

LEGAL NOTICE No. 29

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 paragraph 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>
Tylenol Extra Strength Rapid Release Gels Gelecaps 500 mg	Distributed by McNeil Consumer & Specialty Pharmaceuticals Division of McNeil-PPC Inc. USA (Product of USA)	USA	Freely
DDD Medicated Lotion	DDD Limited	England	do.
DDD Medicated Cream	do.	do.	do.
Lyrica Hard Capsules 25 mg	Pfizer GmbH Arzneimittelwerk	Germany	Third Schedule
Lyrica Hard Capsules 50 mg	do.	do.	do.
Lyrica Hard Capsules 75 mg	do.	do.	do.
Lyrica Hard Capsules 100 mg	do.	do.	do.
Lyrica Hard Capsules 150 mg	do.	do.	do.
Lyrica Hard Capsules 200 mg	do.	do.	do.
Lyrica Hard Capsules 300 mg	do.	do.	do.

*Approval in Respect of New Drugs*

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Parlazin Film-Coated Tablets 10 mg	Egis Pharmaceuticals Ltd.	Hungary	Third Schedule
Parlazin Oral Drops Solution	do.	do.	do.
Talliton Tablets 6.25 mg	do.	do.	do.
Talliton Tablets 12.5 mg	do.	do.	do.
Talliton Tablets 25 mg	do.	do.	do.
Ferriprox Film-Coated Tablets 500 mg	Apotex Inc.	Canada	Third Schedule (For use by Specialist Medical Officers Only)
Cortizone . 10 Quick Shot Spray	Distributed by Pfizer Consumer Healthcare USA (Product of USA)	USA	Third Schedule
Neulastim Solution for injection 6 mg/0.6 ml-Pre-Filled Syringe	F. Hoffmann-La Roche Ltd.	Switzerland	do.
Voltaren Emulgel Dispenser Gel 1%	Novartis Consumer Health, SA	do.	do.
Voltaren Aerosol Solution	Novartis Biocências, S.A.	Brazil	do.
Cymbalta Hard Gastro-Resistant Capsules 30 mg	Lilly S.A.	Spain	do.
Cymbalta Hard Gastro-Resistant Capsules 60 mg	do.	do.	do.
Sandoz-Calcium 400 + D Chewable Tablets-Cherry Flavor	Novartis Farmacéutica S.A. de C. V.	Mexico	Freely
Theraflu Thin Strips Long Acting Cough Medicated Flavored Strips-Cherry Flavor	Distributed by Novartis Consumer Health, Inc. USA (Product of USA)	USA	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Theraflu Thin Strips Multi-Symptom Medicated Flavored Strips-Cherry Flavor	Distributed by Novartis Consumer Health, Inc. USA (Product of USA)	USA	Freely
Triaminic Thin Strips Cough & Runny Nose Grape Flavored Medicated Strips	do.	do.	do.
Olfen Dispersible Tablets	Mepha Ltd.	Switzerland	Third Schedule
Certican Tablets 0.25 mg	Novartis Pharma AG	do.	do.
Certican Tablets 0.75 mg	do.	do.	do.
Certican Tablets 1 mg	do.	do.	do.
Glucosamine Sulphate 1500 mg Granulate Pouches	Sandoz S.A.	Argentina	do.
Emend Capsules	Manufactured by Merck & Co., Inc. USA, Packaged by Merck Sharp & Dohme DE Mexico, S.A. DE C.V.	Mexico	do.
Tylox Solution-Drops 20 g/100 ml	Janssen Cilag, S.A. de C.V.	do.	Freely
Topamax Tablets 50 mg	Made by Janssen Ortho LLC Puerto Rico Packaged by Janssen Cilag, S.A. de C.V.	do.	Third Schedule
Niaspan Prolonged-Released Tablets 500 mg	Manufactured by Kos Pharmaceuticals Inc. USA Packaged by Merck KGaA	Germany	do.
Niaspan Prolonged-Released Tablets 750 mg	do.	do.	do.
Neurobión Film-Coated Tablets	Manufactured by Merck, S.A. de C V for Merck S.A. Guatemala	Mexico	do.

*Approval in Respect of New Drugs*

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Clobetasol Topical Cream 0.05%	Manufactured by Genpharm Inc. Distributed by Merck, S.A. Guatemala	Canada	Third Schedule
Cebión Calcio Vitamin C + Calcium Effervescent Tablets-Orange Flavor	Merck, S.A.	Columbia	Freely
Cebión Tropical Vitamin C Effervescent Tablets 1 g	do.	do.	do.
Cebión Vitamin C Effervescent Tablets 1 g -Orange Flavor	do.	do.	do.
Cebión 2000 Vitamin C Effervescent Tablets 2 g -Orange Flavor	do.	do.	do.
Cytotam-10 Tablets 10 mg	Cipla Ltd.	India	Third Schedule
Cytotam-20 Tablets 20 mg	do.	do.	do.
Baraclude Tablets 0.5 mg	Bristol-Myers Squibb Company	USA	do.
Baraclude Tablets 1.0 mg	do.	do.	do.
Baraclude Oral Solution 0.05 mg/mL	do.	do.	do.
Eye Mo II Eye Drops	GlaxoSmithKline (Tianjin) Co., Ltd.	China	Freely
Uramol 10 Cream	Stiefel Mexicana S.A. de C.V.	Mexico	Third Schedule
Uramol 20 Cream	do.	do.	do.
Uramol 10 Lotion	do.	do.	do.
Fisiogel Cream	Made by Stiefel Laboratories (Ireland), Ltd. Ireland, Packaged by Stiefel Mexicana, S.A. de C.V.	do.	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Zomet Tablets	Intas Pharmaceuticals Ltd.	India	Third Schedule
Calcium-Sandoz 600 + D Coated Tablets	Novartis Biocências, S.A.	Brazil	Freely
Simvastatin 40 mg Film-Coated Tablets	Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	India	Third Schedule
Diclofenac Sodium 50 mg Enteric-Coated Tablets	do.	do.	do.
Omeprazole 20 mg Capsules	do.	do.	do.
Tylenol Allergy Complete Multi-Symptom Geltabs (Change of Name of Product)	Distributed by McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Differin Gel 0.1% (Additional Source)	Manufactured by Galderma Production Canada, Inc. Marketed by Galderma Laboratories, L.P. U.S.A	Canada	Third Schedule
MetroLotion Topical Lotion 0.75% (Additional Source)	do.	do.	do.
Xylocaine Jelly 2% (Change of Name Manufacturer)	Manufactured by Recip Karlskoga AB for AstraZeneca AB Sweden	Sweden	do.
Xylocaine Ointment 5% (Change of Name of Manufacturer)	do.	do.	do.
Emla Cream 5% (Change of Name of Manufacturer)	do.	do.	do.

*Approval in Respect of New Drugs*

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Atacand Tablets 4 mg (Additional Indication)	AstraZeneca AB	Sweden	Third Schedule
Atacand Tablets 8 mg (Additional Indication)	do.	do.	do.
Atacand Tablets 16 mg (Additional Indication)	do.	do.	do.
Tavanic Film-Coated Tablets 500 mg (Additional Presentation)	Manufactured by Usiphar France Packed by Aventis Pharma, S.A.	Guatemala	do.
Streptase 1 500 000 IU Lyophilized Powder for Injectable Solution (Change of Name of Manufacturer)	ZLB Behring GmbH	Germany	do.
Ketozal Shampoo (Additional Indication)	Carlisle Laboratories Limited	Barbados	do.
Zyprexa Coated Tablets 10 mg (Additional Indication)	Eli Lilly and Company Limited	England	do.
Tavegil Tablets 1 mg (Change of Name of Manufacturer)	Manufactured by Novartis Pharma GmbH for Novartis Pharma AG Switzerland	Germany	do.
Voltaren Emulgels 1% (Change of Name of Manufacturer)	Manufactured by Novartis Pharma Produktions GmbH for Novartis Consumer Health SA Switzerland	do.	do.
Mepha Salipax Capsules (Change of Name of Product)	Mepha S.A.	Switzerland	do.
Amilbon Tablets 5 mg (Change of Name of Manufacturer and Change of Artwork Design)	Manufactured by Sandoz Private Limited for Sandoz GmbH Austria	India	do.
Amilbon Tablets 10 mg (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>
Flucss Capsules 150 mg (Change of Name of Manufacturer and Change of Artwork Design)	Manufactured by Novartis (Bangladesh) Limited for Sandoz GmbH Austria	Bangladesh	Third Schedule
Probitor Capsules 20 mg (Change of Name of Manufacturer and Change of Artwork Design)	Manufactured by Laboratorios del Dr. Esteve S.A. for Sandoz GmbH Austria	Spain	do.
Metformin Film-Coated Tablets BP 500 mg (Change of Name of Manufacturer and Change of Formulation)	Alpharma	UK	do.
Singular Tablets 4 mg (Change of Source of Bulk)	Manufactured by Merck Sharp & Dohme Ltd. England Packaged by Merck Sharp & Dohme (I.A.) Corp.	Costa Rica	do.
Timoptic-XE 0.5% Ophthalmic Solution (Change of Source)	Merck Sharp & Dohme	France	do.
Maximum Strength Comtrex Non-Drowsy Cold & Cough Coated Caplets (Change of Formulation and Change of Dosage Regimen)	Distributed by Bristol-Myers Squibb Co. USA (Product of USA)	USA	Freely
Maximum Strength Comtrex Nighttime Cold & Cough Coated Caplets (Change of Formulation and Change of Dosage Regimen)	do.	do.	do.
Maximum Strength Comtrex Day/Night Cold & Cough Coated Caplets (Change of Name of Product, Change of Name of Manufacturer, Change of Formulation and Change of Dosage Regimen)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Copegus Film-Coated Tablets 200 mg (Additional Indication)	Made for F. Hoffmann-La Roche Ltd. Switzerland by Hoffmann-La Roche Inc.	USA	Third Schedule
Nexium Tablets 20 mg (Additional Indication)	AstraZeneca AB	Sweden	do.
Nexium Tablets 40 mg (Additional Indication)	do.	do.	do.
Veterinary Products			
Imidofin Injectable Solution	Revetmex, S.A. DE C.V.	Mexico	To Veterinarians or by Veterinary Prescription Only
Endovet Cream	do.	do.	Freely
Nobloaf Emulsion	Cipla Ltd.	India	do.
Recombitek Equine West Nile Virus Vaccine	Merial, Inc.	USA	To Veterinarians or by Veterinary Prescription Only

Dated this 30th day of November, 2005.

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