

LEGAL NOTICE NO. 237

REPUBLIC OF TRINIDAD AND TOBAGO

FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister on the recommendation of the Drug Advisory Committee in accordance with clause 7, Division 3 of the Second Schedule of the Food and Drugs Regulations.

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

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Eloxatin 50 mg Sterile Lyophilized Powder for Injection	Manufactured by Ben Venue Laboratories for Sanofi- Synthelabo Inc. USA	USA	Third Schedule
Eloxatin 100 mg Sterile Lyophilized Powder for Injection	do.	do.	do.
Avastin Injection 100 mg/4 ml	Manufactured by Genentech Inc. for F. Hoffmann- La Roche Ltd. Switzerland	do.	do.
Avastin Injection 400 mg/16 ml	do.	do.	do.
Velcade for Injection 3.5 mg	Ben Venue Laboratories Inc.	do.	do.
Sufrexal P Gel	Janssen Cilag, S.A. de C.V.	Mexico	do.
Amoebriz Suspension 60/10 mg —Cherry Flavour	do.	do.	Freely
Amoebriz Suspension 60/20 mg —Banana Flavour	do.	do.	do.
Cebión Vitamin C Chewable Tablets 500 mg—Orange	Merck, S.A.	Colombia	do.
Cebión Vitamin C Chewable Tablets 500 mg—Lemon	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Cebión Vitamin C Chewable Tablets 500 mg—Tangerine	Merck, S.A.	Colombia	Freely
Cebión Vitamin C Chewable Tablets 500 mg—Passion Fruit	do.	do.	do.
Cebión Vitamin C Chewable Tablets 500 mg—Strawberry	do.	do.	do.
Vasobion Film-Coated Tablets 1 mg	Merck, S.A. de C.V.	Mexico	do.
Vasobion Film-Coated Tablets 2.5 mg	do.	do.	do.
Vasobion Film-Coated Tablets 5 mg	do.	do.	do.
Lazid Film-Coated Tablets	Emcure Pharmaceuticals Ltd.	India	Third Schedule
Nevir Tablets	do.	do.	do.
Emtri Tablets	do.	do.	do.
Emtri—40 Tablets	do.	do.	do.
Asomex—2.5 Tablets	do.	do.	do.
Asomex—5 Tablets	do.	do.	do.
Para-Denk 500 Tablets	Manufactured by bene- Arzneimittel GmbH for E. Denk OHG Germany	Germany	Freely
Para-Denk 4% Syrup	do.	do.	do.
Denkalgin pain relief Tablets	E. Denk OHG	do.	do.
Captopril + HCT Denk 50/25 Tablets	do.	do.	Third Schedule
Vera-Denk 240 Retard Tablets	do.	do.	do.
CiproDenk 500 Film-Coated Tablets	Manufactured by C.P.M. Contract Pharma GmbH & Co KG for E. Denk OHG Germany	do.	do.
Furo-Denk 40 Tablets	Manufactured by Wülfing Pharma GmbH for E. Denk OHG Germany	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Panadol Ultra Caplets	GlaxoSmithKline Panamá, S.A.	Panama	Freely
Bonefos Tablets 800 mg	Schering Oy	Finland	Third Schedule
Children's Tylenol Meltaways Tablets —Wacky Watermelon Flavor (Ages 2–6)	McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC, INC.	USA	Freely
Children's Tylenol Meltaways Tablets —Bubblegum Burst Flavor (Ages 2–6)	do.	do.	do.
Alimta Powder for Concentrate for Solution for Infusion 500 mg	Lilly France S.A.S.	France	Third Schedule
Xigris Powder for Solution for Infusion—5 mg	Lilly Pharma Fertigung und Distribution GmbH and Co. KG	Germany	do.
Xigris Powder for Solution for Infusion—20 mg	do.	do.	do.
Zyprexa Zydis Orodispersible Tablets 5 mg	Eli Lilly and Company Limited	England	do.
Zyprexa Zydis Orodispersible Tablets 10 mg	do.	do.	do.
QuikClot Adsorbent Hemostatic Agent/Device	Z-Medica	USA	Freely (For use by Emergency Medical Technicians only)
Infants' Advil Concentrated Drops —White Grape Flavored	Wyeth Consumer Healthcare	do.	Freely
Fastorik Plus Tablets	Plethico Pharmaceuticals Limited	India	do.
Fastorik Plus Suspension	do.	do.	do.
Dropstar Sterile Ophthalmic Solution 0.4%	Laboratorios Poen S.A.C.I.F.I.	Argentina	do.
Brimopress Sterile Ophthalmic Solution 0.2%	do.	do.	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Glaucoprost Sterile Ophthalmic Solution 0.004%	Laboratorios Poen S.A.C.I.F.I	Argentina	Third Schedule
Quidex Sterile Ophthalmic Suspension	do.	do.	do.
Glaucotensil D Sterile Ophthalmic Solution 2%	do.	do.	do.
Detrusitol SR Prolonged Released Capsules 2 mg	Manufactured by International Processing Corp. USA Packaged by Pharmacia Italia S.p.A.	Italy	do.
Detrusitol SR Prolonged Released Capsules 4 mg	do.	do.	do.
Hemotin-EPO 6000 Recombinant Human Erythropoietin for Injection	Nanjing Huaxin Bio- Pharmaceutical Co. Ltd.	China	do.
Kivexa Film-Coated Tablets—Bottle	Glaxo Operations UK Limited	United Kingdom	do.
Kivexa Film-Coated Tablets—Blister Pack	do.	do.	do.
Blue Star Ointment	Distributed by G.H.C. Group L.L.C. USA (Product of USA)	USA	Freely
Phillips Laxative Gel Caps	Made by Cardinal Health Argentina Argentina Packed by GlaxoSmithKline Argentina S.A.	Argentina	do.
Andrews Triple Action Sparkling Salts —Sachets (Aspirin Free)	GlaxoSmithKline Costa Rica, S.A.	Costa Rica	do.
Stimuloton Film-Coated Tablets 100 mg	Egis Pharmaceuticals Ltd.	Hungary	Third Schedule
Mycosyst Capsules 100 mg	Gedeon Richter Ltd.	do.	do.
Mycosyst Capsules 200 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Atenolol Tablets 100 mg	Manufactured by Genpharm Inc. Distributed by Merck S.A. Guatemala	Canada	Third Schedule
Valproic Acid Capsules 250 mg	Manufactured by Banner Pharmacaps Ltd. for Genpharm Inc. Canada Distributed by Merck S.A. Guatemala	do.	do.
Verapamil Hydrochloride Extended Release Tablets 120 mg	Manufactured by Pacific Pharmaceuticals Ltd. Distributed by Merck S.A. Guatemala	New Zealand	do.
Para-Life Soluble Tablets	Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	India	Freely
Ketoconazole 200 mg Tablets	do.	do.	Third Schedule
Ketoconazole 2% Cream	do.	do.	do.
Loratadine Syrup	do.	do.	do.
Ibuprofen 600 mg Film-Coated Tablets	do.	do.	do.
Ibuprofen Suspension	do.	do.	Freely
Captopril 25 mg Tablets	do.	do.	Third Schedule
Captopril 50 mg Tablets	do.	do.	do.
Microbar-HD Fruit Flavoured Powder	Eskay Fine Chemicals	do.	do.
Cytarine Injection 500 mg (Change of Name of Manufacturer and Change of Artwork Design)	Dabur Pharma Ltd.	do.	do.
Cytarine Injection 1 g (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Fivoflu Injection 250 mg (Change of Name of Manufacturer and Change of Artwork Design)	Dabur Pharma Ltd.	India	Third Schedule
Fivoflu Injection 500 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Kemoplat Injection 10 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Kemoplat Injection 50 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Vinelbine Injection 10 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Vinelbine Injection 50 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Topotel Injection Concentrate 4 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Kemocarb Injection 450 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Zexate Injection 50 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Diovol Regular Strength Suspension—Fresh Mint (Change of Name of Manufacturer and Change of Formulation)	Church & Dwight Canada Corp.	Canada	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Diovol Plus Suspension —Fresh Mint (Change of Name of Manufacturer and Change of Formulation)	Church & Dwight Canada Corp.	Canada	Freely
Diovol Plus Suspension —Tropical Fruit (Change of Name of Manufacturer and Change of Formulation)	do.	do.	do.
Diovol Plus AF Suspension —Fresh Mint (Change of Name of Manufacturer and Change of Formulation)	do.	do.	do.
Diovol Extra Strength Suspension—Fresh Mint (Change of Name of Manufacturer and Change of Formulation)	do.	do.	do.
Ultra Strength Ovol Softgels 180 mg (Change of Name of Manufacturer)	do.	do.	do.
Maltevol—12 Liquid (Change of Name of Manufacturer)	do.	do.	do.
Rub A535 Ice Gel 4% w/w (Change of Name of Manufacturer)	do.	do.	do.
Zovirax 250 mg Freeze- dried powder for Injection (Change of Name of Manufacturer and Additional Source)	GlaxoSmithKline S.p.A.	Italy	Third Schedule
Twinrix Suspension for Injection-Prefilled Syringe (Change of Presentation)	GlaxoSmithKline Biologicals s.a.	Belgium	do.
Tylenol 8 Hour Extended Release Caplets 650 mg (Change of Name of Product)	McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL PPC, INC.	USA	Freely
Children's Tylenol Oral Suspension —Cherry Blast Flavor (Change of Name of Product)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Exelon Capsules 1.5 mg (Change of Source)	Manufactured by Novartis Farmacéutica S.A. for Novartis Pharma AG Switzerland	Spain	Third Schedule
Exelon Capsules 3 mg (Change of Source)	do.	do.	do.
Exelon Capsules 4.5 mg (Change of Source)	do.	do.	do.
Exelon Capsules 6 mg (Change of Source)	do.	do.	do.
Urobacid Film-Coated Tablets 400 mg (Change of Name of Manufacturer and Change of Logo)	Manufactured by Merck KGaA & Co. for Sandoz GmbH Austria	Austria	do.
Exoderil Cream (Change of Name of Manufacturer and Change of Logo)	do.	do.	do.
Exoderil Solution (Change of Name of Manufacturer and Change of Logo)	Manufactured by Globopharm pharmazeut. Prod.-u. Handels GmbH for Sandoz GmbH Austria	do.	do.
Hapilux Capsules 20 mg (Change of Name of Manufacturer, Change of Source and Change of Logo)	Manufactured by Novartis South Africa (Pty) Ltd. for Sandoz GmbH Austria	South Africa	do.
Thiopental Powder for Injection 0.5 g (Change of Name of Manufacturer and Change of Logo)	Sandoz GmbH	Austria	Controlled Drug
Thiopental Powder for Injection 1 g (Change of Name of Manufacturer and Change of Logo)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Children's Tylenol Meltaways Tablets —Grape Punch Flavor (Ages 2–6) (Change of Name of Product)	McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL- PPC, INC.	USA	Freely
Mephaquin Lactabs (Change of Formulation)	Mepha Ltd.	Switzerland	Third Schedule
Pulmozyme Solution for Inhalation 2500U (2.5 mg) 2.5 ml (New Indication)	Manufactured by Genentech Inc. for F. Hoffmann- La Roche Ltd. Switzerland	USA	do.
Eurax Cream (Change of Artwork Design and Change in Specifications)	Novartis Consumer Health SA	Switzerland	do.
Eurax Lotion 10% (Change of Artwork Design and Change in Specifications)	do.	do.	do.
Pegasys Solution for Injection 135 mcg/0.5 ml —Pre-Filled Syringes (New Indication)	F. Hoffmann- La Roche Ltd.	do.	do.
Pegasys Solution for Injection 180 mcg/0.5 ml —Pre-Filled Syringes (New Indication)	do.	do.	do.
Dormicum Solution for Injection 5 mg/ 5 ml (Change of Name of Manufacturer)	Made under licence from F. Hoffmann- La Roche Ltd. Switzerland by Cenexi SAS	France	Controlled Drug
Dormicum Solution for Injection 15 mg/ 3 ml (Change of Name of Manufacturer)	do.	do.	do.
Valium Injectable Solution 10 mg/2 ml (Change of Name of Manufacturer)	do.	do.	do.
Konakion MM Injectable Solution 10 mg/ml (Change of Name of Manufacturer)	do.	do.	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Diovol Regular Strength Chewable Tablets—Fresh Mint (Change of Name of Manufacturer)	Church & Dwight Canada Corp.	Canada	Freely
Diovol Filmkote Caplets (Change of Name of Manufacturer)	do.	do.	do.
Diovol Plus Chewable Tablets—Fresh Mint (Change of Name of Manufacturer)	do.	do.	do.
Diovol Plus Chewable Tablets—Tropical Fruit (Change of Name of Manufacturer)	do.	do.	do.
Diovol Plus AF Chewable Tablets—Fresh Mint (Change of Name of Manufacturer)	do.	do.	do.
Regular Strength Ovol Chewable Tablets 80 mg—Mint Flavour (Change of Name of Manufacturer)	do.	do.	do.
Ultra Strength Ovol Chewable Tablets 180 mg—Cherry Flavour (Change of Name of Manufacturer)	do.	do.	do.
Gravol Softgel Capsules 50 mg (Change of Name of Manufacturer)	do.	do.	do.
Rub. A535 Dual Action Cream (Change of Name of Manufacturer)	do.	do.	do.
Clexane Injectable Solution 20 mg/0.2 mL (Change of Name of Manufacturer and Additional Source)	Aventis Pharma Spécialitiés	France	Third Schedule
Clexane Injectable Solution 40 mg/0.4 mL (Change of Name of Manufacturer and Additional Source)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Clexane Injectable Solution 60 mg/0.6 mL (Change of Name of Manufacturer and Additional Source)	Aventis Pharma Spécialitiés	France	Third Schedule
Clexane Injectable Solution 80 mg/0.8 mL (Change of Name of Manufacturer and Additional Source)	do.	do.	do.
Trental Injectable Solution for Intravenous Infusion 20 mg/mL (Change of Artwork Design)	Manufactured by Aventis Pharma, S.A. de C.V. Mexico Packed by Aventis Pharma, S.A.	Guatemala	do.
Maalox Plus Antacid Chewable Tablets —Mint Flavor (Change of Artwork Design)	Aventis Pharma S.A. de C.V.	Mexico	Freely
Avelox Film-Coated Tablets 400 mg (Change of Artwork Design)	Made by Bayer AG Germany for Bayer de Mexico, S.A. de C.V. Mexico Packaged by Bayer, S.A.	El Salvador	Third Schedule
Avelox I.V. Solution for Intravenous Infusion (Change of Artwork Design)	do.	do.	do.
Canesten 3 Vaginal Tablets 0.2 g with Applicator (Change of Artwork Design)	Bayer, S.A.	do.	do.
VETERINARY PRODUCTS			
West Nile—Innovator Vaccine	Fort Dodge Animal Health	USA	(To Veterinarians or by Veterinary Prescription Only)

Dated this 26th day of August, 2005.

**J. RAHAEL**  
*Minister of Health*