

LEGAL NOTICE No. 49

REPUBLIC OF TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ACT, CHAP. 30:01

REGULATIONS

MADE BY THE MINISTER UNDER SECTION 25 OF THE FOOD AND DRUGS ACT

THE FOOD AND DRUGS (AMENDMENT) REGULATIONS, 1987

1. These Regulations may be cited as the Food and Drugs (Amendment) Regulations, 1987. Citation

2. The Second Schedule to the Food and Drugs Regulations is amended— Division 2 of
Regulations
amended
(a) by repealing and replacing paragraph 2 of Division 2 as follows—

“2. For the purposes of this Division the following substances and their salts are classified as controlled drugs—

- (a) Amphetamine
- (b) Dexamphetamine
- (c) Mecloqualone
- (d) Methamphetamine
- (e) Methaqualone
- (f) Methylphenidate
- (g) Phencyclidine
- (h) Phenmetrazine
- (i) Amobarbital
- (j) Cyclobarbital
- (k) Glutethimide
- (l) Pentazocine
- (m) Pentobarbital
- (n) Secobarbital
- (o) Alprazolam
- (p) Amfepramone
- (q) Barbital
- (r) Benzphetamine
- (s) Bromazepam
- (t) Camazepam
- (u) Chlordiazepoxide
- (v) Clobazam
- (w) Clonazepam
- (x) Clorazepate
- (y) Clotiazepam
- (z) Cloxazolam

- (aa) Delorazepam
- (bb) Diazepam
- (cc) Estazolam
- (dd) Ethchlorvynol
- (ee) Ethinamate
- (ff) Ethyl loflazepate
- (gg) Fludiazepam
- (hh) Flunitrazepam
- (ii) Flurazepam
- (jj) Halazepam
- (kk) Haloxazolam
- (ll) Ketazolam
- (mm) Lefetamine
- (nn) Loprazolam
- (oo) Lorazepam
- (pp) Lormetazepam
- (qq) Mazindol
- (rr) Medazepam
- (ss) Meprobamate
- (tt) Methyphenobarbital
- (uu) Methyprylon
- (vv) Nimetazepam
- (ww) Nitrazepam
- (xx) Nordazepam
- (yy) Oxazepam
- (zz) Oxazolam
- (aaa) Phendimetrazine
- (bbb) Phenobarbital
- (ccc) Phentermine
- (ddd) Pinazepam
- (eee) Pipradrol
- (fff) Prazepam
- (ggg) Temazepam
- (hhh) Tetrazepam
- (iii) Triazolam.”;

(b) by repealing and replacing paragraphs 2 and 5 of Division 3, as follows—

“2. (1) No person shall import, sell or advertise for sale a new drug unless—

- (a) the manufacturer or importer has filed with the Minister in duplicate, a new drug submission in Form C in the Third Schedule in respect

of that drug, and paid to the Comptroller of Accounts the non-refundable registration fee specified in Form E in the Third Schedule for the registration of the new drug; and

- (b) the Minister has issued to the manufacturer or importer, a notice of approval in respect of the new drug, and the approval has not been withdrawn.

(2) Every new drug submission filed by a manufacturer or importer with the Minister, shall have attached to it the receipt issued by the Comptroller of Accounts in respect of payment of the registration fee.

(3) This regulation shall not apply to a person who has been granted permission by the Minister in accordance with paragraph 12 of this Division.

5. (1) Notwithstanding paragraph 2 but subject to paragraph 12, no person shall import, sell or advertise for sale a new drug in respect of which notice of approval has been given if any material change has been made in—

- (a) the conditions of use of the drug including the indications for use and the route of administration,
- (b) its labels,
- (c) its packaging,
- (d) the pharmaceutical form in which it is sold,
- (e) its dosage, or
- (f) its strength, purity or quality,

which is significantly different from the information contained in the new drug submission filed in respect thereof unless—

- (a) the manufacturer or importer has filed with the Minister in duplicate a supplement to the new drug submission in Form D in the Third Schedule in respect of a variation of formula, a new claim to that drug, or a new packaging and paid to the Comptroller of Accounts the non-refundable registration fee specified in Form E in the Third Schedule for the registration thereof; and
- (b) the Minister has issued to the manufacturer or importer a notice of approval in respect of a variation of formula or a new claim to that drug or a new packaging and the approval has not been withdrawn.

(2) Every supplement to a new drug submission filed by a manufacturer or importer with the Minister shall have attached to it the receipt issued by the Comptroller of Accounts in respect of the payment of the registration fee.”;

(c) by inserting immediately after Form B in the Third Schedule the following new Forms—

FORM C

(Regulation 2)

NEW DRUG SUBMISSION

To: Chief Chemist/Director of Food and Drugs,
Chemistry/Food and Drugs Division,
115, Frederick Street,
Port-of-Spain,
Trinidad.

1. I/We*
(State Name of Importer|Manufacturer|Agent in Trinidad and Tobago)*
of
(State Address)

hereby make a New Drug Submission for.....
.....
(State Name of New Drug)

having its proper name and trade name.....
.....
(State Proper Name and Trade Name of Drug)

*Delete as applicable

and with the following ingredients—

<i>Chemical Name of Ingredient</i>	<i>Quantity Weight or per cent</i>	<i>Chemical Name of Ingredient</i>	<i>Quantity Weight or per cent</i>
1.	11.
2.	12.
3.	13.
4.	14.
5.	15.
6.	16.
7.	17.
8.	18.
9.	19.
10.	20.

2. I/We* undertake to inform you of any subsequent material changes made in the conditions of use, labelling, packaging, pharmaceutical form, dosage or strength, purity or quality of the New Drug.

3. I/We* undertake to inform you of any report of unexpected side effects, injury, toxicity, sensitivity or other adverse reactions in any way associated with the clinical uses, studies, investigations and tests in respect of the New Drug.

4. I/We* attach in DUPLICATE the information contained in the Note hereunder—

*Delete as applicable

NOTE

- (a) A description of the New Drug (including the manufacturer thereof) and a declaration of the proper name if any and the trade name.
- (b) A statement of all ingredients, route of administration, dosage, claims to be made for the new drug and the contra-indications and side effects of the drug (if known), and a description of the pharmaceutical form in which it is to be sold.
- (c) Details of tests applied to control potency purity and safety of the new drug.
- (d) Labels and samples of the new drug in its finished pharmaceutical form (Samples for submission may be imported, provided a permit is issued by the Director. If a submission is not made within one hundred and twenty (120) days of import, the samples shall be surrendered to the Director).
- (e) Samples of the components of the new drug if required by the Director. (Samples for submission may be imported provided a permit is issued by the Director. If a submission is not made within one hundred and twenty (120) days of import, the samples shall be surrendered to the Director).
- (f) Certificates as specified in paragraph 3(f) (i)-(v) of Division 3 of the Second Schedule of the Regulations.

CANADA UNITED KINGDOM F.D.A. U.S.A. AUSTRALIA

- (g) Certificates from State or City authorities in the United States respecting the sale and conditions of sale in the United States.
- (h) Certificates in the English Language from authorities recognised as having adequate experience and facilities for assessing the safety of new drugs by the Ministries of Health in—

BELGIUM NETHERLANDS SWITZERLAND

FRANCE SWEDEN DENMARK

- (i) Certificates (with English translation) from other authorities in.....

- (j) Detailed reports of animal tests

and/or

Clinical trials to establish the safety of the new drug.
(Detailed reports may be required by the Drug Advisory Committee if certificates are not available from countries named in paragraphs (f) (g) and (h) of this Note).

.....
*Importer/Manufacturer/Agent in
Trinidad and Tobago**

Date.....19.....

*Delete as applicable

FORM D

(Regulation 5)

SUPPLEMENT TO NEW DRUG SUBMISSION

VARIATION OF FORMULA/NEW CLAIM/NEW PACKAGING*

To: Chief Chemist/Director of Food and Drugs,
Chemistry/Food and Drugs Division,
115, Frederick Street,
Port-of-Spain.

I/We* (State Name of Importer/Manufacturer/Agent in Trinidad and Tobago)*

of (State Address)

hereby make a supplementary New Drug Submission in DUPLICATE for the drug

(State Name of New Drug)

in support of the changes indicated below:

- (a) Name/Mark (b) Formulation (c) Conditions of Use (d) Indications for Use (e) Dosage (f) Route of administration (g) Packaging (h) Label (i) Pharmaceutical form (j) Any other change

Description of other changes which made the drug different from that in the original New Drug Submission:

The following information is attached in support of the changes indicated:

- (a) Samples of the drug with the changes indicated above in the finished pharmaceutical form in which it is to be sold. (b) Samples of components of the new drug as the Director may require. (c) Certificate of compliance issued to the manufacturer by the authorized Government Agency in the country of origin. (d) Technical literature, describing the changes made to the new drug including tests and results of tests supporting that the quality, potency, efficacy and safety of the new drug are not affected. (e) Any other information that may be required by the Director.

I/We* undertake to inform you of any report of unexpected side effects, toxicity, sensitivity or other adverse reactions associated with the clinical uses, studies, investigations and tests in respect of the new drug or resulting from the material changes made.

Date Importer/Manufacturer/Agent in Trinidad and Tobago*

*Delete as applicable

FORM E

(Regulations 2 and 5)

REGISTRATION FEES

New Drug \$750.00

Variation of Formula New Claim or New Packaging \$100.00

Made this 4th day of February, 1987.

M. HECTOR
Acting Minister of Health, Welfare and
Status of Women