded: if it shall appear, through subseuent advice received from the International Narcotics Control Board (INCB), that the estimates of the country of destination have been adjusted to permit further importation of the dangerous drugs and exempt dangerous drug preparations. An export authorization may then be issued, if otherwise permissible.

On the completion of the export or on the expiry of the time limit fixed therefor, the copy of the import certificate issued by the government of the importing country shall be returned, specifying in the endorsement, the quantity actually exported or that no export has taken place.

SECTION 48. In Transit Shipments — No shipments of dangerous drugs and exempt dangerous drug preparations regardless of country of origin, shall be allowed to pass any port of the Philippines unless it is accompanied by an export authorization issued by the competent authority of the country of origin or other documentary evidence deemed adequate by the office of the DDB, showing that the merchandise is consigned to an authorized permittee, that it is to be applied exclusively to medical and other legitimate uses within the country of destination. It shall be the duty of the Collector of Customs of the port through which such shipment passes to demand the exhibition of the export authorization covering the same and to note on any convenient space therein the fact that the said authorization has been exhibited to him. And that he has no reason to doubt that the quantity of dangerous drugs or exempt dangerous drug preparations indicated thereon was exported in excess of that authorized thereof.

Articles in transit manifested merely as drugs, medicines, or chemicals, without evidence to satisfy the Commissioner of Customs that they are not dangerous drugs nor exempt dangerous drug preparations, shall be impounded and subjected at the carrier’s risk and expense for examination as may be necessary to determine whether they are dangerous drugs or exempt dangerous drug preparations. To avoid inconvenience, the carrier should not accept in transit shipments of such articles unless accompanied by properly verified certificates of the shippers, specifying the items in the shipment and stating whether they are dangerous drugs/exempt dangerous drug preparations or not.

SECTION 49. Duties of Customs Officer —

A. On importation. Upon the receipt in the Bureau of Customs of a package of imported dangerous drugs and exempt dangerous drug preparations and before the delivery thereof to the importer, the Commissioner of Customs, or his duly authorized representative, shall examine the contents of the package thereof and verify the same against his copy of the import certificate or special permit issued by the Board noting the result of such

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verification upon said copy of the import certificate or special permit which he should return to the Dangerous Drugs Board within the first ten days of the month following the receipt of the verified shipment of the dangerous drugs and exempt dangerous drug preparations.

If the dangerous drugs and exempt dangerous drug preparations have not arrived within the period specified in an Import Certificate Form (DDB Form No. 10-72) and Special Permit (DDB Form No. 9-72), it shall be the duty of the Bureau of Customs to return within ten days after the date of expiration the expired copies with the corresponding notation. The Bureau of Customs shall cause such arrangements to be made as will insure the safekeeping of the dangerous drugs and exempt dangerous preparations while in the customs house.

No delivery of dangerous drugs and exempt dangerous drug preparations to the importer from the customs house shall be permitted until the Commissioner or his representative shall be satisfied and shall note on the delivery permit, after personal examination, that the importer has taken all proper precautions for the safe transportation of the dangerous drugs and exempt dangerous drug preparations from the customs house to the importer's premises and that the S-7 license mentioned in Section 6 has been paid.

B. On exportation. It shall be the duty of the Commissioner of Customs or his duly authorized representatives to return an export authorization to the Board within the first ten days of the month following that in which the dangerous drugs and exempt dangerous drug preparations listed therein have been exported, with the notation as to the vessel on which the shipment was made, and the export entry number of such shipment.

SECTION 50. Discontinuance of Business — Holders of S-1, S-3, S-4 and S-5-I and S-5-C licenses before retiring from business shall inform the Board of their intention to do so, and report the kind and quantity of dangerous drugs and exempt dangerous drug preparations that they may still have in their possession. Before actually retiring from business, the licensee shall effect the transfer of his stock of dangerous drugs to another pharmacist possessing an S-3, S-4, S-5-I or S-5-C licenses who should execute an order on DDB Form No. 8-72, addressed to the retiring pharmacist. The order should contain a complete list of the kind and quantity of the dangerous drugs and exempt dangerous drug preparations to be transferred for lack of a transferee. The retiring pharmacist shall deposit his stock of dangerous drugs and exempt dangerous drug preparations if in Manila and Quezon City, with the Dangerous Drugs Custodian, if in the province, with the Provincial Commander, Philippine Constabulary, of the province in which he has his place of business. All unused order forms should be returned to the Dangerous Drugs Board for cancellation.

In case an S-3 license has been issued in the name of a drugstore and dangerous drug orders are filled only for and in its name by a pharmacist in its employ. the owner of the drugstore shall, upon the resignation of the said pharmacist, notify the Board of this fact and state the name of the new pharmacist whom he has employed and authorized to order and dispense dangerous drugs and exempt dangerous drug preparations for and in the name of his drugstore. The incoming pharmacist should assume responsibility for the balance of dangerous drugs and exempt dangerous drug preparations received from the outgoing pharmacist. If the drugstore retires from the business covered by an S-license, the procedure outlined in the next preceding paragraph shall be observed.

SECTION 51. Filing of Orders — The original shall be filed and preserved for a period of two years by the seller. The triplicate copy shall be kept on file by the purchaser for a like period.

Any order form which is improperly executed or mutilated so as to make it unusable, shall not be destroyed, but all copies shall be forwarded to the Board for cancellation.

SECTION 52. Government Officials Required to Use Order Forms — Exempt officials mentioned in Section 53 hereof who purchase dangerous drugs from local firms, shall secure the appropriate order form and use it in the

manner prescribed in Section 27 hereof.

Article IV
Exempt Officials

SECTION 53. Exempt Officials — Officials and employees of the national, provincial, city or municipality governments or any political subdivisions thereof, and of government owned or controlled corporations, who in the exercise of their official duties engage in any of the activities herein described are required to register but are not required to provide themselves with Schedule S-Licenses nor pay the fees when they compound or produce preparations containing dangerous drugs and exempt dangerous drug preparations, but their right to such exemptions shall be evidenced as hereinafter provided. They shall, however, keep records of all transactions in dangerous drugs and exempt dangerous drug preparations as provided in Section 66 hereof.

SECTION 54. Military Officers — On or before January 1 of each year, the Surgeon General of the Armed Forces of the Philippines shall furnish the Dangerous Drugs Board, with a list showing the names, addresses, and official status of officers (preferably pharmacists, physicians, Dental surgeons and veterinarians) authorized to obtain dangerous drugs and exempt dangerous drug preparations for official use. In case of new assignments, amendatory lists showing additions to, eliminations from, or other changes to be made in, previous lists will also be furnished, with respect to procurement of dangerous drugs and exempt dangerous drug preparations and keeping of records, (see Sections 30, 36 and 66 hereof).

SECTION 55. Civil Officers — Each national, provincial, or city or municipal officer of the government who is engaged in any activity mentioned in R.A. 6425, as amended, and who claims exemption from registration and license under the law shall file with the Dangerous Drugs Board a certificate showing the official status and official address of the person claiming exemption. In the case of transfer of station or separation from the service, he shall notify and inform the Dangerous Drugs Board of the balance of the dangerous drugs and exempt dangerous drug preparations under his responsibility.

SECTION 56. Orders and Prescriptions — Orders and prescriptions for dangerous drugs and exempt dangerous drug preparations prepared or issued by exempt officials as such shall be prepared on official order forms (DDB Form No. 8-72) in the former and in the case of prescriptions, shall be prepared on official stationery and shall show besides the requirements mentioned in Section 61 hereof the name, title and official address of the person issuing the same, his S-2 license and shall contain a notation on its face "issued in my official capacity."

If an official engaged in a private business or privately practices a profession in which dangerous drugs are manufactured, administered, or given away, such official shall register and pay the S-2 license for such private activity, and the dangerous drugs for such private purposes shall be secured upon regular order forms.

Officers of the Medical Corps of the Armed Forces, in the course of official medical treatment of army personnel, and members of their official families entitled to receive such treatment, are required to issue prescriptions for these patients which may call for dangerous drugs or exempt dangerous drug preparations. Under circumstances where the drug or preparation required by the patient for medical use cannot be furnished from official stocks, it is necessary that it be obtained pursuant to the official prescription from a drugstore duly qualified by registration under R.A. 6425, as amended, to fill prescriptions for dangerous drugs and exempt dangerous drug preparations.

Such prescriptions, issued in the course of official professional practice only, and prepared on official blanks or stationery and otherwise meeting the requirements of the Dangerous Drugs Board regulations relating to dangerous drugs and exempt dangerous drug preparations prescriptions, may be filled by a duly registered druggist although they do not bear the registry number and current S-License number of the issuing practitioner;

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provided that they shall bear the signature, title and corps of the issuing medical officer and the notation "issued in my official capacity."

This procedure shall not apply in the case of prescriptions written by an army medical officer in the treatment of a private person, i.e., a patient not entitled to receive medical treatment from the physician in the latter's capacity as a service medical officer. In prescribing and dispensing dangerous drugs and exempt dangerous drug preparations to such private persons, the officer is subject to all the requirements of R.A. 6425, as amended including registration and payment of S-2 license fee, as are imposed upon other physicians conducting private medical practice.

Prescriptions issued by exempt officials shall be filled only by registered retail dealers who will be held liable for filling an improperly prepared prescriptions. After filling, orders and prescriptions of exempt officials shall be filed with the regular orders and prescriptions for dangerous drugs and exempt dangerous drug preparations orders and prescriptions.

SECTION 57. Enforcement Officers — Customs agents and inspectors of the Department of Health in connection with their duties are entitled to procure from any person registered under the law, samples of dangerous drugs and exempt dangerous drug preparations, and registrants may lawfully furnish to any such persons for the purpose stated the required samples, taking a receipt therefor, and furnishing the Board with a copy thereof.

SECTION 58. Ocean Vessels — Subject to a determination by the Dangerous Drugs Board of the necessity and propriety in such case, ocean-going vessels and commercial air transports of foreign registry engaged in the international trade may purchase dangerous drugs and exempt dangerous drug preparations in reasonable quantities for stocking medicine chests and dispensaries and for stocking first aid packets or medicine chests on life rafts carried aboard such craft. Dangerous drugs and exempt dangerous drug preparations may be purchased in the case of ocean vessels by the physician or surgeon employed in such vessel who should be duly licensed to practice his profession in some state or country; in the case of air transports by the Chief Medical Officer thereof, through special order forms to be furnished by the Dangerous Drugs Board, after an application has been filed. If the order covers replenishment units, after the initial supply, the application shall state in detail the circumstances which make replenishment necessary, including an accounting for dangerous drugs and exempt dangerous drugs preparations previously disposed of. The Board may require any further explanation of, or information concerning, any order that it may deem necessary.

Article V
Retail Dealers, Practitioners,
Dealers in Exempt Preparations
and Laboratories

SECTION 59. Who May Issue Prescriptions — A prescription for dangerous drugs and exempt dangerous drug preparations may be issued only by a physician, dentist or veterinarian who is duly registered with the Dangerous Drugs Board and has paid the current S-license, or by an exempt official.

SECTION 60. Purpose of Issue — A prescription, in order to be effective in legalizing the possession of dangerous drugs and exempt dangerous drug preparations must be issued for legitimate medical purposes. The responsibility for the proper prescribing and dispensing of the dangerous drugs and exempt dangerous drug preparations is upon the practitioner, but a corresponding liability rests with the druggist who fills the prescription. An order purporting to be a prescription issued to an addict or habitual user of dangerous drugs and exempt dangerous drug preparations, not in the course of professional treatment but for the purpose of providing the user with dangerous drugs and exempt dangerous drug preparations sufficient to keep him comfortable by maintaining his customary

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use, is not a prescription within the meaning and intent of the law, and the person filling such an order, as well as the person issuing it, shall be charged with violation of the law.

Prescriptions issued regularly, calling for dangerous drugs to be administered upon definite patients of doubtful authenticity, should not be honored or filled, inasmuch as such prescriptions are undoubtedly issued for the benefit of drug addicts and therefore illegal. Patients requiring the regular use of dangerous drugs allegedly for the relief of pain not caused by addiction to opium or other dangerous drugs should present a certificate issued by the attending physician to the effect that they really need such treatment. However, they should obtain their supply of dangerous drugs through an order form (DDB Form No. 8-72) signed by their attending physician and approved by the Dangerous Drugs Board, or through medical prescription (DDB Form No. 1-72), provided that such prescription does not exceed the amounts prescribed under Section 61 hereof, provided further, that a monthly clinical chart in duplicate should be submitted to the Board showing the date and hour of disposal, the quantity used and a summary of the amount used during the month, and provided finally that a clinical chart shall not be required in case of purchase through DDB Form No. 1-72.

Prescriptions calling for dangerous drugs are issued for definite patients and for the purpose of giving them instant relief from pain. Accordingly, a prescription sent through the mails should not be honored, or filled, inasmuch as their evident purpose is to enable the sender to keep in stock dangerous drugs to anticipate future needs, orders of this kind should be made in the proper order form (DDB Form No. 8-72) duly approved by the Dangerous Drugs Board.

SECTION 61. Prescription Requirements — Every prescription for dangerous drugs or exempt dangerous drug preparations shall contain the following information:

- Name, residence and office address of the practitioner;

- Registry and number of privilege tax receipt, and current S-License of the practitioner;

- Full name and address of the patient;

- The exact quantity of the dangerous drug or preparation prescribed; and

- Signature of the prescribing practitioner.

No prescription once issued shall be refilled.

All prescriptions shall be dated as of and signed on the day when issued. A practitioner may sign a prescription in the same manner he would sign a check or legal document. Prescriptions should be written in ink or indelible pencil or typewritten and signed personally by the practitioner.

The duty of preparing prescriptions is upon the practitioner, and he is liable to the penalties provided by law in case of failure to state the information required by law. A corresponding liability rests with the druggist who fills the prescription not prepared in the form prescribed by law.

SECTION 62. Who May Fill — A prescription for dangerous drugs and exempt dangerous drug preparations may be filled only by a registered retail dealer, or any exempt official. No dealer shall refill a prescription for dangerous drugs or exempt dangerous drug preparations or fill a similar prescription which he suspects to have been fraudulently issued or obtained.

The furnishing of dangerous drugs pursuant to telephone advice of practitioners is prohibited, whether prescriptions covering such orders are subsequently received or not, except that in an emergency a druggist may deliver dangerous drugs through his employee or responsible agent pursuant to a telephone order, provided that

the employee or agent is supplied with a properly prepared prescription before delivery is made, which prescription shall be turned over to the druggist and filed by him as required by law.

In dispensing to the buyer drug products in unit dose or products which are not in their original containers but transferred to small bottles, tin cans, boxes, plastic and/or paper envelopes and the like, the pharmacist shall place legibly on the required drug outlet's label the following information:

A. Name of patient;
B. Generic name of the drug;
C. Brand name, if any;
D. Manufacturer;
E. Dosage strength;
F. Expiry date;
G. Directions for us; and
H. Name of Pharmacist

Whenever a prescription for dangerous drugs or exempt dangerous drug preparations is filled by a drugstore, it shall be the duty of the drugstore owner to cause the words "used in full" to be stamped in bold prints diagonally across the original copy of said prescription in case the full quantity of the drug therein stated is sold, and the words "used for ____ only" in case the quantity of the drug therein stated in not fully sold.

In partial filling of the prescription, the following shall be written on the face of the prescription:

- The date of partial filling;

- The quantity served and balance of the prescription unserved, and

- Name and address of the drugstore.

The partially-filled prescription shall be returned to the buyer after recording the partial filling in the prescription book. The drugstore which completes the filling of the prescription shall keep the prescription in file.

Dispensing must be done by the pharmacist who shall affix his/her signature on the prescription filled.

The order and instructions of the prescribing practitioner as written on the prescription shall be strictly followed.

SECTION 63. Preservation of Filed Prescriptions — The dealers filling prescriptions for dangerous drugs and exempt dangerous drug preparations shall keep them in a separate file in such manner as to be readily accessible to inspection by investigating officers, for a period of one (1) year. (As per R.A. 6425, as amended)

SECTION 64. Labels on Containers — The dealer filling a prescription shall affix to the package a label showing the date, and address, his name, registry number, the serial number of the prescription, exact quantity of the dangerous drug or exempt dangerous drug prescribed, its strength and the total number of units to be supplied, the name and address of the patient, the name, address, PTR and registry number of the practitioner issuing the prescription.

SECTION 65. Records to be Kept by Dealers — All dealers registered under the provisions of these regulations and exempt officials mentioned in Article IV shall be held strictly responsible for any dangerous drug or any exempt dangerous drug preparation dispensed by themselves or their employees. For each kind and each size of dangerous drugs or exempt dangerous drug preparations, the dealer must keep a separate record consisting of debit and credit accounts. The drugs or preparations on hand, if any, and those subsequently received shall constitute the debit entries on the record. The drugs or preparations sold or dispensed of shall constitute the credit. A separate line shall be used for each entry which must be made legibly in ink and in chronological order. At the

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end of each month, a balance shall be struck showing in red ink the stock on hand of each particular kind of dangerous drugs or exempt dangerous drug preparations, the size of the containers thereof, and the total dangerous drugs contents of all the packages covered in the entry, which shall be carried forward to the account for the succeeding month. No balance, however, need be stricken off for the succeeding month, if after the last balance no sale or purchase of the particular dangerous drugs mentioned in the corresponding account has been made. Such records, before using, shall be presented to the Executive Director of the Board or his duly authorized representative and shall be kept for a period of five years after the date of the last entry for inspection by Drug Regulation Officers or Investigating Officers. Before any record book is presented for registration, there shall be placed on the front cover by the owner thereof an identification as to the kind of record book, registry number, the name and address of the owner, And his kind of business. The pages shall be serially numbered in a permanent and legible manner. Every record book shall be serially numbered and if approved the following authentication shall be made by the approving officer on the reverse side of the front cover thereof.

> "This _____, Volume No. ___ with _____ pages or sheets, is approved on this ____ day of _____ 19__, for the purposes of _____.
>
> _____
> Signature
>
> _____
> Designation of Officer

If the book, register, of record presented for approval is a continuation of previous books, registers, or records, besides the foregoing authentication, the following notation shall be added to the authentication:

> "Volume No. _____ of this _____ was approved on the _____ day of _____, 19____.
>
> _____
> Signature
>
> _____
> Designation of Officer

A. Debit entries. Each entry of dangerous drugs or exempt dangerous drug preparations received shall be made on the date of receipt of the drugs or preparations and shall show:

- Date of receipt of the drugs or preparations;

- Number of permit from the Dangerous Drugs Board;

- Name of the person from whom the drugs or preparations were received; and

- Quantity of dangerous drugs or exempt dangerous drug preparations received.

B. Credit entries. Each entry of dangerous drugs or exempt dangerous drug preparations disposed of shall be made within twenty-four (24) hours after disposal of the drugs or preparations and it shall show:

- Date and hour of disposal;

- Authority for disposal, whether by permit or by prescription; if by prescription, name and address of the prescriber;

- Number of permit issued by the Dangerous Drugs Board or the date of prescription, and the name, PTR and number of the S-license receipt of the person issuing the prescription;

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- Name and address of the person to whom disposed of;

- Quantity of dangerous drugs or exempt dangerous drug preparations disposed of; and

- Daily balance in case transactions have been effected during the day.

SECTION 66. Records to be Kept by Practitioners — Practitioners may dispense dangerous drugs to bonafide patients pursuant to the legitimate practice of their professions without the issuance of prescriptions provided that the drugs are purchased through an order form (DDB Form No. 8-72) duly approved by the Board and provided further, that such practitioner shall keep a record of such drugs received, dispensed, or distributed, showing the amount received, the person from whom the dangerous drugs were ordered, the date of receipt, the amount dispensed or distributed, the date and the name and address of the patient to whom such drugs are dispensed or distributed and diagnosis or a brief explanation of such use.

SECTION 67. Restrictions on Disposition of —

A. Dangerous drugs. Dangerous drugs shall be prescribed only through the official prescription form (DDB Form No. 1-72). Whenever a prescription for dangerous drugs is filled by a pharmacist, it shall be the duty of the pharmacist or his duly authorized representative to cause the words “used in full” to be stamped diagonally in bold prints across the original copy of said prescription in case the full quantity of the drug stated therein is sold, and the words "used for _____ only" in case the quantity of the drug stated therein is not fully sold.

A prescription for dangerous drugs already filled in full shall not be refilled.

B. Exempt dangerous drug preparations. A dangerous drug preparation to be exempt from certain requirements shall be manufactured, sold, distributed, dispensed or possessed as a medicine, and not for the purpose of evading the intention and provisions of the law. A manufacturer, producer or compounder may produce and sell as exempt only preparations readily capable of use for claimed medicinal purposes, and sales thereof, if not to consumers, shall be made only to persons provided with S-license. Sales made to customers, either by manufacturers or dealers, either by manufacturers or dealers, shall be made only in such quantities and with such frequency to the same purchaser as will restrict their use to the medical purpose for which intended.

Orders for exempt dangerous drug preparations are not required to be on any particular form, but an order from a dealer shall not be honored by a manufacturer or other dealer unless it bears the current S-license of the dealer giving the order.

When orders for exempt preparations are taken by a traveling salesman, the salesman shall ascertain the current S-license of the purchaser. The order shall not be filled by the manufacturer or vendor unless she knows the purchaser’s S-license number.

Preparations and remedies which are within the exemption shall be dispensed only through ordinary prescription with S-2 license indicated therein. Such prescription shall not be refilled after it has been used in full.

However, the filling or prescriptions requiring more than one exempt dangerous drug preparation or remedy further reduced or diluted by the addition of non-dangerous drug medicinal agents is authorized, provided, that the preparation is furnished in good faith for medicinal purposes.

SECTION 68. Records Required — Every manufacturer, producer, compounder, wholesaler and retailer of dangerous drugs or exempt preparations shall record all sales, exchanges, gifts or other dispositions, the entries to be made at the time of delivery. The requirement that such records are maintained as herein provided, is absolute, independent, and not merely a condition precedent to securing the exemption granted by the last cited section to manufacturers, producers, compounders, wholesalers, and retailers of dangerous drugs or exempt dangerous drug

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preparations. Failure to keep such record is in itself a violation of the law and regulations and renders the manufacturer, producer, compounder, wholesaler or retailer liable to the penalties set forth in these regulations. Separate records shall be kept of dispositions to registrants and to consumers. The record of dispositions to registrants shall show the name, address, and registry number of the registrant to whom disposed, the name and quantity of the preparation, and the date upon which delivery to the registrant is made. The record of dispositions to consumers shall show the name of the recipient, his address, and the name and quantity of the preparation, and the date of delivery.

The record shall more or less be in the following manner:

Records of Disposition to Registrants
Name of Preparation

_____

Date Registration No. Name of Recipient Address Quantity
of Recipient

_____

_____

_____

_____

Record of Dispositions to Consumers
Name of Preparation

_____

Date Name of Recipient Address Quantity

_____

_____

_____

_____

SECTION 69. Returns Required — Each compounder of dangerous drugs or exempt dangerous drug preparations shall render semi-annual and annual returns on or before the tenth day of the month following the period to the Board substantially in the form and manner indicated after Section 70.

SECTION 70. Medical Schools, Colleges and Laboratories — Persons registered and provided with an S-license may Secure their dangerous drugs through the DDB Form (DDB Form No. 8-72) in the manner described under Section 30.

Any dangerous drug or residue resulting from the use of a dangerous drug or preparation obtained upon an order form, which is desired to be retained for further research, instruction or analysis shall be placed in a container legibly labelled with the name of the product or residue and the date produced.

Name of Exempt Dangerous Drug
Preparation Produced

_____

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Name of
DD

Stock on
Hand

Amt.
Imported

Amt.
Purchased

Total

Amt. Used

Balance

Exempt DDP
Produced

Exempt DDP
Disposed

Exempt DDP
Stock on Hand

_____

_____

_____

Any sale of a dangerous drug or preparation by a holder of an S-license will render him liable to registration and to payment of license as a compounder, manufacturer, wholesaler as the facts may warrant and to compliance with all other requirements of the law and regulation governing sales.

The persons concerned shall keep complete records of receipts, disposals, and stocks on hand of all dangerous drugs and preparations. A special record shall be kept showing the date, kind, and quantity of dangerous drug or preparation used, the particular purpose or object of such use, and the identification and disposition of the dangerous drug or resulting products or residues, and manner of disposition.

Records shall be kept in the following form with sample items as guide.

Dangerous Drug Used Identification and Disposition of
Dangerous Drug or Resulting Products and Residues

Date	Kind	Quantity	Purpose	Date	Products or Residue	Quantity	Disposition (Destroyed, Retained or Returned)
Thebaine	1 oz.	Experimental thesis	None	None	All residues destroyed		
Morphine	1 oz.	Experimental thesis	Codeine	1/2 oz.	Retained for instructional exhibit		
Mineral Analysis	None	None					
Crude Opium	1 lb.	Assay	Crude Opium	1/2 oz.	Returned to registered person desiring assay on Order Form No. _____		

SECTION 71. Interisland Vessels — Vessels engaged in trade between ports of the Philippines may obtain dangerous drugs and preparations for stocking medicine chests and dispensaries maintained on Board through DDB Order Form (DDB Form No. 8-72) duly approved by the Board. The DDB Order Form (DDB Form No. 8-72) should be prepared by the physician or surgeon employed in such vessel who shall be duly registered and have paid his current S-2 license. Records should be kept in the manner described in Section 66.

Article VI
Records and Returns of Importers,
Exporters, Manufacturers,
Compounders and Wholesale Dealers

SECTION 72. Returns Required — Every person registered as an importer, manufacturer, compounder, or wholesaler, shall render semi-annual and annual returns on forms prescribed by the Board which shall show all stocks on hand at the beginning and end of the period, the amounts purchased or imported, the amounts disposed of during the period specifying the amount used for the preparation of dangerous drugs and exempt dangerous drug preparations, and shall be submitted to the Board on or before the tenth day of the month succeeding that of the period for which it is rendered.

SECTION 73. Importers and Wholesalers — Importers and wholesalers of dangerous drugs who also sell the same at retail shall keep separate records of their wholesale and retail sales of the said drugs. Transfer of dangerous

drugs from the wholesale to the retail shall be covered by DDB Form No. 8-72. The records shall be in the manner prescribed in Section 65 except that the debit side shall show the amount of fees and the official receipt number under which it was accounted for.

It shall be the duty of the importer to submit semi-annual and annual reports of the dangerous drugs imported during the year stating the date of receipt, the name and quantity of the dangerous drugs received and the import certificate number and DDB authorization control number.

SECTION 74. Exporters — The exporter shall keep a record of all transactions in dangerous drugs and preparations in the manner prescribed in Section 65 and of any serial numbers that might appear on packages of dangerous drugs in quantities of 30 grams or more in such manner as will identify the foreign consignee. It shall be the duty of the exporter to submit semi-annual and annual reports of dangerous drugs and exempt dangerous drug preparations exported during the period, stating the date of export and the name and address of the consignee.

SECTION 75. Manufacturers and Compounders — Every manufacturer or compounder shall keep a record of all transactions in dangerous drugs in the manner prescribed in Section 65 which shall also show the amount of fees paid and the official receipt number under which they were accounted for.

Manufacturers or compounders with the exception of the manufacturers mentioned in the next succeeding paragraph, shall, before manufacturing, submit on DDB Form No. 8-72 the name and quantity of dangerous drugs to be used, the name and approximate amount of resulting product, and the date of manufacture. The quantity of dangerous drugs used shall be entered on the credit side of the record on that particular drug and the resulting product of manufacture shall be entered on the debit side. Thus, if a permit is issued for the manufacture of 1,000 ampules of morphine sulphate 1/8 GR using 8 grams of morphine sulphate powder, theoretically 1,000 ampules can be produced from eight grams of morphine sulphate, but in actual production, the resulting product is always less due to loss in sterilization and handling. If the resulting product is 950 ampules, that quantity should be the one entered in the debit side under the item "morphine sulphate ampules 1/8 GR." and the eight grams, on the credit side under the item "morphine sulphate powder". Any loss in manufacture and any recoverable wastes salvaged from the manufacture shall be reported.

SECTION 76. Semi-annual and Annual Reports — Holders of S-5-I, S-5-C and S-4 licenses shall submit semi-annual and annual reports to the Dangerous Drugs Board on or before the tenth day of the month following the period for which report is rendered showing the following:

- Name of drug or preparation,

- Number of packages,

- Size of packages,

- Dangerous drug content,

- Stock at the beginning of the period,

- Amount imported,

- Amount locally purchased,

- Amount prepared,

- Total of 5,6, 7 and 8. Amount available,

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- Amount sold to wholesalers,

- Amount sold to retailers,

- Amount used for taxable dangerous drug preparations,

- Amount used for exempt dangerous drug preparations,

- Amount disposed of - totals of 10, 11, 12 and 13, and

- Balance on hand at the end of the period.

Retail drugstores and hospital pharmacies that are holders of S-3 license shall likewise render semi-annual report (every six calendar months).

A certified true copy of his record covering a period of six calendar months, duly signed by the pharmacist or the owner of the drugstore or pharmacy, shall be forwarded to the Board within fifteen (15) days following the last day of every June and December of each year, copy furnished the City or Municipality Health Officer concerned.

Article VII
Administrative Provisions

SECTION 77. Safeguarding of Dangerous Drugs and Exempt Dangerous Drug p Preparations — Dangerous drugs and exempt dangerous drug preparations shall at all times be properly safeguarded and securely kept where they will be available for inspection by Drug Regulation Officers/Inspectors and properly authorized agents. They shall be kept separated from the non-dangerous drugs.

Deliveries of dangerous drugs and exempt dangerous drug preparations shall be made by reliable persons. In no case shall delivery of dangerous drugs and exempt dangerous drug preparations be made through the mails.

Security Requirements:

I. General Security Requirements — All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of dangerous drugs and exempt dangerous drug preparations. In order to determine whether a registrant has provided effective controls against diversion, the Dangerous Drugs Board shall use the security requirements set forth in this section as standard for the physical security controls and operating procedures necessary to prevent diversion.

II. Physical Security Controls for Non-practitioners, Pharmaceutical Laboratories, Storage Areas of Entities Duly Licensed to Deal in Dangerous Drugs and/or Exempt Dangerous Drug Preparations.

1. Outside Perimeter:

- Building Environs. Open areas on the outside perimeters of the establishment should be cleared of debris, high plant growth, stocked boxes etc., so as to make concealment difficult. These areas should be well lighted at night. If the establishment shares a wall with an adjacent building, try to determine the security of the wall. Approximate remedial measures shall be undertaken if adjacent building sharing a common wall with the establishment or storage area poses a security problem.

- Roof. The roofing material should be reinforced with wire mesh or some other material or steel bars, and firmly sealed.

- Walls. Brick or cement block is usually adequate for walls. A less expensive approach would be 3/4" plywood securely mounted from the interior.

- Windows. Back or side windows should either be made of break resistant glass or fitted with securely mounted steel bars. The frames should be anchored securely to the interior beams. Display windows should be made of break resistant glass or fitted with roll back mesh.

- Doors. Only locks that require a key should be used. Hinges should be inaccessible from the outside or sealed so as to preclude their disassembly. The framing should be solid, and not subject to being pried or stretched.

The door itself should be sturdily constructed. If made of wood, it should be solid and at least 2" thick. The most commonly used door is glass with metal framing. The glass should be break-resistant. Side or back doors should be fitted with a sliding metal bar across the framing.

2. Layout:

- Dangerous drugs storage area should be isolated but should be clearly visible from any point within.

- Exempt dangerous drug preparations storage area should also be isolated.

3. Dangerous Drugs Storage:

- A combination lock steel safe or a concrete vault fitted with a combination lock steel door.

- Number of people with knowledge of the combination should be kept to an absolute minimum. Should one of the employees cease working thereat, the Combination should be changed. If possible, avoid reducing the combination to writing. If it is recorded, that record should be either kept off the premises or placed under the security responsibility of a ranking official of the establishment.

4. Exempt Dangerous Drug Preparations

- Locked room or cage constructed of chain link.

III. Physical Security Controls for Practitioner

1. Dangerous drugs and other controlled substances shall be stored in a securely locked specially constructed cabinet or safe. All signs identifying the cabinet or safe should be removed. It should be locked at all times with the key kept by, or combination control known only by the individual responsible for the access to the storage area for dangerous drugs.

2. Access to the storage area for dangerous drugs should be limited to a minimum number of persons.

3. Should one who has knowledge of the key or combination control ceases to be connected at the pharmacy, the lock or combination should be changed.

IV. No person in possession of dangerous drugs and other controlled substances in which paragraphs II and III apply and such drugs are kept for the time being within any place in the building, shall leave that place or that part of the building in which the dangerous drugs are stored for safekeeping.

SECTION 78. Disposition of Surrendered, Seized or Confiscated Dangerous Drugs and Exempt Dangerous Drug Preparations — All dangerous drugs and exempt dangerous drug preparations surrendered, seized or confiscated under R.A. 6425, as amended, shall be disposed of in accordance with the following procedure:

A. A committee composed of one physician from the Department of Health, as Chairman, one chemist from the National Bureau of Investigation (NBI), one chemist from the Philippine Constabulary Crime Laboratory (PCLL), one Pharmacist from the Bureau of Food and Drugs (BFAD), and one pharmacist of the Dangerous Drugs Board (DDB) as Members, each to be designated by the heads of the agencies concerned, is hereby created to examine

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and classify seized or confiscated or voluntarily surrendered dangerous drugs which are in the custody of the NBI as Dangerous Drugs Custodian designated as such by the Board.

B. The committee shall meet as often as necessary, at the call of the Chairman, to list the dangerous drugs in custody and determine which of these drugs have medical, therapeutic or research value. A monthly report of the committee enumerating and specifying the quantity and quality of each drug shall be submitted to the Board, a copy thereof furnished the Bureau of Food and Drugs, the Director of the NBI, the Chief of the Philippine National Police, and the Secretary of Health.

C. Upon receipt of the committee report, the Dangerous Drugs Board shall cause the publication of the list of the drugs which in its opinion are fit for human use and consumption in a newspaper of general circulation. Any government institution or private charitable organization duly authorized to deal in dangerous drugs, having a need for the same for medical or research purposes, may apply with the Chairman of the Dangerous Drugs Board for any of the listed drugs. The institutions and organizations whose requisitions are approved by the Chairman of the Board may receive the said drugs in the form of donation.

D. All useful drugs in the custody of the Board which are not disposed of by way of donation shall be sold by public auction to private enterprises duly authorized to deal in dangerous drugs in such quantity, to be determined by the Board, as may be needed by the buyer for its average consumption for one year.

Any undonated or unsold drugs in excess of the domestic need may be exported by the Board under such conditions as may be prescribed in agreements or conventions relating to dangerous drugs of which the Philippines is a signatory.

Seized or confiscated drugs which are not disposed of within a period of two years from the date they are declared by the Board as fit for human consumption or use shall be destroyed by burning.

E. All donees, whether private or governmental, and all vendees residing in the Philippines, which receive the drugs in accordance with the provisions of the two preceding sections, shall be required to submit a monthly report to the Dangerous Drugs Board, stating therein the amount of drugs consumed; for what purposes used, the name of the patients, if any, to whom the drugs were administered; and the names of the physicians in the employ of the entity who dispensed the drugs; or the name of any personnel thereof who utilized the drug for research purposes.

SECTION 79. Disposition of Surrendered DDB Order Form — DDB Order Form No. 8-72 and importation order books (DDB Form No. 10-72) and order books for exempt preparations (DDB Form No. 9-72) surrendered to this office for cancellation shall be forwarded to the Property Custodian for destruction by burning.

SECTION 80. Statistical Reports — It shall be the duty of the Board to gather data and prepare statistical reports which may be required by the different international bodies in compliance with the different conventions and protocols to make more effective the international control of dangerous drugs and exempt dangerous drug preparations.

SECTION 81. Size of Record Books — Record books of importers, manufacturers, compounders, wholesalers and retail dealers of dangerous drugs shall be approximately 17 X 11 inches and those of physicians and persons dealing in exempt dangerous drug preparations shall at least be 14 1/2 X 8 1/2 inches.

SECTION 82. Penalties — Persons who violate the law or fail to fulfill its requirements in any particular section are liable to administrative sanctions, the maximum liability consisting of a fine not to exceed P20,000.00.

No subsequent license to deal in dangerous drugs shall be issued to a person who has been convicted of illegal

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traffic in dangerous drugs or exempt dangerous drug preparations.

Should the offender, however, desire to extra-judicially settle his violation of these regulations, he may offer as compromise an amount satisfactory to the Board.

SECTION 83. Violations to be Reported — Drug Relation Officers and those deputized by the Board shall report to the Executive Director of the Board every violation of these regulations coming to their knowledge.

SECTION 84. Repealing Clause — All rules and regulations inconsistent herewith are hereby repealed or modified accordingly.

SECTION 85. Date of Effectivity — These regulations shall take effect after completion of their publication for two (2) consecutive weeks in a newspaper of general circulation.

Adopted: 28 Feb. 1991

(SGD.) TOMAS P. MARAMBA, JR., M.D., M.H.A.
Vice-Chairman
(Undersecretary of Health
for Standards and Regulation)

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