

LEGAL NOTICE NO. 13

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> |
|---|-------------------------------|--------------------------|--------------------------|
| Demol Tablets BP | Dee-Pharma Limited | India | Freely |
| Peristil Suspension | Dr. Reddy's Laboratories Ltd. | do. | Third Schedule |
| Peristil-10 Tablets | do. | do. | do. |
| Peristil-5 Tablets | do. | do. | do. |
| Nise Tablets | do. | do. | do. |
| Nise Suspension | do. | do. | do. |
| Stamlo-10 Tablets | do. | do. | do. |
| Stamlo-5 Tablets | do. | do. | do. |
| Osetron Tablets 4 mg | do. | do. | do. |
| Osetron Tablets 8 mg | do. | do. | do. |
| Osetron Injection 4 mg | do. | do. | do. |
| Cetrine Tablets | do. | do. | do. |
| Cetrine Syrup | do. | do. | do. |
| Lanzap Capsules | do. | do. | do. |
| Lomaday Tablets | do. | do. | do. |
| Tisane des Chartreux de Durbon | Carlisle Laboratories Ltd. | Barbados | Freely |
| Sodium Chloride 0.9% w/v and Dextrose 5% w/v Injection B.P. | Bieffe Medital S.A. | Spain | Third Schedule |
| Sodium Chloride Injection 0.9% w/v B.P. | do. | do. | do. |
| Dextrose Injection 5% w/v B.P. | do. | do. | do. |
| Peritoneal Dialysis Solution with Dextrose 4.25% | do. | do. | do. |
| Peritoneal Dialysis Solution 2.5% | do. | do. | do. |
| Peritoneal Dialysis Solution with Dextrose 1.5% | do. | do. | do. |

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|--|-------------------------------------|--------------------------|--------------------------|
| Beclotrim Cream | BDH Industries Ltd. | India | Third Schedule |
| Clotrimazole Vaginal Tablets U.S.P. | do. | do. | Freely |
| AquaPak 0.45% Sodium Chloride Inhalation U.S.P. | Hudson RC1 | U.S.A. | Third Schedule |
| AquaPak 0.9% Sodium Chloride Inhalation U.S.P. | do. | do. | do. |
| AquaPak Sterile Water for Inhalation U.S.P. | do. | do. | do. |
| Concha Sterile Water for Inhalation U.S.P. | do. | do. | do. |
| AddiPak Sterile Water for Inhalation U.S.P. | do. | do. | do. |
| AddiPak Sterile 0.45% Sodium Chloride Solution for Inhalation U.S.P. | do. | do. | do. |
| AddiPak 3ml Sterile 0.90% Sodium Chloride Solution for Inhalation U.S.P. | do. | do. | do. |
| Vasopril Tablets 10 mg | Cipla Ltd. | India | do. |
| Nature Made Oyster Shell Calcium 500 mg with Vitamin D Tablets | Nature Made Nutritional Products | U.S.A. | Freely |
| Triz Tablets | Indoco Remedies Ltd. | India | Third Schedule |
| Detrax Tablets U.S.P | Unique Pharmaceuticals Labs | do. | do. |
| Red Detrax Tablets | do. | do. | do. |
| Kezole Tablets 200 mg U.S.P | International Pharmaceuticals | do. | Freely |
| Ciproglen-500 Tablets U.S.P | Glenmark Pharmaceuticals Ltd. | India | Third Schedule |
| Propilan Capsules | do. | do. | do. |
| Canditral Capsules | do. | do. | do. |
| Etopophos Injection | Bristol Caribbean Inc. | Puerto Rico | do. |
| Serzone 50 mg Tablets | Bristol Laboratories Corp. | do. | do. |
| Priorix Vaccine | SmithKline Beecham Biologicals s.a. | Belgium | do. |
| Tagamet Injection 200 mg/2 ml (Change in Name of Manufacturer) | SmithKline Beecham Pharmaceuticals | England | do. |
| Havrix 720 Junior Monodose Vaccine | SmithKline Beecham Biologicals s.a. | Belgium | do. |

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|--|---|--------------------------|--------------------------|
| Andrews Salts—Original (Change of source) | SmithKline Beecham Costa Rica S.A. | Costa Rica | Freely |
| Twinrix Junior Vaccine | SmithKline Beecham Biologicals s.a. | Belgium | Third Schedule |
| Famvir Tablets 500 mg | SmithKline Beecham Pharmaceuticals | England | do. |
| Coreg Tablets 3.125 mg | do. | U.S.A. | do. |
| Panadol Extra Caplets | SmithKline Beecham | Ireland | Freely |
| Panadol PM Extra Strength Caplets | Sterling Products International S.A. | Panama | do. |
| Panadol Extra Strength Caplets 500 mg (Change of packaging and label) | SmithKline Beecham Sterling Products International S.A. | do. | do. |
| Panadol Childrens Fruit Flavoured Drops (Change of Source) | SmithKline Beecham Costa Rica S.A. | Costa Rica | do. |
| Panadol Childrens Fruit Flavoured Liquid (Change of packaging and label) | do. | do. | do. |
| Panadol Childrens Fruit Flavoured Chewable Tablets (Change of packaging and label) | Sterling Products International S.A. | Panama | do. |
| Panadol Extra Strength Tablets 500 mg (Change of packaging and label) | SmithKline Beecham Sterling Products International S.A. | do. | do. |
| Panadol Multi-Symptom Cold Formula Caplets (Change of packaging and label) | do. | do. | do. |
| Kytril Ampoules 1 mg/ml | SmithKline Beecham Pharmaceuticals | England | Third Schedule |
| Hiberix Vaccine (Change of dosage and packaging) | SmithKline Beecham Biologicals s.a. | Belgium | do. |
| Hidrasc Capsules | SmithKline Beecham for SmithKline Beecham Laboratoires Pharmaceutiques | France | do. |

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|---|---|--------------------------|--------------------------|
| A. Vogel Cough Relief Liquid | Bioforce AG | Switzerland | Freely |
| A. Vogel Cough Relief Tablets | do. | do. | do. |
| A. Vogel Cold and Flu Defense Tablets | do. | do. | do. |
| A. Vogel Cold and Flu Defense Liquid | do. | do. | do. |
| A. Vogel Bladder Irritation Relief Liquid | do. | do. | do. |
| A. Vogel Bladder Irritation Relief Tablets | do. | do. | do. |
| A. Vogel Headache Relief Liquid | do. | do. | do. |
| A. Vogel Headache Relief Tablets | do. | do. | do. |
| Serevent Rotadisks 50 mcg | Glaxo Operations | England | Third Schedule |
| Ventolin Accuhaler 200 mcg | Allen and Hanburys | do. | do. |
| Elequine 500 mg Injectable Solution | OMJ Pharmaceuticals Inc. | Puerto Rico | do. |
| Lipitor Tablets 10 mg | Godecke | Germany | do. |
| Lipitor Tablets 20 mg | do. | do. | do. |
| Lipitor Tablets 40 mg | do. | do. | do. |
| Acne Aid Cream | Stiefel Mexicana, S.A. de C.V. for Stiefel Laboratories Inc. | Mexico | Freely |
| PanOxyl AQ 2 ^{1/2} Acne Gel | do. | do. | do. |
| PanOxyl AQ 5 Acne Gel | do. | do. | do. |
| PanOxyl AQ 10 Acne Gel | do. | do. | do. |
| PanOxyl 5 Acne Gel | do. | do. | do. |
| PanOxyl 10 Acne Gel | do. | do. | do. |
| Aleve Tablets (Change of packaging) | Syntex Ltd. | Puerto Rico | do. |
| Cliane Tablets 2 mg | Schering do Brasil Quimica e Farmaceutica Ltda. | Brasil | Third Schedule |
| Femiane Sugar-coated Tablets | do. | do. | do. |

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|---|---|--------------------------|--------------------------|
| Viracept Tablets 250 mg | Mova Pharmaceutical Corporation for F. Hoffmann- La Roche Ltd. | Puerto Rico | Third Schedule |
| Viracept Oral Powder 50 mg/g | do. | do. | do. |
| Gelofusine Intravenous Plasma Substitute (Change of Name) | B. Braun Melsungen AG | Germany | do. |
| Differin Solution 0.1% | DPT Laboratories Inc. | USA | do. |
| Retoxil with Lutrinol Capsules | Natural Alternatives International for Alcon Pharmaceuticals Ltd. | do. | Freely |
| Combivir Tablets | Glaxo Wellcome Operations | United Kingdom | Third Schedule |
| Diprivan 1% w/v Intravenous Injection (Additional Indication) | Pharmacia & Upjohn AB for Zeneca Limited | Sweden | do. |
| Zestril 5 mg Tablets (Additional Indication) | Zeneca Limited | United Kingdom | do. |
| Zestril 10 mg Tablets (Additional Indication) | do. | do. | do. |
| Zestril 20 mg Tablets (Additional Indication) | do. | do. | do. |
| Seroquel 25 mg Tablets | do. | do. | do. |
| Seroquel 100 mg Tablets | do. | do. | do. |
| Seroquel 200 mg Tablets | do. | do. | do. |
| Seroquel 25 mg & 100 mg Tablets (Patient starter Pack) | do. | do. | do. |
| Lamisil Derm Gel 1% | Novartis Pharma AG | Switzerland | do. |
| Diovan HCT 80/12.5 Tablets | do. | do. | do. |
| Co-Diovan 80/12.5 Tablets | do. | do. | do. |
| Primperan Oral Drops | Laboratories Synthelabo Synthelabo Groupe | France | do. |
| Solian 50 mg Tablets | do. | do. | do. |
| Solian 200 mg Tablets | do. | do. | do. |
| Praxilene 200 mg Tablets | Lipha Sante | do. | do. |
| Srilane Ointment | do. | do. | do. |
| Glucophage Tablets 850 mg | do. | do. | do. |
| Lucidril 250 Tablets | do. | do. | do. |

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|---|--|--------------------------|--------------------------|
| Dobutamine Hydrochloride Injection 250 mg | Abbott Labs. | USA | Third Schedule |
| Norinyl-1 Tablets | Searle, Division of Monsanto p.l.c. | England | do. |
| Singulair 5 mg Chewable Tablets | Merck Sharp & Dohme | do. | do. |
| Singulair 10 mg Tablets | do. | do. | do. |
| Levovist Granules for Injection | Schering AG | Germany | do. |
| Parche Leon Plaster | BDF Centroamerica S.A. | Guatemala | Freely |
| Aredia 90 mg Injection | Ciba-Geigy Limited | Switzerland | Third Schedule |
| Pulmicort 0.125 mg/ml Suspension (for nebulization) | Astra | Sweden | do. |
| Pulmicort 0.25 mg/ml Suspension (for nebulization) | do. | do. | do. |
| Pulmicort 0.5 mg/ml Suspension (for nebulization) | do. | do. | do. |
| Estring Vaginal Ring 2 mg | Ferring AB, for Pharmacia & Upjohn Company | do. | do. |
| Edronax Tablets 4 mg | Pharmacia & Upjohn Limited | United Kingdom | do. |
| Gopten 2 mg Capsules | Roussel Uclaf | France | do. |
| Atacand 4 mg Tablets | Astra | Sweden | do. |
| Atacand 8 mg Tablets | do. | do. | do. |
| Atacand 16 mg Tablets | do. | do. | do. |
| Estraderm MX25 Transdermal Therapeutic Systems | LTS Lohmann Therapie-Systeme for Novartis Pharma Schwen AG | Germany | do. |
| Estraderm MX50 Transdermal Therapeutic Systems | do. | do. | do. |
| Estraderm MX100 Transdermal Therapeutic Systems | do. | do. | do. |
| Dihydroergot Nasal Spray | Novartis Pharma AG | Switzerland | do. |

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|--|--|--------------------------|--------------------------|
| Osteo Bi-Flex Tablets | Sundown Vitamins | USA | Third Schedule |
| Circus Chews Children's Chewable Fruit Flavoured Multivitamins Tablets (Complete formula) | do. | do. | Freely |
| Circus Chews Children's Chewable Fruit Flavoured Multivitamins Tablets (with iron) | do. | do. | do. |
| Circus Chews Children's Chewable Fruit Flavoured Multivitamins Tablets (Extra C formula) | do. | do. | do. |
| B12 1000 mcg Tablets | do. | do. | Third Schedule |
| B Maxi Complex Tablets | do. | do. | Freely |
| Stress Tablets Plus Iron (Advanced Formula) | do. | do. | do. |
| Daily Multiple Vitamins Tablets (w/Beta Carotene) | do. | do. | do. |
| B Complex with 500 mg of C Tablets | do. | do. | do. |
| SunVite Platinum Tablets | do. | do. | do. |
| Naropin 2 mg/ml Infusion | Astra | Sweden | Third Schedule |
| Naropin 2 mg/ml Injection | do. | do. | do. |
| Naropin 7.5 mg/ml Injection | do. | do. | do. |
| Naropin 10 mg/ml Injection | do. | do. | do. |
| Ranitidine Tablets USP 150 mg | Danbury Pharmaceutical, Inc. | USA | do. |
| Ranitidine Tablets USP 300 mg | do. | do. | do. |
| Apo-Diclo SR 75 mg Tablets | Apotex Inc. | Canada | do. |
| Apo-Capto Tablets USP 12.5 mg | do. | do. | do. |
| Apo-Enalapril Tablets 5 mg (Additional Source) | do. | Mexico | do. |
| Apo-Enalapril Tablets 10 mg (Additional Source) | do. | do. | do. |
| Apo-Enalapril Tablets 20 mg (Additional Source) | do. | do. | do. |
| Brufen Suspension (Change of Source) | Quimica Knoll De Mexico S.A. DE C.V. | do. | Freely |
| Cytarabine Injection 100 mg in 5 ml | Delta West Pty Ltd. | Australia | Third Schedule |
| Cytarabine Injection 1000 mg in 10 ml | do. | do. | do. |
| Tavanic Injection 500 mg/100 ml | Hoechst Marion Roussel, S.A. | Guatemala | do. |

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|------------------------------------|-----------------------------------|--------------------------|--------------------------|
| Children's Acetaminophen Elixir | Mova Pharmaceutical Corporation | Puerto Rico | Freely |
| Aldara Cream | 3M Pharmaceuticals | USA | Third Schedule |
| Apo-Chlorax USP Capsules 5/2.5 mg | Apotex Inc. | Canada | Controlled Drug |
| St. John's Wort Tablets | C.E. Jamieson & Co. Ltd. | do. | Freely |
| Chelated Mineral Tablets | Usana, Inc. | USA | do. |
| Lean Team Formula Tablets | do. | do. | Third Schedule |
| CalMag Plus Tablets | do. | do. | Freely |
| CoQuinone Soft-gel Capsules | do. | do. | do. |
| Mega Antioxidant Tablets | do. | do. | do. |
| Kid's Choo-ables Tablets | do. | do. | do. |
| Poly C Tablets | do. | do. | do. |
| Melatonin KL Tablets | do. | do. | do. |
| Proflavanol Tablets | do. | do. | do. |
| Korean Ginseng Root Capsules | Nature's Way Products Inc. | do. | do. |
| Kava Root Capsules | do. | do. | do. |
| Ibuprofen Tablets B.P. 600 mg | Flamingo Pharmaceuticals Ltd. | India | Third Schedule |
| Kemocarb Injection | Dabur India Limited | do. | do. |
| Kemoplat Injection | do. | do. | do. |
| Intaxel Injection | do. | do. | do. |
| Ledoxan Tablets | do. | do. | do. |
| Ledoxan Injection | do. | do. | do. |
| Zexate Tablets I.P. | do. | do. | do. |
| Fytosid Injection | do. | do. | do. |
| Fivoflu Injection | do. | do. | do. |
| Gynatam 10 Tablets | do. | do. | do. |
| Gynatam 20 Tablets | do. | do. | do. |
| Mobidin Capsules | Centaur Pharmaceuticals Pvt. Ltd. | do. | do. |
| Histon Tablets | do. | do. | do. |
| Sinarest Linctus | Centaur Pharmaceuticals Ltd. | do. | do. |
| Micotrat Vaginal Tablets | Nectar Laboratories, Limited | India | Third Schedule |
| Clozid Vaginal Tablets | do. | do. | do. |
| Nectrim-100 Vaginal Tablets U.S.P. | do. | do. | do. |
| Nectrim-200 Vaginal Tablets U.S.P. | do. | do. | do. |
| Nectrim-500 Vaginal Tablets U.S.P. | do. | do. | do. |

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|---|--|--------------------------|--------------------------|
| Salve Solution | Genethics Pharmaceuticals Ltd. | Trinidad | Freely |
| Captogen 25 Tablets U.S.P. | Flamingo Pharmaceuticals Limited | India | Third Schedule |
| Herpevir 200 Tablets B.P. | do. | do. | do. |
| Diclofen 25 Tablets | do. | do. | do. |
| Children's Panadex Suspension (Change in packaging, box and label) | Twins Manufacturing Chemists | Guyana | Freely |
| Nature's Bounty Chromium Picolinate 200 mcg Tablets | Nature's Bounty Inc. | USA | do. |
| Nature's Bounty Antioxidant 4000 Softgels | do. | do. | Third Schedule |
| Nature's Bounty Melatonin 200 mcg Tablets | do. | do. | Freely |
| Nature's Bounty Glucosamine Sulfate 500 mg Capsules | do. | do. | do. |
| Nature's Bounty Green Source Tablets | do. | do. | Third Schedule |
| Nature's Bounty Norwegian Cod Liver Oil Softgels | Nature's Bounty Manufacturing Corp. | do. | Freely |
| Herbal Harvest Ginkgo Biloba Extract 30 mg Tablets | do. | do. | do. |
| Herbal Harvest Cranberry Concentrate with Vitamin C Softgels | Herbal Harvests Inc. | do. | do. |
| Body Fortress Yohimbe Bark Tablets | Body Fortress A Division of U.S. Nutrition | do. | do. |
| Nature's Way Saw Palmetto Berries 585 mg Capsules | Nature's Way Products Inc. | do. | do. |
| Efamol 500 mg Softgels | do. | do. | do. |
| Bengay Cream (Change of Packaging) | Consumer Health Care Group Pfizer Inc. | do. | do. |
| Ultra Strength Bengay Cream (Change of Packaging) | do. | do. | do. |
| Etobay 5% Gel | Bayer de El Salvador S.A. | El Salvador | do. |
| Etobay 10% Cream | do. | do. | do. |
| Etobay Injection Solution 50% | do. | do. | Third Schedule |

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|---|--|--------------------------|--------------------------|
| Trimetoprim Sulfametoxazol BayKid Suspension 40-200 mg/5 ml | Corporacion Bonima, S.A. de C.V. | El Salvador | Third Schedule |
| Acetaminofen BayKid 500 mg Tablets | do. | do. | Freely |
| Acetaminofen BayKid 120 mg/5 ml Syrup | do. | do. | do. |
| Salbutamol BayKid 2 mg/5 ml Syrup | do. | do. | Third Schedule |
| Salbutamol BayKid 1 mg/5 ml Syrup Expectorant | do. | do. | do. |
| Ketoflam SR Capsules | Laboratoires Prographarm for Carlisle Laboratories Ltd. | France | do. |
| Alphagan Ophthalmic Solution 0.2% | Allergan, Inc. | USA | do. |
| Eagle Vitamin E Softgels 400 I.U. | Eagle Chemicals Inc. | do. | Freely |
| Lomflox Tablets | IPCA Laboratories Limited | India | Third Schedule |

Dated this 30th day of December, 2002.

C. IMBERT
Minister of Health