[DDB BOARD REGULATION NO. 4, February 28, 1991]

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

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 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:

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

1. Renewal — License to Operate for 19 __ from BFAD
2. Certificate of Compliance from BFAD
3. Business Permit — 19 __ (Current)
4. Mayor's Permit — 19 __ (Current)
5. PRC — Pharmacist (Unexpired/Updated)
6. PTR — 19 __ (Current)
7. Letter from Pharmacist authorizing the representative to apply and secure S-License.
8. Letter authorizing Pharmacist to deal with Dangerous Drugs.
9. SEC Registration

B. *Requirements for S-2 (License Holders)*

1. Privilege Tax Receipt (PTR) 19 __ (Current)
2. PRC — Physician (Unexpired/Updated)
3. 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 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:

1. 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.

2. Unfitness of the person to hold such license or

3. 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 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 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:

1. Name or style of the person or firm to whom the license was issued,
2. Date of issue,
3. Paragraph and assessment number of the license issued,
4. Amount of fee paid,
5. Period for which such license is paid,
6. Kind of business, occupation, or profession,
7. Place of business, (street, number, municipality and province), and
8. 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.

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