

LEGAL NOTICE NO. 116

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>
Extra Strength Roloids Tablets-Fruit	Distributed by Pfizer Consumer Healthcare USA (Product of Puerto Rico)	Puerto Rico	Freely
Children's Dimetapp DM Cold & Cough Elixir-Red Grape (Alcohol-Free)	Wyeth Consumer Healthcare	USA	do.
Survanta (beractant) Intratracheal Suspension	Manufactured by Hospira, Inc. for Ross Products Division, Abbott Laboratories USA	do.	Third Schedule (To Neonatologists, Paediatricians or Registrars in a Neonatal Unit ONLY) (FROM AGENT ONLY)
Momate Cream	Glenmark Pharmaceuticals Ltd.	India	Third Schedule
Momate Ointment	do.	do.	do.
Beclotis Inhaler BP 50 mcg per actuation	Jewim Pharmaceutical (Shandong) Co., Ltd.	China	do.

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Salbutol Inhalation Aerosol BP 100 mcg per actuation	Jewim Pharmaceutical (Shandong) Co., Ltd.	China	Third Schedule
Fiberex Granules with Pure Florida Orange Flavour	Made by Meyer Healthcare Pvt. Ltd. Exported by Meyer Organics Pvt. Ltd., India	India	Freely
Coversyl Tablets 8 mg	Les Laboratoires Servier Industrie	France	Third Schedule
Califig Syrup	Merck Consumer Health	England	Freely
Glisulin 500 XR Extended Release Tablets	Manufactured by Merck Santé s.a.s. France, Packaged by Merck S.A.	Chile	Third Schedule
Aerius 05 mg/ml Syrup	Manufactured by Schering Plough Labo N.V. under authority of Schering-Plough Corporation USA	Belgium	Freely
Fenistil Drops	Novartis Consumer Health SA	Switzerland	do.
Bonviva Film-Coated Tablets 150mg	F Hoffmann La Roche Ltd.	do.	Third Schedule
Humalog Mix 25 100 IU/mL Suspension	Lilly France S.A.	France	do.
Humalog U-100 Injection 100 units per mL	Eli Lilly & Company	USA	do.
Partobulin SDF Solution for Intramuscular Injection 1250 I.U.-Preloaded Syringe	Baxter AG	Austria	do.
Videx EC Delayed-Release Capsules 200 mg	Bristol-Myers Squibb Immunology A Bristol-Myers Squibb Company	U.S.A.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Videx EC Delayed-Release Capsules 250 mg	Bristol-Myers Squibb Immunology A Bristol-Myers Squibb Company	U.S.A.	Third Schedule
Videx EC Delayed-Release 400 mg	do.	do.	do.
H2K Iron Supplement + Folic Acid Film-Coated Tablets	Manufactured by Atra Pharmaceuticals Ltd for Health 2000 Inc. Canada	India	Freely
H2K Multivitamin Surgar-Coated Tablets	do.	do.	do.
H2K Vitamin B-Complex Film-Coated Tablets	do.	do.	do.
Pioglar Tablets 15 mg	Ranbaxy Laboratories Limited	India	Third Schedule
Pioglar Tablets 30 mg	do.	do.	do.
Simvor 80 Film-Coated Tablets 80 mg	do.	do.	do.
Vamlo Tablets 5 mg	do.	do.	do.
Vamlo Tablets 10 mg	do.	do.	do.
Corpril 2.5 Capsules 2.5 mg	do.	do.	do.
Corpril 5 Capsules 5 mg	do.	do.	do.
Coviro-E 30 Compliance Pack Tablets	do.	do.	do.
Coviro-E 40 Compliance Pack Tablets	do.	do.	do.
Virocomb-E Compliance Pack Tablets	do.	do.	do.
Avostav Capsules 30 mg	do.	do.	do.
Avostav Capsules 40 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Avolam Film-Coated Tablets 150 mg	Ranbaxy Laboratories Limited	India	Third Schedule
Aviro-Z Film-Coated Tablets 300 mg	do.	do.	do.
Avocomb Film-Coated Tablets	do.	do.	do.
QuikClot ACS Advanced Clotting Sponge	Z-Medica Corporation	USA	Freely (for use by Emergency Medical Technician ONLY)
Natrecol Lyophilized Powder for Reconstitution 1.5 mg	Made by Hospira Inc. For SCIOS Inc. USA	USA	Third Schedule (To Registered Cardiologist ONLY) (FROM AGENT ONLY)
Dibron Tablets	Global Pharma Healthcare Pvt. Ltd.	India	Third Schedule
Transvasin Heat Rub Cream (Change of Name of Manufacturer)	Distributed by Thornton & Ross Ltd. UK (Product of UK)	UK	Freely
Transvasin Heat Spray (Change of Name of Manufacturer)	do.	do.	do.
Yeast Vite Tablet (Change of Name of Manufacturer)	do.	do.	do.
Sominex Tablets (Change of Name of Manufacturer)	do.	do.	do.
Mycota Cream (Change of Name of Manufacturer)	do.	do.	do.
Mycota Spray (Change of Name of Manufacturer)	do.	do.	do.
Mycota Powder (Change of Name of Manufacturer)	Manufactured by Custom Pharmaceuticals Ltd. for Thornton & Ross Ltd. UK	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Cozaar Tablets 50 mg (Change of Source)	Manufactured by MERCK SHARP & DOHME DE MEXICO S.A. DE C.V. Mexico Packaged MERCK SHARP & DOHME (I.A.) CORP.	Costa Rica	Third Schedule
Genprofen 200 Film-Coated Tablets 200 mg (Change of Colour of Tablet Coating)	Genethics Pharmaceuticals Ltd.	Trinidad and Tobago	Freely
Gendazole Film-Coated Tablets (Change of Size and Colour of Tablets)	do.	do.	Third Schedule
Gendazole F Film-Coated Tablets (Change of Size and Colour of Tablets)	do.	do.	do.
Gen-Amipril Tablets 5 mg (Change of Colour of Tablets)	do.	do.	do.
Genfurosemide Tablets USP (Change of Appearance of Tablets)	do.	do.	do.
Genclamide Tablets BP 5 mg (Change of Name of Product)	do.	do.	do.
Diaban Tablets 80 mg (Change of Shape and Appearance of Tablets)	do.	do.	do.
Arimidex Tablets 1 mg (Removal of Claim: 'who are unable to take tamoxifen therapy')	Manufactured by AstraZeneca Pharmaceuticals LP for AstraZeneca UK Limited United Kingdom	USA	do.
Mycospor Onichoset Ointment 1% (Additional Source and Change of Artwork Design)	Bayer, S.A.	El Salvador	do.

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Baraclude Tablets 0.5 mg (Additional Name of Manufacturer)	Manufactured by Bristol-Myers Squibb Company Subsidiary of Bristol-Myers Squibb Company USA	USA	Third Schedule
Baraclude Tablets 1 mg (Additional Name of Manufacturer)	do.	do.	do.
Baraclude Oral Solution 0.05 mg/mL (Additional Name of Manufacturer)	do.	do.	do.
Paraplatin (carboplatin aqueous solution) Injection 50 mg per vial (10 mg/mL) (Additional Name of Manufacturer)	Bristol-Myers Squibb Oncology Bristol-Myers Squibb Company	do.	do.
Paraplatin (carboplatin aqueous solution) Injection 150 mg per vial (10 mg/mL) (Additional Name of Manufacturer)	do.	do.	do.
Paraplatin (carboplatin aqueous solution) Injection 450 mg per vial (10 mg/mL) (Additional Name of Manufacturer)	do.	do.	do.
Leukeran Tablets 2 mg (Change of Name of Manufacturer and Additional Source)	Heumann Pharma GmbH	Germany	do.
Nevipan Tablets 200 mg (Change of Source of Bulk)	Ranbaxy Laboratories Limited	India	do.
Schiff Prostate Health Capsules	Distributed by Schiff Products USA (Product of USA)	USA	Freely (Pharmacy ONLY)

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Veterinary Products			
Cipdex Injection	Cipla Ltd.	India	To Veterinarians or by Veterinary Prescription Only
Prazivet Plus Tablets	do.	do.	Freely

Dated this 9th day of May, 2006.

J. RAHAEL
Minister of Health

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