

LEGAL NOTICE NO. 31

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 to 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>
Biofreeze Pain Relieving Gel with Ilex	Performance Health, Inc.	U.S.A.	Freely
Metrogyl Injection 5 mg/ml (Isotonic)	Unique Pharmaceutical Labs. (A Division of J.B. Chemicals & Pharmaceuticals Ltd.)	India	Third Schedule
Rantac Injection 50 mg/2 ml	do.	do.	do.
Paracetamol Tablets BP	Lincoln Pharmaceuticals Ltd.	do.	Freely
Cartiz Softabs	Wockhardt Limited	do.	do.
Winofit Softgels	do.	do.	do.
Vontrol Tablets 25 mg	Sterling Products International S.A.	Panama	Third Schedule
Mencevax ACWY Vaccine	SmithKline Beecham Biologicals S.A.	Belgium	do.
Femhrt Tablets 1 mg/5 mcg	Manufactured by Duramed Pharmaceuticals, Inc. U.S.A. Distributed by Parke-Davis, Div. of Warner-Lambert Co.	U.S.A.	do.
Aricept Tablets 5 mg	Pfizer S.A.	France	do.
Aricept Tablets 10 mg	do.	do.	do.

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Simplaqor Tablets 10 mg	Novartis (Bangladesh) Ltd.	Bangladesh	Third Schedule
Simplaqor Tablets 20 mg	do.	do.	do.
Clerz Plus Lens Drops	Alcon Laboratories, Inc.	U.S.A.	Freely
Bisolvon Elixir—Pediatric	Boehringer Ingelheim Promeco S.A.	Mexico	Freely
Bisolvon Elixir	do.	do.	do.
Tums Ultra Maximum Strength Tablets— Assorted Mint	SmithKline Beecham Consumer Healthcare, L.P.	U.S.A.	do.
Tums Ultra Maximum Strength Tablets— Assorted Fruit	do.	do.	do.
Flucort-C Skin Ointment	Glenmark Pharmaceuticals Ltd.	India	Third Schedule
Flucort MZ Skin Ointment	do.	do.	do.
Schiff Vitamin B Complex 50 Sustained Release Tablets	Schiff Products	U.S.A	Freely
Schiff Vitamin C 500 Tablets with Rose Hips	do.	do.	do.
Progynova Tablets 2 mg	Schering Colombiana S.A.	Colombia	Third Schedule
Advantan Milk 0.1%	Schering Argentina S.A.I.C.	Argentina	do.
Glucophage Film-Coated Tablets 1000 mg	Lipha S.A.	France	do.
Glucovance Film-Coated Tablets 500 mg/2.5 mg	do.	do.	do.
Glucovance Film-Coated Tablets 500 mg/5 mg	do.	do.	do.
Apo-Pravastatin Tablets 10 mg	Apotex Inc.	Canada	do.
Apo-Pravastatin Tablets 20 mg	do.	do.	do.
Fitzroy Mentholated Koff & Kold Syrup	Fitzroy International Ltd.	U.K.	Freely
Fleet Prep Kit #1	C.B. Fleet Co., Inc.	U.S.A	Third Schedule
Ice Blue Analgesic Pain Relief Therapy Gel	International Cosmetics Co. Ltd.	Trinidad and Tobago	Freely
Lan-30 Hard Gelatin Capsules	Intas Pharmaceuticals Ltd.	India	Third Schedule
Dicloflame Injection 75 mg/3 ml	do.	do.	do.
Diclosal Injection 75 mg/3 ml	Strides Arcolab Ltd.	India	do.

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Ostriol Soft-Gelatin Capsules 0.25 mcg	Strides Arcolab Ltd.	India	Third Schedule
Avelox IV Solution for Intravenous Infusion	Bayer AG Germany for Bayer de Mexico, S.A. de C.V. Packed by Bayer, S.A.	El Salvador	do.
Nyolol Ophthalmic Gel	Novartis Ophthalmics AG	Switzerland	do.
Hypo Tears Plus Eye Drops	Lab. CIBA Vision FAURE	France	do.
Zaditen Eye Drops	do.	do.	do.
Vitalux Plus Time Release Multivitamin/Multimineral Coated Tablets with Lutein	NutriCorp International	Canada	Freely
Baxter Propofol 1% Injection 10 mg/ml—Emulsion for Intravenous Infusion	Baxter Healthcare Ltd.	U.K.	Third Schedule
Cutivate Cream (Additional Source)	Glaxo Wellcome S.A.	Brazil	do.
Dermovate Cream (Additional Source)	do.	do.	do.
Eumovate Cream (Additional Source)	do.	do.	do.
Zovirax Cream (Additional Source)	do.	do.	do.
Zofran Tablets 8 mg (Additional Source)	Made by Glaxo Operations U.K. Ltd. U.K. Packed by Glaxo Wellcome Mexico, S.A. de C.V.	Mexico	do.
Imigran Tablets 50 mg (Additional Source)	do.	do.	do.
Imigran Tablets 100 mg (Additional Source)	do.	do.	do.
Flixotide CFC-Free Inhaler 50 mcg (Change of Propellant)	Glaxo Wellcome Operations	U.K.	do.
Eno Sparkling Salts—Lemon (Additional Source)	GlaxoSmithKline Costa Rica S.A.	Costa Rica	Freely
Alkeran Tablets 2 mg (Additional Source)	Glaxo Wellcome Operations	U.K.	Third Schedule
Simulect Powder and Solvent for Solution for Injection/ Infusion (Additional Indications)	Novartis Pharma AG	Switzerland	do.
D.T.N. Psoriasis Ointment (Change of Name of Product)	V & S Pharmaceuticals Ltd.	Trinidad and Tobago	Freely

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Zyrtec Oral Drops (Additional Source)	UCB Pharma S.p.A.	Italy	Third Schedule
Lacipil Tablets 2 mg (Additional Source)	Packed by Glaxo Wellcome Mexico, S.A. de C.V.	Mexico	do.
Lacipil Tablets 4 mg (Additional Source)	do.	do.	do.
Pantogar Capsules (Change of Artwork Design)	Cimex Ltd. for Merz & Co. Germany	Switzerland	Freely
Progynova Tablets 1 mg (Additional Source)	Schering Colombiana S.A.	Colombia	Third Schedule
Timoptic Sterile Ophthalmic Solution 0.25%—Ocumeter Plus Ophthalmic Dispenser (Change of Source)	Laboratories Merck Sharp & Dohme- Chibret	France	do.
Timoptic Sterile Ophthalmic Solution 0.5%—Ocumeter Plus Ophthalmic Dispenser (Change of Source)	do.	do.	do.
Vermox Suspension 20 mg/ml (Change of Source)	Janssen-Cilag, S.A. de C.V.	Mexico	Freely
Diprivan 1% w/v Intravenous Infusion 10 mg/ml (Change of Name of Manufacturer and Change of Formulation)	Manufactured under contract for AstraZeneca U.K. Ltd United Kingdom by Fresenius Kabi AB	Sweden	Third Schedule
Diprivan 1% w/v Intravenous Injection 10 mg/ml (Change of Name of Manufacturer and Change of Formulation)	do.	do.	do.
Diprivan 1% w/v Intravenous Infusion 10 mg/ml— Pre-Filled Syringe (Change of Name of Manufacturer and Change of Formulation)	Manufactured for AstraZeneca U.K. Ltd United Kingdom by AstraZeneca SpA	Italy	do.
Seroquel Tablets 100 mg (Change of Name of Manufacturer)	AstraZeneca U.K. Limited	United Kingdom	do.
Seroquel Tablets 200 mg (Change of Name of Manufacturer)	do.	do.	do.
Tenoret 50 Tablets (Change of Name of Manufacturer)	do.	do.	do.
Tenoretic Tablets (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>
Zoladex Depot 3.6 mg —Prefilled Injection Applicator (Change of Name of Manufacturer)	AstraZeneca U.K. Ltd.	United Kingdom	Third Schedule
Zoladex LA Depot 10.8 mg— Prefilled Injection Applicator (Change of Name of Manufacturer)	do.	do.	do.
Inderal LA-80 Capsules 80 mg (Change of Name of Manufacturer)	do.	do.	do.
Zestoretic-20 Tablets (Change of Name of Manufacturer)	do.	do.	do.
Arimidex Tablets 1 mg (Change of Name of Manufacturer)	Manufactured by AstraZeneca Pharmaceuticals LP for AstraZeneca U.K. Limited United Kingdom	U.S.A	do.
Xylocaine Injection 1% (10 mg/ml) (Change of Name of Manufacturer)	AstraZeneca AB	Sweden	do.
Xylocaine Injection 2% (20 mg/ml) (Change of Name of Manufacturer)	do.	do.	do.
Xylocaine adrenaline Injection 1% (10 mg/ml+5 ug/ml) (Change of Name of Manufacturer)	do.	do.	do.
Xylocaine adrenaline Injection 2% (20 mg/ml+5 ug/ml) (Change of Name of Manufacturer)	do.	do.	do.
Pulmicort Suspension for Nebulization 0.25 mg/ml (Change of Name of Manufacturer)	do.	do.	do.
Pulmicort Suspension for Nebulization 0.5 mg/ml (Change of Name of Manufacturer)	do.	do.	do.
Marcaine Spinal 0.5 % Heavy Injection 5 mg/ml (Change of Name of Manufacturer)	do.	do.	do.
Naropin Injection 2 mg/ml (0.2%) (Change of Name of Manufacturer)	do.	do.	do.
Naropin Injection 7.5 mg/ml (0.75%) (Change of Name of Manufacturer)	do.	do.	do.

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Naropin Injection 10 mg/ml (1%) (Change of Name of Manufacturer)	AstraZeneca AB	Sweden	Third Schedule
Xylocaine Jelly 2% (Change of Name of Manufacturer)	do.	do.	do.
Insuman N Injectable Suspension 100 IU/mL-Vial (Additional Presentation)	Hoechst Marion Roussel	Germany	do.
Insuman R Injectable Solution 100 IU/mL-Vial (Additional Presentation)	do.	do.	do.
Allegra Film-Coated Tablets 120 mg (Change of Name of Manufacturer)	Aventis Pharma, S.A.	Guatemala	do.
Allegra Film-Coated Tablets 180 mg (Change of Name of Manufacturer)	do.	do.	do.
Allegra D Extended Release Film-Coated Tablets (Change of Name of Manufacturer)	Packed by Aventis Pharma, S.A.	do.	do.
Amaryl Tablets 4.0 mg (Change of Name of Manufacturer)	Aventis Pharma, S.A.	do.	do.
Topisolon Ointment 0.25% (Change of Name of Manufacturer)	do.	do.	do.
Topisolon Ointment 0.05% (Change of Name of Manufacturer)	do.	do.	do.
Lasix Injectable Solution (Change of Name of Manufacturer)	do.	do.	do.
Batrafen Solution (Change of Name of Manufacturer)	do.	do.	do.
Batrafen Nail Lacquer (Change of Name of Manufacturer)	Packed by Aventis Pharma, S.A.	do.	do.
Dermatop Cream (Change of Name of Manufacturer)	Aventis Pharma, S.A.	do.	do.
Losec Powder for IV Infusion 40 mg (Change of Name of Manufacturer)	Packed by Aventis Pharma, S.A.	do.	do.
Tritace Tablets 2.5 mg (Change of Name of Manufacturer)	Aventis Pharma, S.A.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Isordil Sublingual Tablets 5 mg (Change of Label Colour)	Wyeth-Ayerst Canada Inc.	Canada	Third Schedule
Isordil Tablets 10 mg (Change of Label Colour)	do.	do.	do.
Isordil Tablets 30 mg (Change of Label Colour)	do.	do.	do.
Spersadex Eye Drops 0.1% (Change of Name of Manufacturer and Change of Source)	Novartis Ophthalmics AG	Switzerland	do.
Voltaren Ophtha Eye Drops (Change of Name of Manufacturer and Change of Source)	do.	do.	do.
Vitreolent Eye Drops (Change of Name of Manufacturer and Change of Source)	do.	do.	do.
Spersallerg Eye Drops (Change of Name of Manufacturer, Change of Source and Change of Colour of Packaging)	do.	do.	do.
Efemoline Eye Drops (Change of Name of Manufacturer and Change of Source)	do.	do.	do.
Triherpine Eye Drops (Change of Name of Manufacturer and Change of Source)	do.	do.	do.
Oculosan Eye Drops (Change of Name of Manufacturer, Change of Source and Change of Colour of Packaging)	do.	do.	do.
Triherpine Eye Ointment (Change of Name of Manufacturer and Change of Source)	do.	do.	do.
Spersacarpine Eye Drops 2% (Change of Name of Manufacturer and Change of Source)	do.	do.	do.
Liv.52 DS Tablets	The Himalaya Drug Co.	India	Freely

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NutraBasic Caplets	Symmetry Corp.	U.S.A.	Freely
Botana-C Caplets	do.	do.	do.
Botana Cleanse Plus	do.	do.	do.
Quarterly Cleansing System			
Fioton Coated Tablets	Tecnandina S.A.	Ecuador	do.
Mites Out Solution	P.V.U. division of Vetoquinol N.-A. Inc.	Canada	To Veterinarians or by Veterinary Prescription only
LIQUID ADE PLUS	Anglian Nutrition Products Company	England	Freely
Aminovit Liquid	do.	do.	do.
Electro-Vit WSP Water Soluble Powder	do.	do.	do.
Furacin Solution 0.2%	Austin, division of Vetoquinol N.-A. Inc.	Canada	do.
Furacin Soluble Dressing Ointment	do.	do.	do.
Mineralytes + Vitamins Water Soluble Powder	Anglian Nutrition Products Company	England	do.
Vitalyte Water Soluble Powder	do.	do.	do.
Alban Suspension 100 mg/ml	Agropharm Limited	U.K.	do.

Dated this 5th day of March, 2003.

C. IMBERT
Minister of Health