

LEGAL NOTICE NO. 293

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 clause 7, Division 3 of the Second Schedule of the Food and Drugs Act.

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>
Celib Capsules 100 mg	Unichem Laboratories Ltd.	India	Third Schedule
Celib Capsules 200 mg	do.	do.	do.
African Sea-Coconut Brand Cough Mixture	Distributed by Luen Fook Medicine Co. Pte. Ltd. Singapore (Product of Malaysia)	Malaysia	Freely
Apo-Levocarb Tablets 100 mg/25 mg	Apotex Inc.	Canada	Third Schedule
Hepsera Tablets 10 mg	Manufactured by Patheon Inc. for GlaxoSmithKline Inc. Canada	do.	do.
Cromolyn Sodium Ophthalmic Solution 2 % w/v	Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	India	do.
Vitamin B Complex Capsules	Vega Nutritionals Ltd.	England	Freely
Malvatricin Plus 5 in 1 Antiseptic Mouthwash Fluoride + Xylitol (Alcohol-Free)	Laboratório Daudt Oliveira Ltda.	Brazil	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Malvatricin Whitening Antiseptic Mouthwash Lemon + Mint + Fluoride (Alcohol-Free, Coloring-Free)	Laboratório Daudt Oliveira Ltda.	Brazil	Freely
Malvatricin Whitening Daily Use Antiseptic Toothpaste Lemon + Mint + Fluoride	do.	do.	do.
Fourrts B Sugar-Coated Tablets	Fourrts (India) Laboratories Pvt. Limited	India	do.
Cofex Expectorant	do.	do.	do.
Selltoc AC Capsules	do.	do.	do.
Redin PN Liquid	do.	do.	do.
Salmodil Expectorant Syrup	FDC Limited	do.	do.
Fitzroy Tonic	Distributed by Fitzroy International Ltd. (Product of UK)	UK	do.
Unat Tablets 2.5 mg	Made by Roche Farma SA for F. Hoffmann-La Roche Ltd. Switzerland	Spain	Third Schedule
Unat Tablets 10 mg	do.	do.	do.
Unat Injection Solution 20 mg/4 ml	Made by Roche Diagnostics GmbH for F. Hoffmann-La Roche Ltd. Switzerland	Germany	do.
Cispa-10 Injection 10 mg/10 ml	Intas Pharmaceuticals Ltd.	India	do.
Cispa-50 Injection 1 mg/ml	do.	do.	do.
Merex-50 Injection 50 mg/2 ml	do.	do.	do.
Arasid-100 Injection 100 mg/1 ml	do.	do.	do.
Abilify Tablets 10 mg	Manufactured by Bristol-Myers Squibb Manufacturing Co. Puerto Rico, USA Subsidiary of Bristol-Myers Squibb Co. USA Packed by Bristol-Myers Squibb Australia Pty. Ltd.	Australia	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Abilify Tablets 15 mg	Manufactured by Bristol-Myers Squibb Manufacturing Co. Puerto Rico, USA Subsidiary of Bristol-Myers Squibb Co. USA Packed by Bristol-Myers Squibb Australia Pty. Ltd.	Australia	Third Schedule
Abilify Tablets 20 mg	do.	do.	do.
Abilify Tablets 30 mg	do.	do.	do.
Vaseretic Tablets 10/25 mg (Change of Source and Change of Name of Manufacturer)	Merck Sharp & Dohme De Mexico S.A. De C.V.	Mexico	do.
Seretide Evohaler 25/250 mcg (Additional Source and and Change of Name of Manufacturer)	Glaxo Wellcome Production	France	do.
Salbutamol 100 mcg HFA Inhaler (CFC-Free) (Change of Name of Product)	Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	India	do.
Beclomethasone 50 mcg HFA Inhaler (CFC-Free) (Change of Name of Product)	do.	do.	do.
Losec Mups Tablets 10 mg (Change of Name of Manufacturer)	AstraZeneca AB	Sweden	do.
Losec Mups Tablets 20 mg (Change of Name of Manufacturer)	do.	do.	do.
Losec Mups Tablets 40 mg (Change of Name of Manufacturer)	do.	do.	do.
Losec Powder and Solvent for Solution for I.V. Injection 40 mg (Change of Name of Manufacturer)	do.	do.	do.
Symbicort Turbuhaler Inhalation Powder 80/4.5 ug/dose (High Dose Application)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Symbicort Turbuhaler Inhalation Powder 160/4.5 ug/dose (High Dose Application)	AstraZeneca AB	Sweden	Third Schedule
Symbicort Turbuhaler Inhalation Powder 320/9 ug/dose (High Dose Application)	do.	do.	do.
Arimidex Tablets 1 mg (Additional Indication)	Manufactured by AstraZeneca Pharmaceuticals LP for AstraZeneca UK Limited United Kingdom	USA	do.
Imovane Scored Tablets 7.5 mg (Change of Name of Manufacturer and Change of Artwork Design)	Usiphar	France	Controlled Drug
Fluorouracil Injection BP 250 mg in 10 mL (Change of Name of Manufacturer)	Pharmacia (Perth) Pty Limited	Australia	Third Schedule
Methotrexate Injection BP 1000 mg in 10 mL (Change of Name of Manufacturer)	do.	do.	do.
Etoposide Injection 100 mg in 5 mL (Change of Name of Manufacturer)	do.	do.	do.
Sterile Potassium Chloride Concentrate Injection Ampoules 0.75 g in 10 mL (Change of Name of Manufacturer)	do.	do.	do.
Atropine Solution for Injection 1200 ug in 1 mL (Change of Name of Manufacturer)	do.	do.	do.
Lexotan Tablets 3 mg (Additional Source and Change of Name of Manufacturer)	Produtos Roche Quimicos e Farmacêuticos S.A.	Brasil	Controlled Drug
Rivotril Tablets 0.5 mg (Additional Source and 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>
Domicum Tablets 7.5 mg (Additional Source and Change of Name of Manufacturer)	Produtos Roche Quimicos e Farmacêuticos S.A.	Brasil	Controlled Drug
Domicum Tablets 15 mg (Additional Source and Change of Name of Manufacturer)	do.	do.	do.
Strepsils Original Flavour Throat Lozenges (Change of Artwork Design)	The Boots Company PLC	England	Freely
Strepsils Vitamin C 100 mg Throat Lozenges (Change of Artwork Design)	do.	do.	do.
Strepsils Honey & Lemon Throat Lozenges (Change of Artwork Design)	do.	do.	do.
Strepsils Menthol & Eucalyptus Throat Lozenges (Change of Artwork Design)	do.	do.	do.
Gammagard S/D Immune Globulin Intravenous (Human) Solvent/ Detergent Treated 0.5G (Change of Name of Product and Labelling Changes to Insert)	Baxter Healthcare Corporation	USA	Third Schedule
Gammagard S/D Immune Globulin Intravenous (Human) Solvent/ Detergent Treated 2.5G (Change of Name of Product and Labelling Changes to Insert)	do.	do.	do.
Gammagard S/D Immune Globulin Intravenous (Human) Solvent/ Detergent Treated 5G (Change of Name of Product and Labelling Changes to Insert)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Gammagard S/D Immune Globulin Intravenous (Human) Solvent/ Detergent Treated 10G (Change of Name of Product and Labelling Changes to Insert)	Baxter Healthcare Corporation	USA	Third Schedule
Econopred Plus Sterile Ophthalmic Suspension 1% (Change of Source)	Alcon Laboratories Inc.	do.	do.
GNO Pain Relieving Oil	W & W Spices Grenada Ltd.	Grenada	Freely
Co-Enzyme Q10 Capsules 30 mg	Vega Nutritionals Ltd.	England	do.
Malvatricin ORGANIC Daily Use NATURAL Mouthwash + Fluoride —Herbal Honey-Lemon-Mint Flavor (Alcohol-Free, Colouring-Free)	Laboratório Daudt Oliveira Ltda.	Brazil	do.
Slim Essentials All Natural Twice a Day Liquid System	Swiss Herbal Remedies Ltd.	Canada	Third Schedule
RespiSure Vaccine (Change in Antigen Level/Dose)	Pfizer Animal Health	USA	To Veterinarians or by Veterinary Prescription Only
RespiSure1 One Vaccine (Extension of Duration of Immunity)	do.	do.	do.

Dated this 20th day of September, 2004.

J. RAHAEL
Minister of Health

