

LEGAL NOTICE NO. 119

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 Cold Multi-Symptom Rapid Release Gels-RR Gelcaps (DAYTIME, Non-Drowsy)	Distributed by McNeil Consumer Healthcare DIVISION OF MCNEIL-PPC, INC. USA (Product of USA)	USA	Freely
Tylenol Sinus Congestion & Pain Rapid Release Gels-RR Gelcaps (DAYTIME, Non-Drowsy)	do.	do.	do.
Endometrin Vaginal Tablets	Manufactured by Ben Chimon FLORISH Ltd. for Ferring Pharmaceuticals Ltd. Israel	Israel	Third Schedule
Omega-3 Fish Oil Softgels 1200 mg—Lemon Flavour	Natrol, Inc.	USA	Freely
Extreme Omega Softgels 1200 mg—Lemon Flavour	do.	do.	do.
Omega 3.6.9 Softgels—Lemon Flavour	do.	do.	do.
Benadryl Allergy Ultratab Tablets	Distributed by Pfizer Consumer Healthcare USA (Product of Puerto Rico, USA)	Puerto Rico USA	do.
Benadryl Allergy & Sinus Headache Caplets	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Panadol Instants, Crystals 1000 mg-Sachets-Refreshing Mint Flavour	GlaxoSmithKline Consumer Healthcare (Block Drug Company, Inc.)	USA	Freely
Avandaryl Tablets 4 mg/1 mg	Manufactured by SmithKline Beecham Corporation d/b/a GlaxoSmithKline USA Packed by GlaxoSmithKline	Canada	Third Schedule
Avandaryl Tablets 4 mg/2 mg	do.	do.	do.
Avandaryl Tablets 4 mg/4 mg	do.	do.	do.
Aclasta Solution for Infusion 5 mg	Manufactured by Norvatis Pharma Stein AG for Norvatis Pharma Schweiz AG Switzerland	Switzerland	do.
Visine Tears Lasting Relief Lubricant Eye Drops	Distributed by Pfizer Consumer Healthcare USA (Product of USA)	USA	Freely
Desitin Clear White Petro- latum Diaper Rash & Skin Protectant Multi-Purpose Ointment	do.	do.	do.
Benadryl Allergy & Cold Caplets	Distributed by Pfizer Consumer Healthcare USA (Product of Puerto Rico, USA)	Puerto Rico, USA	do.
Nexavar Film-Coated Tablets 200 mg	Bayer Healthcare AG	Germany	Third Schedule (To Registered Oncologists ONLY)
Rasilez Film-Coated Tablets 150 mg	Manufactured by Norvatis Pharma Stein AG for Norvatis Pharma Schweiz AG Switzerland	Switzerland	Third Schedule
Rasilez Film-Coated Tablets 300 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Truvada Film-Coated Tablets (Additional Source)	Pharmacare Limited trading as Aspen Pharmacare	South Africa	Third Schedule
Viread Tablets (Additional Source)	do.	do.	do.
Panadol PM Extra Strength Tablets (Change of Name of Manufacturer, Change of Source of Bulk, Change of Artwork Design and Change of Primary Packaging)	Made by GlaxoSmithKline (Dungarvan) Ireland Packed by GlaxoSmithKline Panamá, SA	Panama	Freely
Children's Panadol (2—6 yrs.) Chewable Tablets—Cherry Flavour (Change of Name of Manufacturer and Change of Artwork Design)	GlaxoSmithKline Panamá, SA	do.	do.
Lipitor Tablets 10 mg (Additional Indication)	Manufactured by Pfizer Ireland Pharmaceuticals Ireland Packaged by Pfizer GmbH Arneimittelwerk	Germany	Third Schedule
Lipitor Tablets 20 mg (Additional Indication)	do.	do.	do.
Lipitor Tablets 40 mg (Additional Indication)	do.	do.	do.
Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM ₁₉₇ Protein) Prevnar® -Disposable Syringes (Additional Presentation)	Wyeth Pharmaceuticals Inc.	USA	do.
Cataflam 50 Coated Tablets 50 mg (Additional Source)	Manufactured by Novartis Ürünleri for Novartis Pharma AG Switzerland	Turkey	do.
Intalfa Solution for Subcutaneous Injection 3MIU/1 ml PFS	Intas Biopharmaceuticals Ltd.	India	do.
Intalfa Solution for Subcutaneous Injection 5MIU/1 ml PFS	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Zestoretic Tablets (Lisino- pril anhydrous 20 mg Hydrochlorothiazide 12.5 mg) (Additional Source)	AstraZeneca, S.A. de C.V., Mexico	Mexico	Third Schedule

Dated this 8th day of May, 2008.

J. NARACE
Minister of Health