

LEGAL NOTICE NO. 72

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>
Flexitol Heel Balm	Laderma Pty Ltd.	Australia	Freely
Minirin Spray RTS Nasal Spray 10 microg/dose	Manufacturer: FERRING Gmbh Holder: FERRING AG Switzerland	Germany	Third Schedule
Robitussin Night Time Cough & Cold Adults & Children (Alcohol-Free)—Liquid	Wyeth Consumer Healthcare	USA	Freely
Nexium 10 mg Gastro-resistant Granules for Oral Suspension—Sachets	AstraZeneca AB	Sweden	Third Schedule
Difflam Honey Lemon Sugar Free Lozenges	iNova Pharmaceuticals (Aust) Pty Ltd.	Australia	Freely
Difflam Orange Sugar Free Lozenges	do.	do.	do.
Mycophenolate Mofetil Sandoz Film-Coated Tablets 500 mg	Manufactured by: Sandoz Private Ltd. for Sandoz Gmbh Austria	India	Third Schedule
Byetta 5 micrograms solution for injection, prefilled pen 5 µg	Lilly Pharma Fertigung und Distribution GmbH & Co. KG	Germany	Third Schedule
Byetta 10 micrograms solution for injection, prefilled pen 10 µg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Stamaril Yellow Fever Vaccine (Live) Powder and Solvent for Suspension for injection in vial of 10 doses	Sanofi Pasteur S.A.	France	Third Schedule
Janumet Tablets 50 mg/ 500 mg	Manufactured for: Merck Sharp & Dohme (I.A.) Corp. by MOVA PHARMA- CEUTICAL CORPORATION Puerto Rico, USA Packaged by: MERCK SHARP & DOHME DE MEXICO S.A. DE C.V.	Mexico	do.
Janumet Tablets 50 mg/ 850 mg	do.	do	do.
Janumet Tablets 50 mg/ 100 mg	do.	do.	do.
Listerine Antiseptic Mouthwash (Change of Importer/Local Agent)	Distributed by: Pfizer Consumer Healthcare USA (Product of USA)	USA	Freely
Natural Citrus Listerine Antiseptic Mouthwash (Change of Importer/Local Agent)	do.	do.	do.
Fresh Burst Listerine Antiseptic Mouthwash (Change of Importer/Local Agent)	do.	do.	do.
Cool Mint Listerine Antiseptic Mouthwash (Change of Importer/Local Agent)	do.	do.	do.
Advanced Listerine with Tartar Protection Antiseptic Mouthwash—Arctic Mint™ (Change of Importer/Local Agent)	do.	do.	do.
Listerine Tooth Defense Anticavity Fluoride Rinse-Mint Shield Flavor (Change of Importer/Local Agent)	do.	do.	do.
Listerine Essential Care ® Toothpaste—Powerful Mint Paste (Change of Importer/Local Agent)	do.	do.	do.
Listerine Essential Care ® Toothpaste—Powerful Mint Gel (Change of Importer/Local Agent)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Tartar Control Listerine Essential Care © Tooth- paste—Powerful Mint Gel (Change of Importer/Local Agent)	Distributed by: Pfizer Consumer Healthcare USA (Product of USA)	USA	Freely
Nexium Tablets 20 mg (Additional Source)	Made by: AstraZeneca AB Sweden Packed and distri- buted by: AstraZeneca, S.A. de C.V.	Mexico	Third Schedule
Nexium Tablets 40 mg (Additional Source)	do.	do.	do.
Crestor Coated Tablets 10 mg (Additional Source)	Made by: IPR Pharmaceu- ticals Inc. Puerto Rico for AstraZeneca UK Limited, England Packed and distri- buted by: AstraZeneca, S.A. de C.V.	do.	do.
Zestril Tablets 10 mg (Additional Source, Change of Size of Packaging and Change of Artwork Design)	AstraZeneca, S.A. de C.V.	do.	do.
Zestril Tablets 20 mg (Additional Source, Change of Size of Packaging and Change of Artwork Design)	do.	do.	do.
Difflam Doublemint Sugar Free Lozenges (Change of Name of Manu- facturer)	iNova Pharmaceu- ticals (Aust) Pty Ltd.	Australia	Freely
Difflam Eucalyptus & Menthol Sugar Free Lozenges (Change of Name of Manu- facturer)	do.	do.	do.
Difflam Raspberry Sugar Free Lozenges (Change of Name of Manu- facturer)	do.	do.	do.
Difflam Solution (Change of Name of Manu- facturer)	do.	do.	do.
Difflam mouth gel (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>
Diffiam extra strength gel 5% w/w (Change of Name of Manufacturer and Change of Artwork Design)	iNova Pharmaceu- ticals (Aust) Pty Ltd.	Australia	Freely
Noristerat Injectable Solu- tion 200 mg/ml (Change of Name of Manu- facturer and Additional Source)	Bayer Schering Pharma AG	Germany	Third Schedule
Tarceva Film-Coated Tablets 25 mg (Additional Source)	F. Hoffmann- La Roche Ltd.	Switzerland	do.
Tarceva Film-Coated Tablets 150 mg (Additional Source)	do.	do.	do.
Pegasys Solution for Injection 180 micrograms/0.5 ml—Pre- Filled Syringe (Additional Source)	Made for: F. Hoffmann- La Roche Ltd. Switzerland By Roche Diagnostics GmbH	Germany	do.
Allegra Film-Coated Tablets 120 mg (Change of Name of Manu- facturer)	Manufactured by: sanofi-aventis U.S. LLC USA Packed by: Lancasco S.A. for sanofi-aventis de Guatemala S.A. Guatemala	Guatemala	do.
Allegra Film-Coated Tablets 180 mg (Change of Name of Manu- facturer)	do.	do.	do.
Allegra D Extended Release Film-Coated Tablets (Change of Name of Manu- facturer)	do.	do.	do.
Excedrin Migraine Caplets (Change of Name of Manu- facturer and Change of Artwork Design)	Distributed by: Novartis Consumer Health, Inc., (Product of USA) USA	USA	Freely
Excedrin Tension Headache Caplets (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>
Maximum Strength Comtrex Non-Drowsy Cold & Cough Coated Caplets (Change of Name of Manufacturer and Change of Artwork Design)	Distributed by: Novartis Consumer Health, Inc., (Product of USA) USA	USA	Freely
Stamaril Yellow Fever Vaccine (Live) Powder and Solvent for Suspension for Injection in Prefilled Syringe (Change of Name of Manufacturer)	Sanofi Pasteur S.A.	France	Third Schedule
Refresh Liquigel Lubricant Eye Drops (Sterile) (Change of Artwork Design)	Allergan, Inc.,	USA	Freely
Viread Film-Coated Tablets 300 mg (Additional Source)	Manufactured by: Nycomed Oranien- bury GmbH for Gilead Sciences, Inc. USA	Germany	Third Schedule
Truvada Film-Coated Tablets (Additional Source)	do.	do.	do.
Stadex 40 Film-Coated Tablets 40 mg	ajanta pharma limited	India	do.
Trindid TV Suspension	Manufactured by: U SQUARE LIFESCIENCE PVT. LTD. for Trinpharm Co. Ltd. Trinidad	do.	do.
Trinclob Cream 0.05%	do.	do.	do.
U-Lene Gel 0.1%	do.	do.	do.
Veterinary Product			
Ivomec ® Eprinex Pour-On for Beef and Dairy Cattle (Change of Source)	Manufactured by: Agenta manufacturing Limited for Merial Limited USA	New Zealand	Freely

Dated this 22nd day of January, 2009.

J. NARACE
Minister of Health