

LEGAL NOTICE NO. 235

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 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>
Hyoscine Butylbromide Injection BP 20 mg	Rotex Medica	Germany	Third Schedule
Pancuronium Injection BP 4 mg	do.	do.	do.
Oralcon Sugar-Coated Tablets	Famy Care Ltd.	India	do.
Cerebrolysin Solution for Injection	EBEWE Arzneimittel Ges.m.b.H. Pharmaceutical Laboratories	Austria	do.
Amoebriz Tablets	Janssen-Cilag, S.A. de C.V.	Mexico	do.
Bursaplex™ Bursal Disease Vaccine, Live Virus	Manufactured by Merial Select, Inc. Distributed by Embrex, Inc. USA	USA	To Veterinarians or by Veterinary Prescription Only
Estrofem 1 mg Film-Coated Tablets	Novo Nordisk A/S	Denmark	Third Schedule
Vagifem Film-Coated Vaginal Tablets	do.	do.	do.
Novofem Film-Coated Tablets	do.	do.	do.
Apo-Hydroxyquine Film-Coated Tablets 200 mg	Apotex Inc.	Canada	do.
Apo-Fluconazole Tablets 50 mg	do.	do.	do.
Apo-Paroxetine Film-Coated Tablets 20 mg	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Betaferon Powder and Solvent for Solution for Injection 0.25 mg	Schering AG	Germany	Third Schedule
Coral Calcium + Caplets	Distributed by Vitacorp International (Product of USA)	USA	Freely
Super Stress B Compound with 1000 mg Vitamin C Caplets	Swiss Herbal Remedies Ltd.	Canada	do.
Vitamin C 1000 mg Timed Release Caplets	do.	do.	do.
Schiff Glucosamine 1500 mg Plus MSM 1500 mg per 3 Tablets	Distributed by Schiff Products (Product of USA)	USA	do.
Tylex Flu Tablets	Janssen-Cilag S.A. de C.V.	Mexico	do.
Ziac 10/6.25 Film-Coated Tablets	Merck S.A.	Colombia	Third Schedule
Dolo-Neurobiön N Injectable Solution	Merck S.A. de C.V.	Mexico	do.
Dolo-Neurobiön N Film-Coated Tablets	do.	do.	do.
Flogozán Film-Coated Tablets	do.	do.	do.
Flogozán Drops	do.	do.	do.
Ambril Drops 7.5 mg/ml	Manufactured by Aventis Pharma, S.A. for Merck, S.A. Guatemala	Guatemala	do.
Ambril Solution 15 mg/5 ml	do.	do.	do.
Oral-Dent Antiseptic Mouth Rinse—Amber	Manufactured by International Cosmetics Limited for AM & Associates Inc. Puerto Rico	Trinidad and Tobago	Freely
Oral-Dent Antiseptic Mouth Rinse—Fresh Mint	do.	do.	do.
Oral-Dent Antiseptic Mouth Rinse—Blue Mint	do.	do.	do.
Nexium Powder for Solution for Injection/ Infusion 40 mg	AstraZeneca AB	Sweden	Third Schedule
Redin Plus Capsules	Fourrts (India) Laboratories Pvt. Limited	India	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Pilocar 2% Eye Drops	FDC Limited	India	Third Schedule
Pilocar 4% Eye Drops	do.	do.	do.
Zoxan Eye/Ear Drops	do.	do.	do.
Allercrom Eye Drops 2%	do.	do.	do.
Moisol PFS Solution	do.	do.	do.
Shanferon rHuIFN-a2b Lyophilised Powder for Reconstitution for Injection 3 million IU	Shantha Biotechnics Pvt. Ltd.	do.	do.
Shanvac-B Genetically Engineered Recombinant Vaccine	do.	do.	do.
Avodart Soft Capsules 0.5 mg	RP Scherer S.A.	France	do.
Stalevo Film-Coated Tablets 50/12.5/200 mg	Manufactured by Orion Corporation for Novartis Pharma AG Switzerland	Finland	do.
Stalevo Film-Coated Tablets 100/25/200 mg	do.	do.	do.
Stalevo Film-Coated Tablets 150/37.5/200 mg	do.	do.	do.
Glivec Film-Coated Tablets 100 mg	Novartis Pharma AG	Switzerland	do.
Glivec Film-Coated Tablets 400 mg	do.	do.	do.
Serolux Film-Coated Tablets 50 mg	Manufactured by Novartis (Bangladesh) Limited for Biochemie GmbH Austria	Bangladesh	do.
Estalis 50/140 Transdermale Patches	Manufactured by Noven Pharmaceuticals Inc. for Novartis Pharmaceuticals Corporation USA	USA	do.
Estalis 50/250 Transdermale Patches	do.	do.	do.
Zocon Eye Drops	FDC Limited	India	do.
Electral Forte Oral Rehydration Salts	do.	do.	Freely
Cotaryl Cream	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Apo-Simvastatin Tablets 20 mg	Apotex Inc.	Canada	Third Schedule
Pegasys Solution for Injection 135 mcg/0.5 ml —Pre-Filled Syringe	F. Hoffmann- La Roche Ltd.	Switzerland	do.
Pegasys Solution for Injection 180 mcg/0.5 ml —Pre-Filled Syringe	do.	do.	do.
Zyprexa Powder for Solution for Injection 10 mg	Lilly Pharma Fertigung und Distribution GmbH & Co. KG	Germany	do.
Glucosamine Chondroitin with Stomach Guard Tablets	Nature's Way Products Inc.	USA	Freely
Albendazole Suspension	Manufactured by Meditab Specialities Pvt. Ltd. for Health 2000 Inc. Canada	India	do.
Cetirizine Syrup	do.	do.	Third Schedule
Salbutamol Sulphate and Guaiphenesin Expectorant	do.	do.	Freely
Ebetaxel Concentrate for Infusion 30 mg/5 ml- 30 mg	EBEWE Pharma Ges.m.b.H.Nfg. KG	Austria	Third Schedule
Ebetaxel Concentrate for Infusion 100 mg/16.6 ml- 100 mg	do.	do.	do.
Ebetaxel Concentrate for Infusion 150 mg/25 ml- 150 mg	do.	do.	do.
Ebetaxel Concentrate for Infusion 300 mg/50 ml- 300 mg	do.	do.	do.
Endobulin S/D 500 mg Immunoglobulin (Human) for Intravenous Use, Freeze-Dried Virus Inactivated	Baxter AG	do.	do.
Endobulin S/D 2500 mg Immunoglobulin (Human) for Intravenous Use, Freeze-Dried Virus Inactivated	do.	do.	do.
Endobulin S/D 5000 mg Immunoglobulin (Human) for Intravenous Use, Freeze-Dried Virus Inactivated	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Endobulin S/D 10000 mg Immunoglobulin (Human) for Intravenous Use, Freeze-Dried Virus Inactivated	Baxter AG	Austria	Third Schedule
Mirelle Film-Coated Tablets (Change of Source)	Manufactured by Wyeth Medica Ireland Packed by Schering Columbiana, S.A.	Columbia	do.
Econaderm Solution (Change of Name of Product and Change of Packaging)	Carlisle Laboratories Ltd.	Barbados	do.
Allegra Film-Coated Tablets 120 mg (Additional Source)	Manufactured by Aventis Pharmaceuticals, Inc. USA Packed and Distributed by Aventis Pharma, S.A.	Guatemala	do.
Calcort Tablets 6 mg (Additional Source)	Manufactured by Aventis Pharma, S.p.A. Italy Packed by Aventis Pharma, S.A.	do.	do.
Lopresor 100 Coated Tablets 100 mg (Additional Source)	Manufactured by Novartis Ürünleri A.S. for Novartis Pharma A.G. Switzerland	Turkey	do.
Minulet Tablets (Additional Source)	Wyeth Medica Ireland	Ireland	do.
Trinordiol Tablets (Additional Source)	do.	do.	do.
Nordette Tablets (Additional Source)	do.	do.	do.
Procmil s/c Tablets 5 mg (Regularization of Registration)	Walter Ritter GmbH + Co.	Germany	do.
Ethylchloride Spray (Regularization of Registration)	do.	do.	do.
Oilatum Natural Soap (Change of Name of Product and Change of Source)	Stiefel Mexicana, S.A. de C.V.	Mexico	Freely

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Hemofil M Antihemophilic Factor (Human) Method M, Monoclonal Purified FVIII Powder for Reconstitution and Sterile Water for Injection, USP (Change of Artwork Design and Change of Labelling)	Baxter Healthcare Corporation	USA	Third Schedule
Xeloda Tablets 500 mg (Additional Indication)	Made by Hoffmann-La Roche Inc. for F. Hoffmann-La Roche Ltd. Switzerland	do.	do.
Bactrim forte Tablets 800/160 mg (Additional Source)	Produtos Roche Químicos e Farmacêuticos S.A.	Brasil	do.
Coreg Tablets 6.25 mg (Additional Source)	do.	do.	do.
Coreg Tablets 12.5 mg (Additional Source)	do.	do.	do.
Coreg Tablets 25 mg (Additional Source)	do.	do.	do.

Dated this 5th day of July, 2004.

J. RAHAEL  
*Minister of Health*

