[DDB BOARD REGULATION NO. 1, s. 1987, February 19, 1987]

AMENDMENT OF BOARD REGULATION NO. 2-A, SERIES 1985, PRESCRIBING UNIFORM CONDITIONS/REQUIREMENTS FOR EXEMPTED PHARMACEUTICAL PREPARATIONS CONTAINING ANY OF THE BENZODIAZEPINE SUBSTANCES

Pursuant to the powers vested in the Dangerous Drugs Board under Section 36 (a), Article VIII of Republic Act 6425, as amended, Board Regulation No. 2-A, Series of 1985 is hereby amended as follows:

SECTION 1. Definition

Preparation means (i) Any solution or mixture, in whatever physical state, containing benzodiazepine substances; (ii) Any benzodiazepine substances in dosage form.

SECTION 2. Unless specifically classified by regulations as Regulated Drugs, pharmaceutical preparations in whatever form containing a quantity of the following benzodiazepine substances are hereby classified as exempt preparations:

International Non-proprietary Names (INN)	**Chemical Name**
a. Alprazolam	8-chloro-1-methyl-6 phenyl-4H-s triazolo [4,3-a] benzodiazepine
b. Bromazepam	7-bromo-1, 3-dihydro-5-(pyridil-2H-1, 4-benzo diazepin-2-one
c. Camazepam	7-chloro-1, 3-dihydro-3 hydroxy-1 methyl-5 phenyl-2H-1, 4-benzodiazepin-2-one dimethylcarbamate (ester)
d. Chlordiazepoxide	7-chloro-2 (methylamine) 5-phenyl-3H 1, 4-benzodiazepin-4-oxide
e. Clobazam	7-chloro-1-methyl-5- phenyl-1H-1, 5-benzodiazepine-2,4 (3H, 5H)-dione
f. Clonazepam	5-(o- chlorophenyl)-1. 3-dihydro-7 nitro-2H-1 ,4-benzodiazepin-2-one
g. Clorazepate	7-chloro-2, 3-dihydro-2-oxo-5-phenyl-1-1H 1 ,4-benzodiazepine-3-carboxylic acid
h. Clotiazepam	5-(chlorophenyl)-7-ethyl-1, 3-dihydro-1- methyl-2H-thieno [2, 3-e]-1, 4-diazepin-2-one
i. Clonazolam	10-chloro-11b-(o- chlorophenyl)-2, 3, 7, 11b-tetrahydrooxazolo-[3,

	2-d] [1, 4] benzodiazepin-6 (5H)-one
j. Delorazepam	7-chloro-5-(o-chlorophenyl)-1, 3-dihydro-2H 1, 4- benzodiazepine-2-one
k. Diazepam	7-chloro-1, 3-dihydro-1-methyl-5-phenyl-2H-1, 4-benzodia-zepin-2-one
l. Estazolam	8-chloro-6-phenyl-4H-s-triazolo [4, 3-a] [1, 4] benzodiazopine
m. Ethyl Loflazepate	Ethyl-7-chloro-5-(o-fluorophenyl)-2, 3-dihydro-2-oxo-1H, 4-benzodia-zepine-3-carboxylate
n. Fludiazepam	7-chloro-5-(o- fluorophenyl)-1, 3-dihydro-1-methyl-2H-1, 4-benzodiazepine-2-one
o. Flurazepam	7-chloro-1-[2-diethylamine) ethyl]-5-(ofluorophenyl)-1, 3-dihydro-2H-1, 4-benzodiazepin-2-one
p. Helazepam	7-chloro-1, 3-dihydro-5-phenyl-1-(2, 2, 2-trifluoroethyl)-2H-1, 4-benzo-diazepin-2- one
q. Haloxazolam	10-bromo-11b-tetrahy-drooxazolo [3,2-d]-benzodiazepine-6 [5H]-one
r. Ketazolam	11-chloro-8, 12b dihydro-2, 8-dimethyl-12b-phenyl-4H [1, 3]-oxazine-[3. 2-d] [1, 4] benzodiazepine-4, 7 (6H)- dione
s. Loprazolam	6-(chlorophenyl)-2, 4-dihydro-2-[4-methyl-1-piperra-Zinyl) methylene]-8-nitro-1H-imidazo [1, 2-a) [1,4] benzodia-zepin-1-one
t. Lorazepam	7-chloro-5-(o- chlorophenyl)-1, 3-dihydro-3-hydroxy-2H-1, 4-benzodiazepine-2-one
u. Lormetazepam	7-chloro-5-(o- chlorophenyl)-1,3-dihydro-3-hydroxy-1-methyl-2H-1, 4-benzdiazepin-2-one
v. Medazepam	7-chloro-2, 3-dihydro-1-methyl-5-phenyl-1H-1, 4-benzodiazepine
w. Nimetazepam	1,3-dihydro-1-methyl-7-nitro-5-phenyl-2H-2, 4-benzodiazepin-2-one
x. Nordazepam	7-chloro-1,3-dihydro 5-phenyl-2H-1, 4-benzodiazepin-2-one
y. Oxazepam	7-chloro-1, 3-dthydro-3-hydroxy-5-phenyl-2H-1, 4-benzdiazepin-2-one
z. Oxazolam	10-chloro-2, 3, 7, 11b-tetrahydro-2-methyl-11b-phenylloxazolo [3, 2-

		d] [1, 4] benzodiazepin-6 (5H)-one
aa.	Pinazepam	7-chloro-1, 3-dihydro-5-phenyl-1(2-propynyl)-2H-1, 4-benzodiazepin-2-one.
ab.	Prazepam	7-chloro-1, (cyclopropyl-methyl)-1,3-dihydro-5-phenyl-1 (2-propynyl)-2H-1, 4-benzodiazepin-2-one
ac.	Temazepam	7-chlaro-1, 3-dihydro 3-hydroxy-1-methyl-5-phenyl-2H 1, 4-benzodiazepin-2-one
ad.	Triazolam	8-chloro-6-(o-chlorophenyl)-1-methyl-4H-S- triazolo [4,3-a] [1,4] Benzodiazepine
ae.	Tetrazepam	7-chloro-5-(cylohexen-1-yl)-1, 3-dihydro-1-methyl-2H 1, 4-benzodiazepin -2 one

Provided, however, that the benzodiazepine substance is not in association with (a) another benzodiazepine substance, (b) a regulated drug, (c) a prohibited drug, (d) a psychoactive drug not under international control with known abuse potential.

SECTION 3. All exempted benzodiazepine 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 representatives if situated outside of the Metro Manila Area.

2. Bureau of Food and Drugs — Benzodiazepine 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 BFD as Importer, Manufacturer, Producer, Compounder, Distributor at wholesale or retail, shall maintain a true and accurate record for any benzodiazepine drug preparations, 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 D.D. /or drug benzodiazepine preparations received shall be made on the date of receipt of the drugs or preparation. The following data shall appear in the record book:

1. <u>Manufacturer, Compounder, Producer</u>

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 preparation imported.

b. Name and quantity of raw material finished drug product imported.

c. Number of import permit and the date issued by 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 benzodiazepine 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.