

LEGAL NOTICE NO. 217

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 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>
Zintrepid Tablets 10 mg/10 mg	Made by Merck Sharp & Dohme Technology Singapore Pte. Ltd. Singapore Packaged by Merck Sharp & Dohme De Mexico S.A. de C.V.	Mexico	Third Schedule
Zintrepid Tablets 10 mg/20 mg	do.	do.	do.
Zintrepid Tablets 10 mg/40 mg	do.	do.	do.
Aqualase Balanced Salt Liquefaction Solution	Alcon Laboratories, Inc.	USA	do.
Fluorescite 10% Injection Solution	Manufactured by Cardinal Health Manufacturing Services B.V. for Alcon Laboratories, Inc. USA	Puerto Rico, USA	do.
Brimonidine Tartrate Ophthalmic Solution 0.2%	Manufactured by ALCON Manufacturing Ltd. Distributed by FALCON Pharmaceuticals Ltd. USA	USA	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Timolol GFS Ophthalmic Gel Forming Solution 0.25%	Manufactured by ALCON Manufacturing Ltd. Distributed by FALCON Pharmaceuticals Ltd. USA	USA	Third Schedule
Timolol GFS Ophthalmic Gel Forming Solution 0.5%	do.	do.	do.
Clobex Shampoo 0.05%	Manufactured by DPT Laboratories, Ltd. Marketed by Galderma Laboratories, L.P. USA	do.	do.
Clobex Topical Lotion 0.05%	do.	do.	do.
Vytorin Tablets 10/10 mg	Manufactured by MSD Technology Singapore Pte. Ltd. Singapore Packaged by Merck Sharp & Dohme De Mexico S.A. de C.V.	Mexico	do.
Vytorin Tablets 10/20 mg	do.	do.	do.
Vytorin Tablets 10/40 mg	do.	do.	do.
Vytorin Tablets 10/80 mg	do.	do.	do.
Advantage I-125 Brachytherapy Seeds	IsoAid, L.L.C.	USA	do.
Biogesic Suspension 120 mg/5 mL	Manufactured by United Laboratories, Inc. for Biomedis, Inc. Philippines	Philippines	Freely
Diatabs Capsules 2 mg	do.	do.	Third Schedule
Motilium Suspension	Janssen Cilag, S.A. de C.V.	Mexico	do.
Reminyl ER Extended Release Capsules 8 mg	do.	do.	do.
Reminyl ER Extended Release Capsules 16 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Summer's Eve Anti-Itch Gel-Maximum Strength	Marketed by Personal Laboratories, a Division of C.B. Fleet Co., Inc. USA (Product of USA)	USA	Freely
Telzir Film-Coated Tablets 700 mg	Glaxo Operations UK Limited	United Kingdom	Third Schedule
Bendex Suspension	Cipla Ltd.	India	Freely
TopCort Ointment	do.	do.	Third Schedule
Bo-Lax Enteric-Coated Tablets	do.	do.	Freely
Lovir Cream 5% w/w	Ranbaxy Laboratories Limited	do.	Third Schedule
Angeliq Film-Coated Tablets	Manufactured by Schering GmbH & Co. Produktions KG Germany Packed by Schering Colombiana, S.A.	Colombia	do.
Fludara Powder for Solution for Injection 50 mg	Manufactured by Schering S.p.A. Italy Packed by Schering Colombiana, S.A.	do.	do.
Apo-Omeprazole Capsules 20 mg	Apotex Inc.	Canada	do.
Apo-Lisinopril Tablets 10 mg	do.	do.	do.
Apo-Ciproflox Tablets 500 mg	do.	do.	do.
Apo-Midazolam Injectable Solution 5 mg/mL	do.	do.	Controlled Drug
Bondronat Film-Coated Tablets 50 mg	F. Hoffmann-La Roche Ltd.	Switzerland	Third Schedule
Bonviva Film-Coated Tablets 2.5 mg	do.	do.	do.
Bondronat Concentrate for Solution for Infusion 6 mg/6 ml	Made by Roche Diagnostics GmbH for F. Hoffmann-La Roche Ltd. Switzerland	Germany	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Recormon Solution for Injection 30 000 IU/0.6 ml-Pre-Filled Syringe	Made by Roche Diagnostics GmbH for F. Hoffmann-La Roche Ltd. Switzerland	Germany	Third Schedule
Protopic Ointment 0.03%	Fujisawa Healthcare, Inc.	USA	do.
Protopic Ointment 0.1%	do.	do.	do.
Timed Release Super Swiss One "50" Multivitamin and Mineral Caplets with Lutien	Swiss Herbal Remedies Ltd.	Canada	do.
Hi Potency Cal Tablets 650 mg	do.	do.	Freely
Ranitin Injection 25 mg/ml	Torrent Pharmaceuticals Ltd.	India	Third Schedule
Ranitin-150 Film-Coated Tablets	do.	do.	do.
Ranitin-300 Film-Coated Tablets	do.	do.	do.
Cytax 30 Injection 30 mg/5 ml	Intas Pharmaceuticals Ltd.	do.	do.
Cytax 100 Injection 100 mg/16.7 ml	do.	do.	do.
Cytax 200 Injection 200 mg/33.4 ml	do.	do.	do.
Cytax 300 Injection 300 mg/50 ml	do.	do.	do.
Nature Made Vitamin B-1 Tablets 100 mg	Distributed by Nature Made Nutritional Products USA (Product of USA)	USA	Freely
Nature Made Vitamin B-6 Tablets 100 mg	do.	do.	do.
Nature Made Vitamin B-12 Timed Release Tablets 1000 mcg	do.	do.	do.
Nature Made Cod Liver Oil Softgels	do.	do.	do.
Nature Made Maximum Strength Omega-3/Omega-6 Fish Oil Softgels 1200 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Poentimol Sterile Ophthalmic Solution 0.25%	Laboratorios Poen S.A.C.I.F.I.	Argentina	Third Schedule
Dflam Injection	Claris Lifesciences Limited	India	do.
Diretif Injection 10 mg	do.	do.	do.
Eminil Injection	do.	do.	do.
Emistop Injection	do.	do.	do.
Levofloxacin Infusion I.V.	do.	do.	do.
Myotil Injection	do.	do.	do.
Sedoz Injection	do.	do.	Controlled Drug
Cain Injection 50 mg/2 ml	Neon Laboratories Limited	do.	Third Schedule
Itracare Capsules 100 mg	Manufactured by Liconsa S.A. for Sandoz GmbH Austria	Spain	do.
Rispolux Film-Coated Tablets 1 mg	Manufactured by Novartis (Bangladesh) Limited for Sandoz GmbH Austria	Bangladesh	do.
Rispolux Film-Coated Tablets 2 mg	do.	do.	do.
Rispolux Film-Coated Tablets 3 mg	do.	do.	do.
Simplaqor Tablets 40 mg	do.	do.	do.
Lisdene Tablets 5 mg	Manufactured by Delta Ltd. for Sandoz GmbH Austria	Iceland	do.
Lisdene Tablets 10 mg	do.	do.	do.
Lisdene Tablets 20 mg	do.	do.	do.
Apidra Injectable Solution 100 IU/mL—Vials	Aventis Pharma Deutschland GmbH	Germany	do.
Apidra Solution for Injection 100 U/ml in Pre-Filled Pen (OptiSet)	do.	do.	do.
Cytosan Powder for Injection 500 mg	Manufactured by Baxter Oncology GmbH Distributed by Bristol-Myers Squibb Company USA	do.	do.
Cytosan Powder for Injection 1 g	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Sertraline 50 mg Film-Coated Tablets	Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	India	Third Schedule
Ranitidine 25 mg/ml Injection	do.	do.	do.
Strattera Hard Capsules 10 mg	Marketing Authorisation Holder Eli Lilly and Company Limited England (Product of Puerto Rico, USA)	Puerto Rico, USA	do.
Strattera Hard Capsules 18 mg	do.	do.	do.
Strattera Hard Capsules 25 mg	do.	do.	do.
Strattera Hard Capsules 40 mg	do.	do.	do.
Strattera Hard Capsules 60 mg	do.	do.	do.
Rotarix Oral Vaccine	Manufactured by GlaxoSmithKline Biologicals s.a. Belgium Packed by GlaxoSmithKline Mexico, S.A. de C.V.	Mexico	do.
Isorane Liquid for Inhalation	Nicholas Piramal India Limited	India	do.
Ciloxan Ophthalmic Ointment (Change of Source)	Manufactured by S.A. Alcon- Couvreur N.V. for Alcon Laboratories, Inc. USA	Belgium	do.
Combivent Inhalation Aerosol 20ug/120ug /metered dose (Change of Source)	Boehringer Ingelheim do Brasil Quim. e Farm. Ltda.	Brazil	do.
Dianeal PD-2 Peritoneal Dialysis Solution with 1.5% Dextrose (Change of Name of Manufacturer and Additional Source)	Laboratorios Baxter S.A.	Colombia	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Dianeal PD-2 Peritoneal Dialysis Solution with 2.5% Dextrose (Change of Name of Manufacturer and Additional Source)	Laboratorios Baxter S.A.	Colombia	Third Schedule
Dianeal PD-2 Peritoneal Dialysis Solution with 4.25% Dextrose (Change of Name of Manufacturer)	do.	do.	do.
Children's Tylenol Plus Cold Nighttime Oral Suspension—Grape Flavor (Change of Name of Product, Change of Formulation and Overdose Warning)	McNeil Consumer & Specialty Pharmaceuticals Division of McNeil-PPC, Inc.	USA	Freely
Children's Tylenol Plus Cold & Cough Oral Suspension—Cherry Flavor (Change of Formulation and Overdose Warning)	do.	do.	do.
Primoteston Depot Injectable Solution 250 mg (Change of Source)	Schering Mexicana, S.A. de C.V.	Mexico	Third Schedule
Scheriproct Suppositories (Change of Source)	do.	do.	do.
Alkeran Film-Coated Tablets 2 mg (Additional Source)	Heumann Pharma GmbH	Germany	do.
Myleran Film-Coated Tablets 2 mg (Additional Source)	do.	do.	do.
Monopril Tablets 10 mg (Change of Name of Manufacturer and Pediatric Dosing)	Bristol-Myers Squibb Company	USA	do.
Monopril Tablets 20 mg (Change of Name of Manufacturer and Pediatric Dosing)	do.	do.	do.
Daxotel Injection Concentrate 20 mg (Change of Name of Manufacturer and Change of Artwork Design)	Dabur Pharma Ltd.	India	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Solvent for Docetaxel Injection Concentrate-20 (Change of Name of Manufacturer and Change of Artwork Design)	Dabur Pharma Ltd.	India	Third Schedule
Daxotel Injection Concentrate 80 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Solvent for Docetaxel Injection Concentrate-80 (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Fytosid Injection 100 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Intaxel Injection Concentrate 30 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Intaxel Injection Concentrate 100 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Kemocarb Injection 150 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Cytarine Injection 100 mg (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Femara Tablets 2.5 mg (New Indication)	Novartis Pharma AG	Switzerland	do.
Sandostatin LAR 20 mg— Pre-Filled Syringe (Change of Name of Manufacturer and Change of Presentation)	Manufactured by Sandoz GmbH for Novartis Pharma AG Switzerland	Austria	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Canesten Powder (Change of Artwork Design)	Bayer, S.A.	El Salvador	Third Schedule
Canesten Solution (Change of Artwork Design)	do.	do.	do.
Canesten Cream 1% (Change of Artwork Design)	do.	do.	do.
Glucobay 50 Tablets 50 mg (Change of Artwork Design)	do.	do.	do.
Glucobay Tablets 100 mg (Change of Artwork Design)	do.	do.	do.
TriHEMIC 600 Film-Coated Tablets (Change of Name of Manufacturer, Change of Source, Change of Formulation and Change of Packaging)	Wyeth, S.A. de C.V.	Mexico	Freely
Lasix Tablets 40 mg (Change of Artwork Design)	Aventis Pharma S.A.	Guatemala	Third Schedule
Trental Sugar-Coated Tablets 400 mg (Change of Artwork Design)	do.	do.	do.
Daonil Tablets 5 mg (Change of Artwork Design)	do.	do.	do.
Lasix Injectable Solution 20 mg/2 mL (Change of Artwork Design)	Manufactured by Aventis Pharma, S.A. de C.V. Mexico Packed by Aventis Pharma, S.A.	Guatemala	do.
Seroquel Tablets 25 mg (Additional Indication)	AstraZeneca UK Limited	United Kingdom	do.
Seroquel Tablets 100 mg (Additional Indication)	do.	do.	do.
Seroquel Tablets 200 mg (Additional Indication)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Aldara Cream 5% (Additional Indication)	3M Health Care Ltd.	England	Third Schedule
Strepsils Orange with Vitamin C 100 mg Throat Lozenges (Change of Formulation)	The Boots Company PLC	do.	Freely
Endoxan Powder for Injection 200 mg (Change of Name of Manufacturer and Change of Formulation)	Baxter Oncology GmbH	Germany	Third Schedule
Endoxan Powder for Injection 500 mg (Change of Name of Manufacturer and Change of Formulation and Change of Name of Product)	do.	do.	do.
Endoxan Powder for Injection 1 g (Change of Name of Manufacturer, Change of Formulation and Change of Name of Product)	do.	do.	do.
Tamiflu Capsules 75 mg (Additional Indication)	F. Hoffmann- La Roche Ltd.	Switzerland	do.
Evista Film-Coated Tablets 60 mg (Additional Source)	Lilly S.A.	Spain	do.
Zyprexa Powder for Solution for Injection (Change of Source and Additional Indication)	Lilly Pharma Fertigung und Distribution GmbH & Co. KG	Germany	do.
Humulin N Injectable Suspension (Change of Source)	Eli Lilly y Compañía de Mexico S.A. de C.V.	Mexico	do.
Humulin R Injectable Solution (Change of Source)	do.	do.	do.
Humulin 70/30 Injectable Suspension (Change of Source)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
VETERINARY PRODUCT			
Na Pentobarbital Injectable Solution	Kela N.V.	Belgium	Controlled Drug (To Veterinarians or by Veterinary Prescription Only)

Dated this 9th day of August, 2004.

J. RAHAEL
Minister of Health