

LEGAL NOTICE NO. 313

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>
Aurocet-P Film-Coated Tablets	Manufactured by: Aurochem Laboratories (I) Pvt. Ltd. Marketed by: Trinpharm Co. Ltd. Trinidad & Tobago	India	Third Schedule
Trosec Delayed Release Capsules USP 20 mg	do.	do.	do.
Feverlet Tablets BP 500 mg	do.	do.	Freely
Calci-D Film-Coated Tablets	do.	do.	do.
Rumifen-200 Film-Coated Tablets BP 200 mg	do.	do.	do.
Rumifen-400 Film-Coated Tablets BP 400 mg	do.	do.	Third Schedule
Glytor Tablets BP 0.5 mg	do.	do.	do.
Dr. Smith's Vitamin E Soft Gelatin Capsules USP 400 mg	Cipla Ltd.	do.	Freely
Panadol Advance Film-Coated Tablets 500 mg	GlaxoSmithKline Dungarvan Limited	Ireland	do.
Renvela Film-Coated Tablets 800 mg	Manufactured by: Genzyme Ireland Ltd. for Genzyme Corporation USA	do.	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Hectorol Capsules 0.5 mcg	Manufactured by: Catalent Pharma Solutions USA Packaged by: Anderson Packaging, Inc. for Genzyme Corporation USA	USA	Third Schedule
Hectorol Capsules 2.5 mcg	do.	do.	do.
Sevoflurane Inhalation Anesthetic	Baxter Healthcare Corporation	do.	do.
Actonel Film-Coated Tablets 150 mg	Manufactured by: Norwich Pharmaceuticals, INC. under license of: Procter & Gamble Pharmaceuticals, INC. USA	do.	do
Allegra Pediatric Oral Suspension 30 mg/5 mL	sanofi-aventis Farmacêutica Ltda.	Brazil	Freely
Alimta Powder for Injection 100 mg	Eli Lilly and Company	USA	Third Schedule
Glypressin Injection Powder and Solvent for Solution for Injec- tion	Powder Manufacturer: Ferring GmbH Germany Solvent Manufacturer: W lfang Pharma GmbH Germany Packager: Ferring International Center SA Holder: Ferring AG Switzerland	Switzerland	Third Schedule (For use by Internal Medicine Specialists & Gas- troenterologists ONLY)
Bravelle Powder and Solvent for Solution for Injection 75 IU	do.	do.	Third Schedule
Zemplar Capsules 1 mcg	Abbott Laboratories	USA	do.
Zemplar Capsules 2 mcg	do.	do.	do.
Zemplar Capsules 4 mcg	do.	do.	do.
Levofloxacin Sandoz Film-Coated Tablets 500 mg	Manufactured by: Lek Pharmaceuti- cals d.d. for Sandoz GmbH Austria	Slovenia	do.
CyClean Solution (Starter Pack)	Sauflon Pharmaceuti- cals Ltd.	England	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Natrol My Favorite Multiple Prime Capsules	Natrol, Inc.	USA	Freely
Aspirin 81 Delayed Release Enteric-Coated Tablets USP 81 mg	Morepen Laboratories Limited	India	do.
Lancer-30 Delayed Release Capsules USP 30 mg	Manufactured by: Aurochem Laboratories (I) Pvt. Ltd. Marketed by: Trinpharm Co. Ltd. Trinidad & Tobago	do.	Third Schedule
Junior Panadol Suspension-6 to 12 years Orange Flavour	GlaxoSmithKline México, S.A. de C.V.	Mexico	Freely
Natele Easy Gels Soft Capsules	Manufactured by: Catalent Brasil Ltda. for Bayer S.A. Brasil	Brasil	do.
Tamiflu Capsules 45 mg	Manufactured by: F. Hoffmann-La Roche Ltd. Licensor: Gilead Sciences USA	Switzerland	Third Schedule
Para-Denk 125 Suppos Suppositories (Change of Name of Product, Change of Name of Manufacturer and Change of Dosing Regimen)	Manufactured by: RubiePharm Arzneimittel GmbH for DENK PHARMA GmbH & Co. KG Germany	Germany	Freely
Para-Denk 250 Suppos Suppositories (Change of Name of Product, Change of Name of Manufacturer and Change of Dosing Regimen)	do.	do.	do.
Para-Denk 500 Tablets (Change of Dosing Regimen)	Manufactured by: bene-Arzneimittel GmbH for DENK PHARMA GmbH & Co. KG Germany	do.	do.
Infanrix hexa™ Powder and Suspension for Intramuscular Injection (Change of Name of Manufacturer and Change of Formulation)	GlaxoSmithKline Biologicals s.a.	Belgium	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Rotarix™ Powder and Solvent for Oral Suspension (Change of Source)	GlaxoSmithKline Biologicals s.a.	Belgium	Third Schedule
Combivir Coated Tablets 150 mg–300 mg (Change of Artwork Design)	Made by: Glaxo Operations UK Limited Trading as: Glaxo Wellcome Operations United Kingdom	United Kingdom	do.
Ziagen Coated Tablets 300 mg (Change of Artwork Design)	do.	do.	do.
Fisiogel Cream (Change of Manufacturer of Bulk)	Stiefel Mexicana, S.A. de C.V.	Mexico	Freely
Alimta Powder for Injection 500 mg (Additional Source and Change of Label Declaration)	Eli Lilly and Company	USA	Third Schedule
Enterogermina Oral Suspension 2 billion/5 mL (Change of Name of Manufacturer and Change of Artwork Design)	Manufactured by: Laboratoire Unither France Packed by: sanofiaventis S.p.A.	Italy	Freely (Pharmacy Only)
Lamisil Spray 1% (Change of Name of Manufacturer, Change of Source and Change of Artwork Design)	Manufactured by: Novartis Pharma S.A.S. for Novartis Consumer Health S.A. Switzerland	France	Third Schedule
Lamisil DermGel 1% (Change of Name of Manufacturer and Change of Artwork Design)	Novartis Consumer Health S.A.	Switzerland	do.
Procto-Glyvenol Cream (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Voltaren Emulgel Gel 1.16% (Change of Packaging 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>
Centrum Multivitamin/ Multimineral Supple- ment Tablets (Change of Formulation and Reduced Size and Mass of Tablets)	Marketed by: Wyeth Consumer Healthcare USA (Product of USA)	USA	Freely
Centrum Silver Multi- vitamin/Multimineral Supplement Tablets (Change of Formulation and Reduced Size and Mass of Tablets)	Marketed by: Wyeth Consumer Healthcare USA (Product of USA)	do.	do.
Rivotril Tablets 2 mg (Additional Source)	Made for: F. Hoffmann-La Roche Ltd. Switzerland by Roche Farma SA	Spain	Controlled Drug
Roaccutane Capsules 10 mg (Change of Colourant of Capsule Shell and Change of Printing Ink of Capsule)	Made for: F. Hoffmann-La Roche Ltd. Switzerland by R.P. Scherer GmbH & Co KG Germany Packaged by: F. Hoffmann-La Roche Ltd.	Switzerland	Third Schedule
Roaccutane Capsules 20 mg (Change of Colourant of Capsule Shell and Change of Printing Ink of Capsule)	do.	do.	do.
MabThera Concentrate for Solution for Infusion 100 mg/10 ml (New Indication and Change of Artwork Design)	F. Hoffmann-La Roche Ltd.	do.	do.
MabThera Concentrate for Solution for Infusion 500 mg/50 ml (New Indication and Change of Artwork Design)	do.	do.	do.
Pegasys® Solution for Injection 180 micro- grams/0.5 ml-Pre-Filled Syringe (New Indication 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>
Singulair Chewable Tablets 4 mg (Additional Source)	Manufactured by: Merck Sharp & Dohme Ltd. England Packaged by: Merck Sharp & Dohme De Mexico S.A. De C.V.	Mexico	Third Schedule
Singulair Chewable Tablets 5 mg (Additional Source)	do.	do.	do.
Singulair Tablets 10 mg (Additional Source)	do.	do.	do.
Arcoxia Tablets 60 mg (Additional Source)	Manufactured by: Merck & Co. Inc, USA Packaged by: Merck Sharp & Dohme De Mexico S.A. De C.V.	do.	do.
Arcoxia Tablets 90 mg (Additional Source)	do.	do.	do.
Arcoxia Tablets 120 mg (Additional Source)	do.	do.	do.
Hyzaar Tablets 50/12.5 mg (Additional Source)	Manufactured by: Merck Sharp & Dohme De Mexico S.A. De C.V. Mexico Packaged by: Merck Sharp & Dohme De Mexico S.A. De C.V.	do.	do.
Vasotec Tablets 5 mg (Additional Source)	do.	do.	do.
Vasotec Tablets 10 mg (Additional Source)	do.	do.	do.
Vasotec Tablets 20 mg (Additional Source)	do.	do.	do.
Nimbex Injection 10 mg in 5 ml (Change of Name of Manufacturer)	GlaxoSmithKline Manufacturing S.p.A.	Italy	do.
Ventolin Oral Solution 2 mg/5 mL (Change of Name of Manufacturer)	GlaxoSmithKline México, S.A. de C.V.	Mexico	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Crestor Coated Tablets 10 mg (Change of Label Declaration)	Made by: IPR Pharmaceuticals Inc. Puerto Rico Packed and Distri- buted by: AstraZenca, S.A. de C.V.	Mexico	Third Schedule
Nasonex Aqueous Nasal Spray 0.05%-Scent Free (Change of Formulation and Change of Artwork Design)	Manufactured by: Schering-Plough Labo N.V. under authority of Schering- Plough Corporation	Belgium	do.
Diane-35 Tablets (Change of Name of Manufacturer and Change of Artwork Design)	Bayer Schering Pharma AG	Germany	do.
Logynon Coated Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Microgynon 30 Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Microgynon 30 ED Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Femiane Sugar-Coated Tablets (Change of Artwork Design)	Manufactured by: Schering do Brasil, Química e Farma- cêutica Ltda. Under license of: Bayer Schering Pharma AG Germany	Brasil	do.
Cliane Coated Tablets (Change of Artwork Design)	do.	do.	do.
Bonefos Film-Coated Tablets 800 mg (Change of Name of Manufacturer and Change of Artwork Design)	Manufactured by: Bayer Schering Pharma Oy Under license of: Bayer Schering Pharma AG Germany	Finland	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Proviron Tablets 25 mg (Change of Artwork Design)	Manufactured by: Schering do Brasil, Química e Farmacêutica Ltda. Under license of: Bayer Schering Pharma AG Germany	Brazil	Third Schedule
Scheriproct Suppositories (Change of Name of Manufacturer and Change of Artwork Design)	Bayer de México, S.A. de C.V.	Mexico	do.
Spasmintas-10 Tablets BP 10 mg	Intas Pharmaceuticals Ltd.	India	do.
Plavix Film-Coated Tablets 300 mg	Distributed by: Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership USA (Product of France)	France	do.
First Degree™ Therapeutic Burn Cream	Distributed by: The Akshay Wellness Group, Inc. USA (Product of USA)	USA	Freely
SunBurnt Therapeutic After Sun Relief Gel with Aloe	do.	do.	do.

Dated this 6th day of November, 2009.

J. NARACE
Minister of Health