

LEGAL NOTICE NO. 150

REPUBLIC OF TRINIDAD AND TOBAGO

FOOD AND DRUGS ACT, CHAP. 30:01

NOTIFICATION

APPROVAL IN RESPECT OF NEW DRUGS

ISSUED by the Minister of Health on the advice of the Drug Advisory Committee, in accordance with paragraph 7, Division 3 of the Second Schedule of the Food and Drugs Regulations.

The Minister of Health 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> |
|--|---|--------------------------|--------------------------|
| pms-Valproic Acid Capsules 250 mg | Pharmascience Inc. | Canada | Third Schedule |
| pms-Timolol Ophthalmic Solution 0.5% | do. | do. | do. |
| pms-Bromocriptine Tablets 2.5 mg | do. | do. | do. |
| pms-Propranolol Tablets 40 mg | do. | do. | do. |
| pms-Atenolol Tablets 50 mg | do. | do. | do. |
| pms-Lithium Carbonate Capsules 300 mg | do. | do. | do. |
| pms-Metoclopramide Tablets 10 mg | do. | do. | do. |
| pms-Isoniazid Tablets 100 mg | do. | do. | do. |
| Asaphen EC Delayed-Release Tablets 81 mg | do. | do. | Freely |
| Aerius Tablets 5 mg | Schering-Plough Labo N.V. | Belgium | Third Schedule |
| Clariflu Sustained-Release Tablets | Schering-Plough, S.A. DE C.V. | Mexico | do. |
| Metalyse 6,000 U Powder and Solvent for Solution for Injection | Manufactured by Boehringer Ingelheim Pharma KG forBoehringer Ingelheim International GmbH | Germany | do. |
| Metalyse 8,000 U Powder and Solvent for Solution for Injection | do. | do. | do. |

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| Metalysse 10,000 U Powder and Solvent for Solution for Injection | Manufactured by Boehringer Ingelheim Pharma KG for Boehringer Ingelheim International GmbH | Germany | Third Schedule |
| Cellugel Ophthalmic Visco-surgical Device | Distributed by Alcon Laboratories, Inc. USA Made by Alcon-Couvreur | Belgium | do. |
| Filgen 30 MIU Injectable Solution | Laboratorios Gautier S.A. Argentina | Argentina | do. |
| Growgen-GM 300 ug Injectable Lyophilized Powder and Solvent for Solution for Injection | do. | do. | do. |
| INF 5 MIU Injectable Lyophilized Powder and Solvent for Solution for Injection | do. | do. | do. |
| VP-gen Injectable Solution 100 mg | do. | do. | do. |
| Panataxel Injectable Solution 30 mg | do. | do. | do. |
| Panataxel Injectable Solution 100 mg | do. | do. | do. |
| Panataxel Injectable Solution 300 mg | do. | do. | do. |
| Mitoxgen Injectable Solution 20 mg | do. | do. | do. |
| Fluoxetine Capsules 20 mg | Norton Health-care Ltd. | England | do. |
| Salamol CFC-Free Inhaler | Norton (Waterford) Ltd. | Ireland | do. |
| Salamol Easi-Breathe CFC-Free Inhaler | do. | do. | do. |
| Salamol 2.5 mg Steri-Neb Nebuliser Solution | do. | do. | do. |
| Salamol 5 mg Steri-Neb Nebuliser Solution | do. | do. | do. |
| Beclazone 50 Easi-Breathe CFC-Free Inhaler | do. | do. | do. |
| Beclazone 100 Easi-Breathe CFC-Free Inhaler | do. | do. | do. |

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| Beclazone 250 Easi-Breathe CFC Free Inhaler | Norton (Waterford Ltd. | Ireland | Third Schedule |
| Beclazone 50 CFC-Free Inhaler | do. | do. | do. |
| Beclazone 100 CFC-Free Inhaler | do. | do. | do. |
| Beclazone 250 CFC-Free Inhaler | do. | do. | do. |
| Cardioace Capsules | Vitabiotics Ltd. | England | Freely |
| Visionace Capsules | do. | do. | do. |
| Dr. Meyer's FER-B-VIT Liquid | Meyer Organics Ltd. | India | do. |
| Becoactin Syrup | do. | do. | do. |
| MIM Drops | do. | do. | do. |
| Clasifel Cream | Stiefel Mexicana, S.A. de C.V. | Mexico | Third Schedule |
| Novagesic-Flu Capsules | Scanpharm | Denmark | Freely |
| Nimegesic T-Gel 1% | Alembic Limited | India | Third Schedule |
| Bro Zeet Liquid | do. | do. | do. |
| Cancidas Powder for Injection 50 mg | Merck & Co., Inc. | USA | do. |
| Cancidas Powder for Injection 70 mg | do. | do. | do. |
| Vioxx Tablets 50 mg | Merck Sharp & Dohme (I.A.) Corp. | Costa Rica | do. |
| Hyzaar Tablets 100/25 mg | do. | do. | do. |
| Atropine Injection BP 0.6 mg/mL | Bioniche Inc. | Canada | do. |
| Carbachol Tablets 2 mg | Bioniche Pharma, Division of Bioniche Inc. | do. | do. |
| Dextrose 50% Injection USP | do. | do. | do. |
| Parvolex Injection 200 mg/mL | do. | do. | do. |
| Promethazine Hydrochloride Injection USP 25 mg/mL | Bioniche Inc. | do. | do. |
| Metoclopramide Hydrochloride Injection HS 5 mg/mL | Bioniche Pharma, Division of Bioniche Inc. | do. | do. |
| 1% Lidocaine Hydrochloride Injection USP | Bioniche Inc. | do. | do. |
| 2% Lidocaine Hydrochloride Injection USP | Bioniche Pharma, Division of Bioniche Inc. | do. | do. |
| 2% Lidocaine Hydrochloride & Epinephrine Injection USP | do. | do. | do. |
| Succinylcholine Chloride Inj. USP | do. | do. | do. |

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| Chlorpromazine Hydrochloride Injection USP 50 mg/2 mL | Bioniche Inc. | Canada | Third Schedule |
| Gengraf Capsules 25 mg | Abbott Laboratories | USA | do. |
| Gengraf Capsules 50 mg | do. | do. | do. |
| Gengraf Capsules 100 mg | do. | do. | do. |
| Serlift Film-Coated Tablets 25 mg | Ranbaxy Laboratories Limited | India | do. |
| Serlift Film-Coated Tablets 50 mg | do. | do. | do. |
| Serlift Film-Coated Tablets 100 mg | do. | do. | do. |
| Covance 25 Film-Coated Tablets 25 mg | do. | do. | do. |
| Covance 50 Film-Coated Tablets 50 mg | do. | do. | do. |
| Plendil Extended Release Tablets 2.5 mg | Astra | Sweden | do. |
| Pulmicort Turbuhaler Powder Inhaler 100 micrograms/dose | do. | do. | do. |
| Casodex Tablets 150 mg | Manufactured by Zeneca GmbH for Zeneca Limited UK | Germany | do. |
| Betaloc Solution For Injection 1 mg/mL | Astra | Sweden | do. |
| Betaloc ZOK Controlled Release Tablets 50 mg | do. | do. | do. |
| Betaloc ZOK Controlled Release Tablets 100 mg | do. | do. | do. |
| Betaloc ZOK Controlled Release Tablets 200 mg | do. | do. | do. |
| Entocort Modified Release Capsules 3 mg | do. | do. | do. |
| Tritace Tablets 10 mg | Aventis Pharma, S.A. | Guatemala | do. |
| Stimuloton Film-Coated Tablets 50 mg | Egis Pharmaceuticals Ltd. | Hungary | do. |
| Viramune Tablets 200 mg (Changes in Basic Product Information) | Boehringer Ingelheim (Canada) Ltd. | Canada | do. |
| Viramune Oral Suspension 50 mg/5 mL (Changes in Basic Product Information) | Roxane Laboratories Inc. | USA | do. |
| Lotrisone Cream (Additional Source) | Schering-Plough Labo N.V. | Belgium | do. |

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| Theragran-M Advanced Formula Caplets (Change of Packaging) | Bristol-Myers Squibb Com- pany, China for Bristol-Myers Products | USA | Freely |
| Taxol Injection 30 mg (6 mg/mL) (Change of Name of Manufacturer) | Bristol-Myers Squibb Caribbean Company | Puerto Rico | Third Schedule |
| Taxol Injection 100 mg (6 mg/mL) (Change of Name of Manufacturer) | do. | do. | do. |
| Taxol Injection 300 mg (6 mg/mL) (Change of Name of Manufacturer) | do. | do. | do. |
| Clinoril Tablets 200 mg (Change of Country of Manufacture) | Merck Sharp & Dohme (I.A.) Corp. | Costa Rica | do. |
| Efudix Cream (Change of Name of Manufacturer) | ICN Pharma- ceuticals Ltd. | UK | do. |
| Redoxon Chewable Vitamin C Sugar Free Tablets 500 mg- Orange (Change of Packaging) | Roche Consumer Health | do. | Freely |
| Redoxon Effervescent Vitamin C Tablets 1000 mg-Black- currant (Change of Packaging) | do. | do. | do. |
| Redoxon Effervescent Vitamin C Tablets 1000 mg-Lemon (Change of Packaging) | do. | do. | do. |
| Redoxon Effervescent Vitamin C Tablets 1000 mg-Orange (Change of Packaging) | do. | do. | do. |
| Carbocaine 3% Injection (Change of Name of Manufacturer) | Manufactured by Abbott Labora- tories Marketed by Eastman Kodak Company, Dental Products USA | USA | Third Schedule |
| Carbocaine 2% with Neo- Cobefrin Injection (Change of Name of Manufacturer) | do. | do. | do. |

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| Lasix Injectable Solution 20 mg/mL (Additional Source of Manufacture) | Manufactured by Aventis Pharma, S.A. de C.V. Mexico Packaged by Aventis Pharma, S.A. | Guatemala | Third Schedule |
| Calcort Tablets 30 mg (Additional Source of Manufacture) | Manufactured by Aventis Pharma, S.p.A. Italy Packaged by Aventis Pharma, S.A. | Guatemala | do. |
| Calcort Oral Suspension Drops 22.75 mg/mL (Additional Source) | Manufactured by Gruppo Lepetit S.p.A. Distri- buted by Aventis Pharma S.A. Guatemala | Italy | do. |
| Xanax XR Extended-Release Tablets 0.5 mg (Change of Name of Manufacturer and Change of Artwork Design) | Pharmacia N.V./S.A./ | Belgium | Controlled |
| Xanax XR Extended-Release Tablets 1 mg (Change of Name of Manufacturer and Change of Artwork Design) | do. | do. | do. |
| Lignocaine Injection 1% (50 mg/5 mL) (Change of Name of Manufacturer) | Pharmacia & Upjohn (Perth) Pty Limited | Australia | Third Schedule |
| Lignocaine Injection 2% (100 mg/5 mL) (Change of Name of Manufacturer) | do. | do. | do. |
| Allesse-21 Tablets (Change of Name of Product and Change of Artwork Design) | Wyeth Labora- tories Inc. A Wyeth-Ayerst Company | USA | do. |
| Voltaren 50 Enteris-Coated Tablets (Additional Source) | Manufactured by Novartis Farma S.p.A. for Novartis Pharma AG, Switzerland | Italy | do. |
| Sirdalud Tablets 4 mg (Additional Source) | Manufactured by Novartis Pharma GmbH for Novartis Pharma AG, Switzerland | Germany | do. |

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| Xylocaine 10% Spray Solution (10 mg/puff) (Prior 1965: Regularization of Status) | Astra | Sweden | Third Schedule |
| Marcaine 0.25% Injection (2.5 mg/mL) (Prior 1965: Regularization of Status) | do. | do. | do. |
| Marcaine 0.5% Injection (5 mg/mL) (Prior 1965: Regularization of Status) | do. | do. | do. |
| Marcaine spinal 0.5% heavy Injection (5 mg/mL) (Prior 1965: Regularization of Status) | do. | do. | do. |
| Evana Film-Coated Tablets | Plantamed Arzneimittel GmbH for Boehringer Ingelheim International GmbH | Germany | do. |
| Menofem Film-Coated Tablets | do. | do. | do. |
| Nutraplex Tablets | Arnet Pharmaceutical Corp. | USA | Freely |
| Stresscom Capsules | Dabur India Ltd. | India | Third Schedule |
| New Livfit Film-Coated Tablets | do. | do. | Freely |
| Agiolax Granulate-5 g Sachets | Manufactured by Tecnandina S.A. for Grunenthal Ecuatoriana C. LTDA. under license of Madaus AG Laboratories Germany | Ecuador | Third Schedule |
| Agiolax Granulate-100 g High Density Polyethylene Bottle | do. | do. | do. |
| Benjie's Arthritis Balm | V & S Pharmaceuticals Ltd. | Trinidad and Tobago | Freely |

Dated this 28th day of October, 2002.

C. IMBERT
Minister of Health