

LEGAL NOTICE NO. 74

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>
Pepcid Complete Acid Reducer + Antacid with Dual Action Cool Mint Flavored Chewable Tablets	Distributed by Johnson & Johnson. Merck Consumer Pharmaceuticals Co. USA (Product of USA)	USA	Third Schedule
Pepcid Complete Acid Reducer + Antacid with Dual Action Berry Blend Flavored Chewable Tablets	do.	do.	do.
Children's Motrin Cold Oral Suspension—Original Berry Flavor (Alcohol Free)	Distributed by McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	do.	Freely
Children's Motrin Oral Suspension—Grape Flavor (Alcohol Free)	do.	do.	do.
Children's Motrin Oral Suspension—Bubble Gum Flavor (Alcohol Free)	do.	do.	do.
Imodium Advanced Anti-Diarrheal + Anti-Gas Caplets	do.	do.	Third Schedule
Imodium Advanced Anti-Diarrheal + Anti-Gas Mint Flavored Chewable Tablets	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Tylenol Extra Strength EZTabs Tablets 500 mg	Distributed by McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Motrin IB Coated Tablets 200 mg	do.	do.	do.
Nebido 1000 mg/4 ml Solution for Injection	Manufactured by Jenahexal Pharma GmbH for Schering AG Germany	Germany	Third Schedule
Eutirox 125 Tablets 125 mcg	Merck, S.A. de C.V.	Mexico	do.
Eutirox 150 Tablets 150 mcg	do.	do.	do.
Eutirox 175 Tablets 175 mcg	do.	do.	do.
Eutirox 200 Tablets 200 mcg	do.	do.	do.
Cebión 100 mg/mL Vitamin C Drops Solution— Strawberry Flavor	Merck S.A.	Colombia	Freely
Concerta Extended— Release Tablets 27 mg	Manufactured by ALZA Corporation Distributed and Marketed by McNeil Consumer & Specialty Pharmaceuticals USA	USA	Controlled Drug
Extra Strength Roloids Tablets—Tropical Punch	Distributed by Pfizer Consumer Healthcare USA (Product of Puerto Rico)	Puerto Rico	Freely
Extra Strength Roloids Tablets—Cool Strawberry	do.	do.	do.
Extra Strength Roloids Tablets—Freshmint	do.	do.	do.
Strepsils Strawberry Sugar Free Lozenges	Crookes Healthcare Limited	UK	do.
Fenistil Roll-on Emulsion 0.1%	Novartis Consumer Health S.A.	Switzerland	do.
Invirase Film-Coated Tablets 500 mg	Made under licence from F. Hoffmann- La Roche Ltd. Switzerland by Roche Farma SA	Spain	Third Schedule
Fastorik-N Nasal Drops BP 0.1%-Adults	Plethico Pharmaceuticals Limited	India	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Therasil Sore Throat Formula Antibacterial Antiseptic Lozenges—Orange Flavor	Plethico Pharmaceuticals Limited	India	Freely
Corizan Aqueous Nasal Spray 50 µg/dose	Laboratorios Celsius S.A.	Uruguay	Third Schedule
Certican Dispersible Tablets 0.25 mg	Novartis Pharma AG	Switzerland	do.
Certican Dispersible Tablets 0.1 mg	do.	do.	do.
Certican Dispersible Tablets 0.5 mg	do.	do.	do.
Cebión Vitamin C 500 mg Chewable Tablets— Blueberry	Merck, S.A.	Colombia	Freely
Cilostal 50 Tablets	Manufactured by Laboratorios Richam Internacional, S.A. for Merck S.A. Guatemala	Guatemala	Third Schedule
Cilostal 100 Tablets	do.	do.	do.
Nevanac Ophthalmic Suspension 0.1%	Alcon Laboratories, Inc.	USA	do.
Tylenol Cold Daytime Non-Drowsy Caplets with Instant Cool Burst Sensation (Change of Coating)	Distributed by McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	do.	Freely
Climen Tablets (Change of Source and Change of Artwork Design)	Manufactured by Schering do Brasil, Química e Farmacêutica Ltda. Brasil Packaged by Schering Colombiana, S.A.	Colombia	Third Schedule
Methotrexat "Ebewe" Tablets 2.5 mg (Change of Appearance of Tablet and Change of Artwork Design)	EBEWE Pharma Ges.m.b.H.Nfg.KG	Austria	do.
Avandamet Tablets 2 mg/500 mg (Additional Source)	Glaxo Wellcome, S.A.	Spain	do.
Tylenol Cold Nighttime Caplets with Instant Cool Burst Sensation (Change of Name of Product)	Distributed by McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	USA	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Tylenol Arthritis Pain Extended Release Caplets 650 mg (Change of Name of Product)	Distributed by McNeil Consumer & Specialty Pharmaceuticals DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Tetagam P Solution (ready-for-use) for Intramuscular Administration (Change of Name of Manufacturer)	ZLB Behring GmbH	Germany	Third Schedule
Mebucaine Lozenges (Additional Source and Change of Artwork Design)	Manufactured by Novartis Saglik under the licence of Novartis Consumer Health Switzerland	Turkey	Freely
Strattera Hard Capsules 10 mg (Additional Source)	Eli Lilly and Company Limited	England	Third Schedule
Strattera Hard Capsules 18 mg (Additional Source)	do.	do.	do.
Strattera Hard Capsules 25 mg (Additional Source)	do.	do.	do.
Strattera Hard Capsules 40 mg (Additional Source)	do.	do.	do.
Strattera Hard Capsules 60 mg (Additional Source)	do.	do.	do.
Gemzar for Injection 200 mg (Additional Indication)	do.	USA	do.
Gemzar for Injection 1 g (Additional Indication)	do.	do.	do.
Serviflox 250 Film-Coated Tablets 250 mg (Change of Name of Manufacturer and Change of Artwork Design)	Manufactured by Novartis (Bangladesh) Limited for Sandoz GmbH Austria	Bangladesh	do.
Serviflox 500 Film-Coated Tablets 500 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Simplaqr Tablets 10 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Simplaqr Tablets 20 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.

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Tirlor Tablets 10 mg (Change of Name of Manufacturer and Change of Artwork Design)	Manufactured by Novartis (Bangladesh) Limited for Sandoz GmbH Austria	Bangladesh	Third Schedule
Flucess Capsules 200 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Serolux Film-Coated Tablets 50 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Lectrum 3.75 mg Lyophilized Microspheres for Injection (Change of Name of Manufacturer and Change of Artwork Design)	Manufactured by Eriochem S.A. Distributed by Sandoz S.A. Argentina	Argentina	do.
Lectrum 7.5 mg Lyophilized Microspheres for Injection (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Hypo Tears Plus Eye Drops (Change of Name of Manufacturer)	Manufactured by Excelvision for Novartis Pharma AG Switzerland	France	do.
Gen Teal Lubricant Eye Drops (Change of Name of Manufacturer)	do.	do.	Freely
Zaditen Eye Drops (Change of Name of Manufacturer)	do.	do.	Third Schedule
Oculosan Eye Drops (Change of Name of Manufacturer)	Manufactured by Novartis Ophthalmics AG for Novartis Pharma AG Switzerland	Switzerland	do.
Spersallerg Eye Drops (Change of Name of Manufacturer)	do.	do.	do.
Cebrotonin f/c Tablets 800 mg	Walter Ritter GmbH + Co.	Germany	do.
Colon Super Cleanse Capsules	Manufactured for Vitamin Hut International USA (Product of USA)	USA	Freely

Dated this 6th day of March, 2006.

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