

APPLICATIONS FOR REGISTRATION AND LICENSE TO DEAL IN DANGEROUS DRUGS AND EXEMPT PREPARATIONS

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Pursuant to the powers vested in the Dangerous Drugs Board under Section 36(a) and (1) of Republic Act 6425, as amended, the following procedures governing the registration and the issuance of license to qualified persons or entities to deal in dangerous drugs and exempt preparations are hereby prescribed:

SECTION 1. With Whom to Register and File Application — All applications for registration and for the issuance of a license to deal in dangerous drugs and exempt preparations shall be filed with the Dangerous Drugs Board, or with the Board's authorized representatives if situated outside of the Metro Manila area. Persons or entities situated outside of the Metro Manila area shall file their applications with the Special Processing Officers deputized as such by the Board under Section 3 hereof.

SECTION 2. Requirements to be Complied With — Until such time as the new or modifying rules and regulations are passed by the Board and take effect, all requirements currently being imposed in connection with such registration and applications for license shall be complied with.

SECTION 3. Deputation of Drug Regulation Officers in the Regional Offices of the Ministry of Health as Special Processing Officers of the Board — Drug Regulation Officers of the Ministry 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 exempted 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 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 applications, 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 Ministry 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 preparations shall, upon effectivity of this Regulation, repose on the Dangerous Board. Accordingly, such records as are in the custody of the Food and Drug Administration shall be turned over to the Board on or immediately before December 31, 1982 except those in the Health Regional Offices which shall be transferred to the custody of the Regional Drug Regulation Officers deputized as Special Processing officers of the Board under Section 3 hereof.

SECTION 5. Inspections of Persons or Entities Authorized to Import, Export, Manufacture, Distribute, Prescribe, Dispense, Deal In, or Sell Dangerous Drugs or Exempt Preparations — For the purposes of RA 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, and Drug Regulation Officers and such other officers as may be deputized in writing as Drug Regulation Officers by the Chairman of the Board.

SECTION 6. This Regulation shall take effect January 1, 1983.

Adopted: 17 Nov. 1982

(SGD.) J. C. AZURIN
(Minister of Health)
Chairman

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