

LEGAL NOTICE NO. 7

REPUBLIC OF TRINIDAD AND TOBAGO

FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

NOTICE OF 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>
Diclo-Denk 50 Enteric Coated Tablets 50 mg (Change of Package Insert)	Denk Pharma GmbH & Co. KG	Germany	Third Schedule
Diclo-Denk 100 Retard Delayed-Release Tablets 100 mg (Change of Package Insert)	do.	do.	do.
Cipro-Denk 500 Film-Coated Tablets 500 mg (Change of Package Insert)	Manufactured by: allphamed PHARBIL Arzneimittel GmbH For: DENK PHARMA GmbH & Co. KG Germany	do.	do.
Member's Selection Vitamin E Softgels 400 I.U. (Change of Name of Legal Entity)	Manufactured by: Avéma Pharma Solutions Distributed by: PriceSmart, Inc., USA	USA	Freely
Member's Selection Calcium +D Caplets 600 mg (Change of Name of Legal Entity)	Avéma Pharma Solutions USA (Product of USA)	do.	do.
PMG Vitamin C Caplets 1000 mg (Change of Name of Legal Entity)	do.	do.	do.

*Approval in Respect of New Drugs*

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Member's Selection Vitamin C Chewable Tablets with Rose Hips 500 mg (Change of Name of Legal Entity)	Manufactured by: Avéma Pharma Solutions Distributed by: PriceSmart Inc. USA	USA	Freely
Member's Selection Omega 3 Fish Oil Softgels 1000 mg (Change of Name of Legal Entity)	do.	do.	do.
Member's Selection Soy Lecithin Softgels 1200 mg (Change of Name of Legal Entity)	do.	do.	do.
PMG Ginkgo Biloba Tablets 60 mg (Change of Name of Legal Entity)	do.	do.	do.
PMG Glucosamine Capsules 750 mg (Change of Name of Legal Entity)	do.	do.	do.
Lastacraft Ophthalmic Solution 0.25% (Change of Name of Manufacturing Site)	Allergan Sales, LLC	do.	Third Schedule
PredForte Ophthalmic Suspension 1% (Change of Name of Manufacturing Site)	do.	do.	do.
Singulair Oral Granules 4 mg (Change of Name of Manufacturing Site)	Patheon Manufacturing Services LLC	do.	do.
Virucid 800 mg Tablets (Change of Name of Manufacturer)	Delorbis Pharmaceuticals Ltd.	Cyprus	do.
Virucid 400 mg Tablets (Change of Name of Manufacturer)	do.	do.	do.
Virucid 200 mg Tablets (Change of Name of Manufacturer)	do.	do.	do.
Fluozal 150 mg Capsules (Change of Name of Manufacturer and 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>
Flucozal 50 mg Capsules (Change of Name of Manufacturer and Change of Artwork Design)	Delorbis Pharmaceuticals Ltd.	Cyprus	Third Schedule
Viprolox 500 mg Film-Coated Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Viprolox 250 mg Film-Coated Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Lasoprol 30 mg Capsules (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Tredol 50 mg Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Tredol 100 mg Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Fluxil 20 mg Capsules (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Ormal 25 mg Tablets (Change of Name of Manufacturer and Change of Artwork Design)	do.	do.	do.
Salve Antiseptic Liquid (Change of Name and Address of Manufacturer, Change of Artwork Design)	Bpi Genethics Limited	Trinidad	Freely
Genethics Sports Balm/Ointment (Change of Name and Address of Manufacturer, 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>
Genethics Zinc & Castor Oil Cream B.P. with Lanolin (Change of Name and Address of Manufacturer, Change of Artwork Design and Change of Product Description)	Bpi Genethics Limited	Trinidad	Freely
Genethics Arthritis Relief Cream (Change of Name and Address of Manufacturer, Change of Artwork Design and Change of Product Description)	do.	do.	do.
Genethics Pain Freeze Gel (Change of Name and Address of Manufacturer, Change of Artwork Design and Change of Product Description)	do.	do.	do.
Genethics Baby Chest Rub/Ointment (Change of Name and Address of Manufacturer and Change of Artwork Design)	do.	do.	do.
Genethics Baby Chest Rub Nighttime/Ointment (Change of Name and Address of Manufacturer, Change of Artwork Design, Change of Product Description)	do.	do.	do.
Beconase Aqueous Nasal Spray/50 mcg (Additional Packaging Site)	Manufactured by: Glaxo Wellcome, S.A Spain Packed by: Glaxo Wellcome S.A de C.V.	Mexico	Third Schedule
Synflorix Suspension for Injection /Prefilled Syringe (Additional Formulation, Change of Packaging and Filling Site and Change of Release Site)	Formulation, Filling, Packaging by: GlaxoSmithKline Biologicals Holder and Release Site: GlaxoSmithKline Biologicals SA Belgium	France	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Seroquel Film-Coated Tablets 25 mg (Change of Manufacturing and Packaging Site)	Manufactured by: AstraZeneca Pharmaceuticals LP USA Packed by: AstraZeneca S.A. De C.V. For: AstraZeneca UK Limited United Kingdom	Mexico	Third Schedule
Seroquel Film-Coated Tablets 300 mg (Change of Manufacturing and Packaging Site)	do.	do.	do.
Voltaren Aerosol Solution 1.16% (Change of Name of Manufacturer)	Manufactured by: Anovis Industrial Farmaceutica Ltda.	Brazil	do.
Methodex Honey & Lemon Lozenges (Change of Formulation and Packaging)	Made in EEC For Bell, Sons & Co. (Druggists) Ltd.	England	Freely
Methodex Menthol & Eucalyptus Lozenges (Change of Formulation and Packaging)	do.	do.	do.
Premarin Tablets 0.3 mg (Change of Name of Manufacturer, Change of Formulation and Change of Artwork Design)	Manufactured and Packaged by: Pfizer Ireland Pharmaceuticals License Holder: Pfizer Healthcare Ireland	Ireland	Third Schedule
Premarin Tablets 0.625 mg (Change of Name of Manufacturer, Change of Formulation and Change of Artwork Design)	do.	do.	do.
Viagra ODT® Orodispersible Tablets 50 mg (Change of Name of Manufacturer)	Manufactured by: Fareva Amboise France Licence Holder: Pfizer Limited	France	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Aleve Coated Tablets 220 mg -Extra Strength-Long Lasting Relief (Change of Primary & Secondary Artwork Design)	Made in Germany By: Bayer Bitterfeld GmbH Packaged by: Bayer S.A.	Guatemala	Freely
Phillip's Milk of Magnesia- Original Liquid (Change of Marketing Authorization Holder and Change of Artwork Design)	Manufactured by: GlaxoSmithKline Costa Rica S.A. For: Aspen Caricam S.A. Costa Rica	Costa Rica	do.
Phillip's Milk of Magnesia- Mint Liquid (Change of Marketing Authorization Holder and Change of Artwork Design)	do.	do.	do.
Xalacom 50 mcg/ml + 5 mg/ml Eye Drop Solution (Change of Artwork Design)	Manufacturer: Pfizer Manufacturing Belgium N.V.	Belgium	Third Schedule

Dated this 10th day of January, 2018

T. DEYALSINGH  
*Minister of Health*