

LEGAL NOTICE NO. 61

REPUBLIC OF TRINIDAD AND TOBAGO

THE FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister of Health on the advice of the Drug Advisory Committee, in accordance with paragraph 7, Division 3 of the Second Schedule of the Food and Drugs Act.

The Minister of Health signifies his approval in respect of the following new drugs listed hereunder:

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
MetroLotion Topical Lotion 0.75%	D.P.T. Laboratories Ltd. U.S.A. for Galderma Laboratories Inc.	U.S.A.	Third Schedule
Cetaphil Antibacterial Bar	Bradford Original Soap Works U.S.A. for Galderma Laboratories Inc.	do.	Freely
OXY 2.5 Vanishing Lotion	SmithKline Beecham	Costa Rica S.A.	do.
OXY 5% Vanishing Lotion (Change of Source, Packaging and Label)	do.	do.	do.
OXY 5% Tinted Lotion (Change of Source, Packaging and Label)	do.	do.	do.
OXY 10 Tinted Lotion (Change of Source, Packaging and Label)	do.	do.	do.
OXY 10 Vanishing Maximum Strength Lotion (Change of Source, Packaging and Label)	do.	do.	do.
KYTRIL Paediatric Liquid	SmithKline Beecham Pharmaceuticals	England	Third Schedule
Infanrix IPV Hib Suspension Injection	SmithKline Beecham Biologicals s.a.	Belgium	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
MYLANTA Supreme Antacid Liquid Smooth Mint Crème	Johnson & Johnson MERCK, Consumer Pharmaceuticals Co.	U.S.A.	Freely
Gonal-F 75 Injection	Laboratories Serono S.A.	Switzerland	Third Schedule
Gonal-F 150 Injection	do.	do.	do.
I.L.XB ₁₂ Caplets	Hi-Tech Pharmacal U.S.A. for Kenwood Laboratories	U.S.A.	Freely
I.L.B ₁₂ Elixir	do.	do.	do.
DEPAKENE Capsules USP 250 mg	Abbott Laboratories	do.	Third Schedule
DEPAKOTE Tablets 125 mg	do.	do.	do.
DEPAKOTE Tablets 250 mg	do.	do.	do.
DEPAKOTE Tablets 500 mg	do.	do.	do.
Tinset Suspension 2.5 mg/ml	Janssen Farmaceutica S.A. de C.V.	Mexico	do.
Tinset Tablets 30 mg	do.	do.	do.
Pariet Tablets 20 mg	Eisai Co. Limited Japan for Janssen Farmaceutica S.A. de C.V.	do.	do.
Natrilix SR Tablets (Change of Packaging & Label)	Les Laboratories Servier	France	do.
Risperdal Oral Solution 1 mg/ml	Jenssen Pharmaceutica	Belgium	do.
Zinc Lozenges with Vitamin C	C.E. Jamieson & Company Limited	Canada	Freely
Zinc Lozenges with Vitamin C Fortified with Echinacea	Jamieson Laboratories	do.	do.
Apo-Ketorolac Tablets 10 mg	Apotex Inc.	do.	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Apo-Clonazepam Tablets USP 0.5 mg	Apotex Inc.	Canada	Controlled Drug
Apo-Clonazepam Tablets USP 2 mg	do.	do.	do.
Apo-Bromazepam Tablets 1.5 mg	do.	do.	do.
Apo-Bromazepam Tablets 3 mg	do.	do.	do.
Apo-Bromazepam Tablets 6 mg	do.	do.	do.
CombiPatch 50/140 Transdermal System	Noven Pharmaceuticals Inc. U.S.A. for Rhone-Poulenc Rorer Pharmaceuticals Inc.	U.S.A.	Third Schedule
CombiPatch 50/250 Transdermal System	do.	do.	do.
Tracrium Injection 50 mg in 5 ml	The Wellcome Foundation Ltd.	England	do.
Raxar Tablets 400 mg	Glaxo Wellcome Operations	UK	do.
Raxar Tablets 600 mg	do.	do.	do.
Effexor XR Extended-Release Capsules 37.5 mg	Wyeth Laboratories Inc.	U.S.A.	do.
Effexor XR Extended-Release Capsules 75 mg	do.	do.	do.
Effexor XR Extended-Release Capsules 150 mg	do.	do.	do.
Tetagam P 1 ml (250 IU) Ampoule	Centeon Pharma GmbH	Germany	do.
Calcium 600 MG+D Tablets	Rexall Sundown Inc. U.S.A. for Sundown Vitamins	U.S.A.	Freely
Sundown E 1000 IU Softgels	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Comtan Tablets 200 mg	Orion Corporation, Finland for Novartis Pharma AG	Switzerland	Third Schedule
Rhincort Aqua 32 micrograms/dose Nasal Spray	Astra	Sweden	do.
Rhincort Aqua 64 micrograms/dose Nasal Spray	do.	do.	do.
Bausch & Lomb Moisture Eyes Drops	Bausch & Lomb Incorporated	U.S.A.	Freely
Paramette Syrup (Change in Formulation)	Wyeth-Ayerst Canada Inc.	Canada	do.
Prostin E2 Vaginal Tablets (Change of Source)	Pharmacia & Upjohn N.V./S.A.	Belgium	Third Schedule
Brufen Cream	Quimica Knoll de Mexico S.A. de C.V.	Mexico	Freely
Tavanic Tablets 250 mg	Hoechst Marion Roussel, S.A.	Guatemala	Third Schedule
Tavanic Tablets 500 mg	do.	do.	do.
Cataflam Drops 1.5 % (Change in Name of Manufacturer)	Novartis Pharma S.A. France for Novartis Pharma AG	Switzerland	do.
Estraderm TTS 50 Transdermal Therapeutic System (Change in Name of Manufacturer)	Novartis Pharma AG	do.	do.
Melleril Tablets 100 mg (Change in Name of Manufacturer)	do.	do.	do.
Leponex Tablets 100 mg (Change in Name of Manufacturer)	do.	do.	do.
Zaditen Syrup 1 mg/5 ml (Change in Name of Manufacturer)	do.	do.	do.
Estraderm TTS 100 Transdermal Therapeutic System (Change in Name of Manufacturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Foradil Capsules (Change in Name of Manufacturer)	Novartis Pharma AG	Switzerland	Third Schedule
Tegretol Syrup 2% (Change in Name of Manufacturer)	do.	do.	do.
Zaditen Tablets 1 mg (Change in Name of Manufacturer)	do.	do.	do.
Anafranil 10 Tablets 10 mg (Change in Name of Manufacturer)	do.	do.	do.
Glyvenol 400 Capsules 400 mg (Change in Name of Manufacturer)	do.	do.	do.
Methergin Tablets 0.125 mg (Change in Name of Manufacturer)	do.	do.	do.
Sandomigran Tablets (Change in Name of Manufacturer)	do.	do.	do.
Cataflam Disposable Tablets 46.5 mg (Change in Name of Manufacturer)	Novartis Farmaceutica S.A. de C.V.	Mexico	do.
Estracomb TTS Transdermal Therapeutic Systems (Change in Name of Manufacturer)	Novartis Pharma AG	Switzerland	do.
Plavix Tablets 75 mg	Sanofi Winthrop Industrie France for Sanofi Pharmaceuticals Inc.	U.S.A.	do.
Calciumfolinat doEbewedo 50 mg Solution for Injection	EBEWE Arzneimittel Ges.m.b.H.	Austria	do.
5-Fluorouracil doEbewedo 250 mg Solution for Infusion	do.	do.	do.
Cisplatin doEbewedo 50 mg Solution for Infusion	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Methotrexat doEbewedo Tablets 2.5 mg	EBEWE Arzneimittel Ges.m.b.H.	Austria	Third Schedule
Engystol Tablets	Heel	Germany	do.
Gripp-Heel Tablets	do.	do.	do.
Hepeel Tablets	do.	do.	do.
Lymphomyosot Tablets	do.	do.	do.
Oculoheel Eye Drops	do.	do.	do.
A. Vogel Prostan Softgel Capsules 460 mg	Bioforce AG Switzerland for Bioforce U.S.A.	U.S.A.	Freely
A. Vogel Ginkgoforce Liquid	do.	do.	do.
Arouse Capsules	Health 2000 Inc.	Canada	do.
Proanthens Bio- Complex Tablets 50 mg	Life Plus International	U.S.A.	Third Schedule
Protx 111 Tablets	do.	do.	Freely
Vita-E-Plus 400 Capsules	do.	do.	do.
TVM-49 Tablets	do.	do.	Third Schedule
Cardio-Chelex Tablets	do.	do.	Freely
Vita-C-1000 Tablets	do.	do.	do.
Colodyne Powder	do.	do.	do.
AminoLyze Liquid	do.	do.	Third Schedule
Gammagard S/D Immune Globulin Intravenous (Human) 5 g	Baxter Healthcare Corporation	do.	do.
Gravinate Liquid (Change of Name— formerly Gravomine Syrup)	Carlisle Laboratories Ltd.	Barbados	Freely
Pepto-Bismol Liquid (New Label)	Procter & Gamble	U.S.A.	do.

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<u>VETERINARY PRODUCTS</u>			
Rimadyl Caplets 25 mg	Pfizer Animal Health	U.S.A.	To Veterinarians or by Veterinary Prescription only
Rimadyl Caplets 75 mg	do.	do.	do.
Rimadyl Caplets 100 mg	do.	do.	do.
Mecadox Premix 10%	Pfizer Animal Health Pfizer S.A.	Venezuela	To Feed Manufacturers only
Heartgard Plus Chewables 68 mcg ivermectin and 57 mg pyrantel	Merck AgVet Division Merck & Co. Inc.	U.S.A.	To Veterinarians or by Veterinary Prescription only
Heartgard Plus Chewables 136 mcg ivermectin and 114 mg pyrantel	do.	do.	do.
Heartgard Plus Chewables 272 mcg ivermectin and 227 mg pyrantel	do.	do.	do.

Dated this 17th day of February, 2000.

H. RAFEEQ
Minister of Health