

LEGAL NOTICE NO. 127

REPUBLIC OF TRINIDAD AND TOBAGO

THE 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 listed below:

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Imusporin Oral Solution 100 mg/ml	Cipla Ltd.	India	Third Schedule
Methocip Injection 50 mg/2 ml	do.	do.	do.
Neophos 200 Sterile Powder for Reconstitution for Injection 200 mg	do.	do.	do.
5% Dextrose Injectable Solution	Corpaul	Columbia	do.
10% Dextrose Injectable Solution	do.	do.	do.
Fluxil Capsules 20 mg	Aegis Ltd.	Cyprus	do.
Viprolox 250 Tablets	do.	do.	do.
Viprolox 500 Tablets	do.	do.	do.
Celemin 10 Plus Injection with Electrolytes	Claris Lifesciences Limited	India	do.
Celepid 10% Intravenous Fat Emulsion	do.	do.	do.
Celepid 20% Intravenous Fat Emulsion	do.	do.	do.
Provive 1% Intravenous Infusion	do.	do.	do.
Tenaflox Injection 0.5% w/v	do.	do.	do.
Exomax Injection 2 mg/ml	do.	do.	do.
Ciproquin Injection 0.2% w/v	do.	do.	do.
Lonol 100 Tablets 100 mg	Khandelwal Laboratories Pvt. Ltd.	do.	do.
Norzen Eye/Ear Drops	FDC Limited	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Salbutamol Oral Solution BP 2 mg	Fourrts (India) Laboratories Pvt. Limited	India	Third Schedule
Calcigard Retard Sustained Release Film-Coated Tablets 20 mg	Torrent Pharmaceuticals Ltd.	do.	do.
Angiopril-25 Tablets	do.	do.	do.
Betacard-50 Film-Coated Tablets	do.	do.	do.
Betacard-100 Film-Coated Tablets	do.	do.	do.
Herpex Tablets	do.	do.	do.
Syscan-100 Hard Gelatin Capsules	do.	do.	do.
Carbatol-200 Tablets	do.	do.	do.
Fungicide Tablets 200 mg	do.	do.	do.
Converten-10 mg Tablets 10 mg	Khandelwal Laboratories Pvt. Ltd.	do.	do.
Durea Capsules 500 mg	Samarth Pharma Private Limited for Puerto Rico Pharmaceutical, Inc. Puerto Rico, USA	do.	do.
Azoran Tablets	RPG Life Sciences Ltd.	do.	do.
Robitussin Flu Syrup (Alcohol Free)	Wyeth Consumer Healthcare	USA	Freely
Children's Advil Cold Oral Suspension-Grape Flavor (Alcohol Free)	do.	do.	do.
Children's Dimetapp Cold & Allergy Elixir (Alcohol Free)	do.	do.	do.
Reyataz Capsules 100 mg	Bristol-Myers Squibb U.S. Pharmaceutical Group Subsidiary of: Bristol-Myers Squibb Company USA	do.	Third Schedule
Reyataz Capsules 150 mg	do.	do.	do.
Reyataz Capsules 200 mg	do.	do.	do.
Clearasil Tinted Acne Treatment Cream (Adult)	Manufactured for Boots Healthcare USA, Inc. USA (Product of Germany)	Germany	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Pentaxim Powder and Suspension for Injection in Pre-Filled Syringe	Aventis Pasteur SA	France	Third Schedule
Levitra Tablets 5 mg	Made by Bayer AG for Bayer de Mexico, S.A. de C.V. Mexico	Germany	do.
Levitra Tablets 10 mg	do.	do.	do.
Levitra Tablets 20 mg	do.	do.	do.
Streptase 1.500.000 IU Lyophilized Powder for Injectable Solution	Aventis Behring GmbH	do.	do.
Valparin-200 Alkalets Enteric-Coated Tablets	Torrent Pharmaceuticals Ltd.	India	do.
Syscan-150 Hard Gelatin Capsules	do.	do.	do.
Fungid B Cream	Fourrts (India) Laboratories Pvt. Limited	do.	do.
Alphadol Soft Gelatin Capsules	Panacea Biotec Ltd.	do.	do.
Alphadol-1 Soft Gelatin Capsules	do.	do.	do.
FITLIV Soft Gelatin Capsules	Marketed by Best on Health Ltd. (A SBU of Panacea Biotec Ltd.) India (Product of India)	do.	Freely
HIQU Soft Gelatin Capsules	do.	do.	do.
Clotrimazole 1% Cream	Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	do.	Third Schedule
5% Dextrose in 0.9 % Sodium Chloride Injectable Solution	Corpaul	Columbia	do.
Polio rix Suspension for Injection	GlaxoSmithKline Biologicals, s.a.	Belgium	do.
Copegus Film-Coated Tablets 200 mg	Made by Hoffmann-La Roche Inc. for F. Hoffmann-La Roche Ltd. Switzerland	USA	do.
Fuzeon Powder for Solution for Injection 90 mg/ml and Water for Injections	F. Hoffmann-La Roche Ltd.	Switzerland	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Norbactin 400 Film-Coated Tablets (Additional Manufacturing Site)	Ranbaxy Laboratories Limited	India	Third Schedule
Maximum Strength Clearasil Tinted Acne Treatment Cream (Change of Name of Manufacturer and Additional Source)	Manufactured for Boots Healthcare USA, Inc. USA (Product of Germany)	Germany	Freely
Maximum Strength Clearasil Vanishing Acne Treatment Cream (Change of Name of Manufacturer and Additional Source)	do.	do.	do.
Zantac Injectable Solution 25 mg/ml (Additional Source)	Made by GlaxoSmithKline S.p.A. Italy Packed by GlaxoSmithKline Brasil Ltd.	Brazil	Third Schedule
Serevent Inhaler 25 mcg (Change of Name of Manufacturer and Additional Source)	Made by Glaxo Wellcome Production France Packed by GlaxoSmithKline Mexico, S.A. de C.V.	Mexico	do.
Zofran Zydis Freeze dried, fast dispersing Wafers 4 mg (Change of Name of Product, Change of Name of Manufacturer and Additional Source)	Made by Scherer DDS Limited England for Glaxo Wellcome GmbH & Co. Germany Packed by Glaxo Wellcome GmbH & Co.	Germany	do.
Zofran Zydis Freeze dried, fast dispersing Wafers 8 mg (Change of Name of Product, Change of Name of Manufacturer and Additional Source)	do.	do.	do.
Insuman R 100 IU/mL Injectable Solution in OptiSet with 3 mL Cartridges (Change of Name of Manufacturer and Additional Presentation)	Aventis Pharma Deutschland GmbH	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Insuman N 100 IU/mL Injectable Suspension in OptiSet with 3 mL Cartridges (Change of Name of Manufacturer and Additional Presentation)	Aventis Pharma Deutschland GmbH	Germany	Third Schedule
Insuman Comb 75N/25R 100 IU/mL Injectable Suspension in OptiSet with 3 mL Cartridges (Change of Name of Manufacturer and Additional Presentation)	do.	do.	do.
Insuman Comb 75N/25R Injectable Suspension 100 IU/mL (Change of Name of Manufacturer and Additional Presentation)	do.	do.	do.
Tavanic Film-Coated Tablets 500 mg (Additional Presentation)	Aventis Pharma, S.A.	Guatemala	do.
Tavanic Solution for I.V. Infusion 500 mg (Change of Name of Manufacturer)	Aventis Pharma Deutschland GmbH	Germany	do.
Batrafen Nail Lacquer (Additional Source)	do.	do.	do.
Gravinate Tablets (Additional Package Design)	Carlisle Laboratories Ltd.	Barbados	Freely
Scheriproct Ointment (Change of Name of Manufacturer and Change of Source)	Schering Argentina S.A.I.C.	Argentina	Third Schedule
Hiberix Vaccine (Change of Name of Manufacturer)	GSK Biologicals s.a.	Belgium	do.
Seretide Evohaler 25/50 mcg (Change of Name of Manufacturer and Additional Source)	Made by Glaxo Wellcome Production for GlaxoSmithKline AG Switzerland	France	do.
Seretide Evohaler 25/125 mcg (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>
ZNP Bar (Additional Source)	Distributed by Stiefel Laboratories, Inc. USA (Product of Mexico)	Mexico	Freely
Inhibace Tablets 2.5 mg (Change of Name of Manufacturer and Additional Source)	Produtos Roche Quimicos e Farmaceuticos S.A.	Brazil	Third Schedule
Inhibace Tablets 5 mg (Change of Name of Manufacturer and Additional Source)	do.	do.	do.
Atropine Sulphate Injection BP 600 mcg/1 ml (Change of Artwork Design)	Martindale Pharmaceuticals	UK	do.
Children's Cetamol Liquid (Change of Name of Product and Change of Artwork Design)	Federated Pharmaceutical Co. Ltd.	Jamaica	Freely
Salbutamol Inhaler 100 mcg	Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	India	Third Schedule
Bazzeys' Black Draught Tisane Liquid (Change of Formulation and Change of Labelling)	Bazzeys' Drugs (1998)	Trinidad and Tobago	Freely

Dated this 15th day of June, 2004.

J. RAHAEL
Minister of Health