

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>
Tylenol Allergy Multi-Symptom Rapid Release Gels-RR Gelcaps	Distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc. USA (Product of USA)	USA	Freely
Blopress Plus Tablets 16 mg/12.5 mg	Abbott Laboratories Argentina S.A.	Argentina	Third Schedule
Invega Extended-Release Tablets 3 mg	Manufactured by ALZA Corporation USA Packaged by Janssen-Cilag S.p.A.	Italy	do.
Invega Extended-Release Tablets 6 mg	do.	do.	do.
Invega Extended-Release Tablets 9 mg	do.	do.	do.
Mircera Solution for Injection 50 micrograms/0.3 ml-Pre-Filled Syringe	Made for F. Hoffmann-La Roche Ltd Switzerland by Roche Diagnostics GmbH	Germany	do.
Mircera Solution for Injection 75 micrograms/0.3 ml-Pre-Filled Syringe	do.	do.	do.
Mircera Solution for Injection 100 micrograms/0.3 ml-Pre-Filled Syringe	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Mircera Solution for Injection 150 micrograms/0.3 ml- Pre-Filled Syringe	Made for F. Hoffmann-La Roche Ltd Switzerland by Roche Diagnostics GmbH	Germany	Third Schedule
Mircera Solution for Injection 200 micrograms/0.3 ml- Pre-Filled Syringe	do.	do.	do.
Mircera Solution for Injection 250 micrograms/0.3 ml- Pre-Filled Syringe	do.	do.	do.
Duratocin Injection IV 100 µg/1 mL	Distributed by Ferring Inc. Canada (Product of Canada)	Canada	do.
Tractocile Solution for Injec- tion 7.5 mg/ml	Ferring AB	Sweden	do.
Tractocile Concentrate for Solution for Infusion 7.5 mg/ml	do.	do.	do.
Bi-Profenid Prolonged- Release Tablets 150 mg	sanofi-aventis Farma- cêutica Ltda.	Brazil	Freely
dpa LIFEStyles Gold Omega-3 Softgel Capsules 500 mg	Produced for DPA LIFEStyles a division of LaShang Inc. Canada (Product of Canada)	Canada	do.
Conjugase 0.625 Sugar-Coated Tablets USP	Elder Pharmaceuti- cals Ltd.	India	Third Schedule
Human Albumin 50 g/l Baxter 5% Solution for Infusion	Baxter AG	Austria	do.
Human Albumin 250 g/l Baxter 25% Solution for Infusion	do.	do.	do.
Sandoglobulin 1 g Human Normal Immunoglobulin Lyophilised Powder for Solution for Intravenous Administra- tion 1 g (Change of Name of Manu- facturer)	CSL Behring AG	Switzerland	do.
Sandoglobulin 6 g Human Normal Immunoglobulin Lyophilised Powder for Solution for Intravenous Administra- tion 6 g (Change of Name of Manu- facturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Dormicum 50 mg/10 ml i.v. Solution for Injection (Additional Source and Amendment to Sourcing Statement)	Made for F. Hoffmann-La Roche Ltd Switzerland by CENEXI SAS	France	Controlled Drug
Xenical Capsules 120 mg (Amendment to Sourcing Statement)	Made for F. Hoffmann-La Roche Ltd Switzerland by Roche S.p.A.	Italy	Third Schedule
Konakion MM 10 mg oral/i.v. for Oral Use or I.V. Injection Mixed - micelles Solution (Amendment to Sourcing Statement and Additional Route of Administration)	Made for F. Hoffmann-La Roche Ltd Switzerland by CENEXI SAS	France	do.
Kytril 3 mg/3 ml i.v. Injectable Solution (Additional Source)	do.	do.	do.
Coversyl Scored Tablets 4 mg (Additional Indication)	Les Laboratoires Servier Industrie	do.	do.
Rhophylac 300 Solution for Intravenous or Intramuscular Injection in Pre-Filled Syringe 300 µg (1500UI/IU) (Change of Name of Manufacturer)	CSL Behring AG	Switzerland	do.
Allegra Film-Coated Tablets 120 mg (Additional Source)	Manufactured by sanofi-aventis U.S. LLC USA Packed by sanofi-aventis de Venezuela S.A.	Venezuela	do.
Allegra Film-Coated Tablets 180 mg (Additional Source)	do.	do.	do.
Allegra D Extended Release Film-Coated Tablets (Additional Source)	do.	do.	do.
Calcort Tablets 6 mg (Additional Source)	Manufactured by Aventis Pharma S.p.A. Italy Packed by sanofi-aventis de Venezuela S.A.	do.	do.
Calcort Tablets 30 mg (Additional Source)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Tritace Tablets 10 mg (Additional Source)	Manufactured by Aventis Pharma S.p.A. Italy Packed by sanofi-aventis de Venezuela S.A.	Venezuela	Third Schedule
Tavanic Film-Coated Tablets 500 mg (Additional Source)	Manufactured by Aventis Intercon- tinental France Packed by sanofi-aventis de Venezuela S.A.	do.	do.
Tenormin Tablets 50 mg (Additional Source)	AstraZeneca, S.A. de C.V. Mexico	Mexico	do.
Tenormin Tablets 100 mg (Additional Source)	do.	do.	do.
Tenoretic Tablets (Atenolol 50 mg, Chlorthalidone 12.5 mg) (Additional Source)	do.	do.	do.
Tenoretic Tablets (Atenolol 100 mg, Chlorthalidone 25 mg) (Additional Source)	do.	do.	do.
Children's Panadol Syrup (2 to 6 years)—Raspberry Flavour (Change of Art- work Design and Change of Dosing Regimen)	GlaxoSmithKline Costa Rica S.A.	Costa Rica	Freely
Baby's Panadol Drops (1 month to 2 years)— Raspberry Flavour (Change of Name of Manufacturer, Change of Artwork Design and Change of Dosing Regimen)	do.	do.	do.
Multisymptom Panadol Children Syrup—Raspberry Flavour (Change of Name of Manufacturer, Change of Artwork Design and Change of Dosing Regimen)	do.	do.	do.
Scott Extra Emulsion— Orange Flavour (Change of Artwork Design)	GlaxoSmithKline México, S.A. de C.V.	Mexico	do.
Scott Extra Emulsion— Cherry Flavour (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>
FluaRix Suspension for Injection—Pre-Filled Syringe (Change of Viral Strain)	SSW Dresden Germany a branch of SB Pharma GmbH & Co. KG	Germany	Third Schedule
Benadryl Allergy Kapseals (Change of Name of Manufacturer and Application of Safety Band on Capsules)	Distributed by Pfizer Consumer Healthcare USA (Product of Puerto Rico, USA)	Puerto Rico, USA	Freely
Herceptin 440 mg Powder for Concentrate for Solution for Infusion (Additional Indication)	Made for F. Hoffman-La Roche Ltd. Switzerland by Genentech Inc.	USA	Third Schedule

Dated this 20th day of March, 2008.

J. NARACE
Minister of Health