

LEGAL NOTICE NO. 299

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>
Apo-Brimonidine Ophthalmic Solution 0.2% w/vè	Apotex Inc.	Canada	Third Schedule
Fosamax Plus Tablets 70 mg/2800 IU	Manufactured by MSD FROSST IBÈRICA, S.A. Spain Packaged by MERCK SHARP & DOHME DE MEXICO, S.A. DE C.V.	Mexico	do.
Imodium A-D Caplets	Distributed by McNeil Consumer & Speciality Pharmaceuticals DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Tamiflu Powder for Oral Suspension 12 mg/ml	Made by F. Hoffmann -La Roche Ltd. Licenser: Gilead Sciences USA	Switzerland	Third Schedule
Regular Strength ex.lax Pills	Novartis Consumer Health, Inc.	USA	Freely
Maximum Strength ex.lax Pills	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Cari Med Antiseptic Mouthwash-Original	Distributed by Cariba International Corp. USA (Product of USA)	USA	Freely
Cari Med Antiseptic Mouthwash-Icy Mint	do.	do.	do.
Cari Med Antiseptic Mouthwash-Citrus Fresh	do.	do.	do.
Exifine Cream 1% w/w	Dr. Reddy's Laboratories Ltd.	India	Third Schedule
Flexbumin 25%, Albumin (Human), USP, 25% Solution	Baxter Healthcare Corporation	USA	do.
Actilyse 50 mg Powder and Solvent for Solution for Injection (Actilyse Treatment-Set)	Manufactured by Boehringer Ingelheim Pharma GmbH & Co. KG for Boehringer Ingelheim International GmbH Germany	Germany	do.
Levemir Penfill Solution for Injection in a Cartridge 100 U/ml	Novo Nordisk A/S	Denmark	do.
Prexige Film-Coated Tablets 100 mg	Novartis Pharma AG	Switzerland	do.
Prexige Film-Coated Tablets 400 mg	do.	do.	do.
Vitamin B12 Timed Release Tablets 1200 mcg	Jamieson Laboratories	Canada	Freely
Bunny's Corn & Wart Remover Colloidal Solution	Manufactured by Supreme Chemicals Ltd. for Bunny Products Jamaica	Jamaica	do.
Xatral LP Prolonged Release Tablets 10 mg	Manufacturer: Sanofi Winthrop Industrie Distributor: Sanofi-Synthelabo France	France	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Procoralan Film-Coated Tablets 5 mg	Manufacturer: Les Laboratories Servier Industrie License Holder: Les Laboratories Servier France	France	Third Schedule
Procoralan Film-Coated Tablets 7.5 mg	do.	do.	do.
Exjade Dispersible Tablets 125 mg	Novartis Pharma AG	Switzerland	Third Schedule
Exjade Dispersible Tablets 250 mg	do.	do.	do.
Exjade Dispersible Tablets 500 mg	do.	do.	do.
Diovan 320 Tablets	Packaged by Novartis Biociências S.A.	Brazil	do.
Robitussin Cough & Cold CF Non-Drowsy Cold Formula (Alcohol-Free) (Change of Name of Product, Change of Formulation and Change of Artwork Design)	Wyeth Consumer Healthcare	USA	Freely
Children's Dimetapp Cold & Allergy Elixir - Yummy Grape Taste (Alcohol-Free) (Change of Formulation and Change of Artwork Design)	do.	do.	do.
Children's Dimetapp DM Cold & Cough Elixir - Great Red Grape Taste (Alcohol-Free) (Change of Formulation)	do.	do.	do.
Tylenol Allergy Multi-Symptom Cool Burst Caplets (Change of Name of Product, Change of Formulation and Labelling Changes)	Distributed by McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC INC. USA (Product of USA)	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Tylenol Cold Head Congestion Severe Daytime Non-Drowsy Cool Burst Caplets (Change of Name of Product, Change of Formulation and Labelling Changes)	Distributed by McNeil Consumer & Specialty Phamaceuticals DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Tylenol Sinus Congestion & Pain Daytime Non-Drowsy Cool Burst Caplets (Change of Name of Product, Change of Formulation and Labelling Changes)	do.	do.	do.
Tylenol Sinus Congestion & Pain Severe Daytime Non-Drowsy Cool Burst Caplets (Change of Formulation)	do.	do.	do.
Eltroxin Tablets 50 mcg (Change of Formulation)	Glaxo Wellcome GmbH & Co.	Germany	Third Schedule
Eltroxin Tablets 100 mcg (Change of Formulation)	do.	do.	do.
Tarceva Film-Coated Tablets 25 mg (Additional Indication)	Made under licence from F. Hoffmann- La Roche Ltd. Switzerland by Schwarz Pharma Manufacturing Inc.	USA	do.
Tarceva Film-Coated Tablets 100 mg (Additional Indication)	do.	do.	do.
Tarceva Film-Coated Tablets 150 mg (Additional Indication)	do.	do.	do.
Vit-B-Denk Film-Coated Tablets (Change of Name of Manufacturer)	DENK PHARMA GmbH & Co. KG	Germany	Freely
Nifedi-Denk 10 Retard Tablets (Change of Name of Manufacturer)	do.	do.	Third Schedule
Nifedi-Denk 20 Retard Tablets (Change of Name of Manufacturer)	do.	do.	do.
Metformin Denk 500 f.c. Tablets (Change of 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>
Metformin Denk 850 f.c. Tablets (Change of Name of Manufacturer)	DENK Pharma GmbH & Co. KG	Germany	Third Schedule
Diclo-Denk 75 Injection (Change of Name of Manufacturer)	do.	do.	do.
Acyclovir Denk 200 Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Clotri-Denk 100 Vaginal Tablets with Applicator (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Paracetamol Denk 125 Suppos Suppositories (Change of Name of Manufacturer)	Manufactured by RubiePharm Arzneimittel GmbH for DENK PHARMA GmbH & Co. KG Germany	Germany	Freely
Paracetamol Denk 250 Suppos Suppositories (Change of Name of Manufacturer)	do.	do.	do.
Levemir FlexPen Solution for Injection in a Pre-Filled Pen 100 U/ml (Additional Presentation)	Novo Nordisk A/S	Denmark	Third Schedule
NovoRapid FlexPen Solution for Injection in a Pre-Filled Pen 100 U/ml (Additional Presentation)	do.	do.	do.
Trental Sugar-Coated Tablets 400 mg (Additional Source)	Aventis Pharma S.A.	Venezuela	do.
Allesse 28 Tablets (Additional Indication, Additional Source and Additional Artwork Design)	Wyeth Canada	Canada	do.
Leponex Tablets 25 mg (Additional Indication)	Manufactured by Novartis Pharmaceuticals UK Ltd. for Novartis Pharma AG Switzerland	Great Britain	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Leponex Tablets 100 mg (Additional Indication)	Manufactured by Novartis Pharmaceuticals UK Ltd. for Novartis Pharma AG Switzerland	Great Britain	Third Schedule

Veterinary Product

Protektor Spray 0.25% w/v	Cipla Ltd.	India	To Veterinarians or by Veterinary Prescription Only
---------------------------	------------	-------	---

Dated this 10th day of October, 2006.

J. RAHAEL
Minister of Health

