[DDB BOARD REGULATION NO. 3, s. 1987, March 19, 1987]

EXEMPTING PHARMACEUTICAL PREPARATIONS CONTAINING PHENOBARBITAL SUBSTANCES FROM CERTAIN REQUIREMENTS OF RA 6425, AS AMENDED

SECTION 1. Definition

Preparation means (i) Any solution or mixture, in whatever physical state, contain **phenobarbital** substances;

(ii) Any **phenobarbital** substance in dosage form.

SECTION 2. Unless specifically classified by Regulations as Regulated Drugs, all pharmaceutical preparations in whatever form containing a quantity of phenobarbital substances are hereby classified as exempt preparations. Provided, however, that the phenobarbital substance is not in association with: (a) regulated drug; (b) a prohibited drug; (c) a psychoactive drug not under international control with known abuse potential.

SECTION 3. Exempted phenobarbital preparations shall be subjected to the following requirements:

a. Registration (With whom to register and file application):

1. Dangerous Drugs Board — 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 representative if situated outside of the Metro Manila area.

2. Bureau of Food and Drugs — phenobarbital drug preparations shall be duly registered with the Bureau of Food and Drugs.

b. Records to be maintained:

Every person or any establishment registered with the DDB and BFAD as Importer, Manufacturer, Producer, Compounder, Distributor at wholesale or retail, shall maintain a true and accurate record for any phenobarbital drug preparation, as defined herein, received by him and its disposal, in a record book designed for the purpose to be kept for at least two (2) years after the last entry has been made, and is subject to inspection and verification at any time of the day at reasonable hours by authorized officers of the DDB. Each entry of dangerous drugs or phenobarbital drug preparations received shall be made on the date of receipt of the

drugs or preparations. The following data shall appear in the record book:

1. Manufacturer, compounder, producer

   (a) Date raw materials received.

   (b) Name and quantity of raw materials on hand.

   (c) Name and total quantity and description of finished product.

   (d) Name and address of drug establishment and registry number of the registrant to whom the drug was delivered.

   (e) Name and quantity of finished products disposed or sold.

   (f) Balance of stock on hand.

2. Importer, producer

   (a) Date of receipt of the raw materials or preparations imported.

   (b) Name and quantity of raw materials/finished drug product imported.

   (c) Number of import permit and the date issued by the DDB.

   (d) Name and quantity of drug disposed or sold.

   (e) Name and address of person or establishment to whom it was delivered.

   (f) Date of delivery.

   (g) Balance of stock on hand.

3. Retailer

   (a) Date of receipt of phenobarbital drug preparations.

   (b) Name and quantity of drug received or purchased.

   (c) Name and address of supplier.

   (d) Date and quantity when drug was disposed or sold under prescription.

      i. Date of prescription

ii. Name and address of prescriber

iii. Preparation and quantity prescribed

iv. Name and address of patient

v. Privilege Tax Receipt Number of the prescribing physician

vi. S-2 (narcotic license) number of the prescribing physician

Provided, however, that when a **phenobarbital** preparation contains not more than 8 mg for oral or injectable use and 16 mg for suppositories, S-2 license of the doctor is not required and the recording will be done in the ordinary prescription book.

(e) Balance of stock on hand.

Provided, however, that in the case of records of **phenobarbital** drug preparations dispensed for in-patients in hospitals and/or similar institutions, the following shall be observed:

i. Each entry of phenobarbital drug preparations disposed of shall be recorded in a prescribed format containing the following information:

Record of Phenobarbital Drug Preparation In-patient in Hospitals and Similar Institutions

Name of Phenobarbital Drug Preparation _____

Dispensing Pharmacist _____

Date _____

Date	Time	Full Name of Patient	Bed No.	Room No.	Quantity Dispensed	Name Physician

and thereafter transferred to the additional opium book at the end of the period.

ii. At the end of each prescribed period, an ending balance for the day of stocks on hand shall be indicated in the record book in red ink, the quantities of