Legal Notice No. 212

## 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:

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| Now E—400 20% Mixed<br>Tocopherols + Selenium<br>Softgels                                      | Now Foods   | USA               | Freely            |
| Taxotere Concentrate<br>Injectable for Solution<br>for I.V. Infusion 20 mg/4 mL                | Aventis Pharma<br>Dagenham  | United Kingdom    | Third Schedule    |
| Taxotere Concentrate<br>Injectable for Solution<br>for I.V. Infusion 80 mg/4 mL                | do.   | do.               | do.               |
| Amaryl M Film-Coated<br>Tablets 4 mg/1000 mg   | Manufactured by:<br>Laboratories Silanes,<br>S.A. de C.V. for<br>sanofi-aventis<br>de Mexico S.A. de<br>C.V. Mexico | Mexico            | do.               |
| Somatuline Autogel<br>Prolonged-Release<br>Solution for Injection<br>60 mg—Pre-Filled Syringe  | Ipsen Pharma<br>Biotech   | France            | do.               |
| Somatuline Autogel<br>Prolonged-Release<br>Solution for Injection<br>90 mg—Pre-Filled Syringe  | do.   | do.               | do.               |
| Somatuline Autogel<br>Prolonged-Release<br>Solution for Injection<br>120 mg—Pre-Filled Syringe | do.   | do.               | do.               |
| Theraflu Severe Cold & Cough<br>Day Powder for Oral<br>Solution—Sachets                        | Novartis Consumer<br>Health Inc.  | USA               | Freely            |
| Priorix-Tetra Powder and<br>Solvent for Solution for<br>Injection—Pre-Filled<br>Syringe        | GlaxoSmithKline<br>Biologicals s.a.   | Belgium           | Third Schedule    |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale            |
|--|--|-------------------|------------------------------|
| Revolade Film-Coated<br>Tablets 25 mg  | Glaxo Operations UK<br>Limited   | United Kingdom    | Third Schedule               |
| Revolade Film-Coated<br>Tablets 50 mg  | do.  | do.               | do.                          |
| Combigan Ophthalmic<br>Solution 0.2%/0.5%  | Allergan, Inc.   | USA               | do.                          |
| Prevnar 13 Pneumococcal<br>13-valent Conjugated Vaccine<br>(Diphtheria CRM 197<br>Protein) Pre-Filled<br>Syringe | Wyeth Pharmaceu-<br>tical, Division of<br>Wyeth Holdings<br>Corporation  | do.               | do.                          |
| Prevnar 13 Pneumococcal<br>13-valent Conjugated Vaccine<br>(Diphtheria CRM 197<br>Protein) Pre-Filled<br>Syringe | Baxter Pharmaceu-<br>tical Solutions<br>LLC  | do.               | do.                          |
| Enbrel 50 mg Solution for<br>Injection in Pre-Filled<br>Syringe  | Wyeth Medica<br>Ireland  | Ireland           | do.                          |
| Pristiq Extended-Release<br>Tablets 100 mg   | Wyeth Pharmaceu-<br>ticals Company   | Puerto Rico       | do.                          |
| Zanlan Film-Coated<br>Tablets 10 mg  | Manufactured by:<br>Salutas Pharma<br>GmbH Germany<br>for Sandoz GmbH<br>Austria<br>Packaged by:<br>Salutas Pharma<br>GmbH | Germany           | do.                          |
| Sodium Chloride Isotonic<br>Solution 0.9% I.V.   | Laboratorios<br>Biogalenic,<br>S.A. DE C.V.  | El Salvador       | do.                          |
| L-Mesitran Hydro   | Theo Manufacturing<br>B.V.   | The Netherlands   | Freely                       |
| L-Mesitran Border  | do.  | do.               | do.                          |
| L-Mesitran Net   | do.  | do.               | do.                          |
| L-Mesitran Soft Wound<br>Gel 15g   | do.  | do.               | do.                          |
| L-Mesitran Wound<br>Ointment 20g   | do.  | do.               | do.                          |
| Natrol CoQ-10 Softgel 50 mg  | Natrol, Inc.   | USA               | do.                          |
| Natrol CoQ-10 Softgel 100 mg   | do.  | do.               | do.                          |
| Natrol L-Arginine Tablets<br>1000 mg   | do.  | do.               | Freely<br>(Pharmacy<br>ONLY) |

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|--|--|-------------------|------------------------------|
| Natrol DHA 500 Super<br>Strength Softgels 500 mg     | Natrol, Inc.   | USA               | Freely                       |
| Natrol Theanine Tablets                              | do.  | do.               | do.                          |
| Natrol Niacin TR Time Release<br>Tablets 500 mg      | do.  | do.               | do.                          |
| Natrol Biotin Tablets 1000 mcg                       | do.  | do.               | do.                          |
| Biotrue Multi-Purpose Solution                       | Bausch & Lomb  | do.               | do.                          |
| Exforge Film-Coated Tablets<br>10 mg/320 mg          | Manufactured by:<br>Novartis Pharma<br>Stein AG for<br>Novartis Farma-<br>céutica S.A. (AC)<br>Guatemala               | Switzerland       | Third Schedule               |
| Exforge HCT Film-Coated<br>Tablets 5 mg/160 mg/25 mg | do.  | do.               | do.                          |
| Rasilez HCT Film-Coated<br>Tablets 150 mg/12.5 mg    | Manufactured by:<br>Novartis Farma<br>S.p.A. for Novartis<br>Pharma AG,<br>Switzerland                                 | Italy             | do.                          |
| Rasilez HCT Film-Coated<br>Tablets 300 mg/12.5 mg    | do.  | do.               | do.                          |
| Rasilez HCT Film-Coated<br>Tablets 300 mg/25 mg      | do.  | do.               | do.                          |
| Qlaira Film-Coated Tablets                           | Manufactured by:<br>Schering GmbH &<br>Co. Produktions<br>Under License of:<br>Bayer Schering<br>Pharma AG,<br>Germany | Germany           | do.                          |
| Gadovist Solution for Injection<br>1.0 mmol/ml       | Bayer Schering<br>Pharma AG  | do.               | do.                          |
| Momate-S Ointment                                    | Glenmark Pharma-<br>ceuticals Ltd.   | India             | do.                          |
| Liquiband Optima Topical<br>Skin Adhesive            | Medlogic Global Ltd.   | United Kingdom    | Freely<br>(Pharmacy<br>ONLY) |
| Systane Balance Sterile<br>Lubricant Eye Drops       | Alcon Laboratories<br>Inc.   | USA               | Freely                       |
| Priligy Film-Coated Tablets<br>30 mg                 | Manufactured by:<br>Janssen Ortho LLC<br>Puerto Rico<br>Packaged by:<br>Janssen-Cilag S.p.A                            | Italy             | Third Schedule               |

| Trade Name and Form  | Manufacturer  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| Priligy Film-Coated Tablets<br>60 mg   | Manufactured by:<br>Janssen Ortho LLC<br>Puerto Rico<br>Packaged by:<br>Janssen-Cilag S.p.A   | Italy             | Third Schedule    |
| Rotarix Oral Suspension  | GlaxoSmithKline<br>Biologicals s.a.   | Belgium           | do.               |
| Valdureim IM/IV Powder for<br>Solution for Injection<br>40 mg/2 mL             | Powder<br>Manufactured by:<br>Pharmacia & Upjohn<br>Company, USA<br>Solvent<br>Manufactured by:<br>Actavis Italia S.p.A.<br>Italy<br>Secondary Packager:<br>Pfizer S.A. de C.V. |                   | do.               |
| Vigadexa Sterile Ophthalmic<br>Solution  | Alcon Laboratórios<br>Do Brasil Ltda.   | Brazil            | do.               |
| Chloraseptic Total Multi-<br>Symptom Relief Sugar<br>Free Lozenges-Wild Cherry | Distributed by:<br>Medtech Products<br>Inc., USA<br>(Product of USA)  | USA               | Freely            |
| Chloraseptic Total Multi-<br>Symptom Relief Lozenges-<br>Wild Cherry           | do.   | do.               | do.               |
| Chloraseptic Max Sore Throat<br>Lozenges-Wild Berries                          | do.   | do.               | do.               |
| Chloraseptic Sore Throat<br>Lozenges-Honey Lemon                               | do.   | do.               | do.               |
| Chloraseptic Sore Throat<br>Lozenges-Cherry                                    | do.   | do.               | do.               |
| Chloraseptic Sore Throat<br>Lozenges-Citrus                                    | do.   | do.               | do.               |
| Caduet Tablets 5/20 mg   | Manufactured by:<br>Gödecke GmbH<br>Germany<br>Packaged by:<br>Pfizer, S.A. de C.V.   | Mexico            | Third Schedule    |
| Valdyne Capsules 200 mg  | Manufactured by:<br>Pfizer Pharma-<br>ceuticals LLC<br>Puerto Rico<br>Packed by:<br>Pfizer Manufacturing<br>Deutschland GmbH  | do.               | do.               |
| Rapamune Tablets 0.5 mg  | Wyeth Pharma-<br>ceuticals Company  | Puerto Rico       | do.               |

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|--|---|-------------------|-------------------|
| Eraxis Injection 100 mg/vial   | Pharmacia & Upjohn<br>Company   | USA               | Third Schedule    |
| Sayana Suspension for<br>Injection 104 mg/0.65 mL  | Pfizer Manufacturing<br>Belgium NV.   | Belgium           | do.               |
| Today Vaginal Contraceptive<br>Pessaries   | Bliss GVS Pharma<br>Ltd.  | India             | Freely            |
| Flutisone Ointment BP 0.005%   | Manufactured by:<br>Aurochem Labora-<br>tories (l) Pvt. Ltd.<br>Marketed by:<br>Trinpharm Company<br>Ltd., Trinidad and<br>Tobago | do.               | do.               |
| Motrin IB Caplets 200 mg   | Distributed by:<br>McNeil Consumer<br>Healthcare,<br>DIVISION OF<br>McNEIL-PPC, INC.<br>USA (Product of<br>USA)                   | USA               | do.               |
| Nature's Plus Animal Parade<br>Vitamin D3 Children's<br>Chewable Tablets 12.5 mcg<br>(500IU)—Vegetarian  | Natural Organics<br>Laboratories, Inc.  | do.               | do.               |
| Nature's Plus Vitamin D<br>Softgels Bioavailable D3<br>Active Form 25µg/1000IU   | do.   | do.               | do.               |
| Gonal-F Solution for Injection<br>in Pre-Filled Pen 300IU/0.5 ml   | Merck Serono S.p.A.   | Italy             | Third Schedule    |
| Gonal-F Solution for Injection<br>in Pre-Filled Pen 450IU/0.75 ml  | do.   | do.               | do.               |
| M-M-R II Measles, Mumps<br>and Rubella Virus Vaccine<br>Live 0.5 mL Vials-Single-Dose  | Merck & Co., Inc.   | USA               | do.               |
| Imovane Film-Coated Tablets<br>7.5 mg (Change of Name of<br>Manufacturer and Change<br>of Artwork Design)  | Sanofi Winthrop<br>Industrie  | France            | Controlled Drug   |
| Primperan Scored Supposit-<br>ories 10 mg (Change of Name<br>of Marketing Authorisation<br>Holder and Change of Art-<br>work Design)                 | do.   | do.               | Third Schedule    |
| Primperan Solution for<br>Injection 10 mg/2 ml-Ampoule<br>(Change of Name of Market-<br>ing Authorisation Holder<br>and Change of Artwork<br>Design) | do.   | do.               | do.               |

| Trade Name and Form   | Manufacturer                              | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Rilutek Film-Coated Tablets<br>50 mg (Change of Name of<br>Manufacturer and Change<br>of Artwork Design)  | Sanofi Winthrop<br>Industrie              | France            | Third Schedule    |
| Dogmatil Capsules 50 mg<br>(Change of Name of Market-<br>ing Authorisation Holder and<br>Change of Artwork Design)                                      | do.                                       | do.               | do.               |
| Plavix Film-Coated Tablets<br>75 mg (Change of Name of<br>Marketing Authorisation<br>Holder and Change of Art-<br>work Design)                          | do.                                       | do.               | do.               |
| Batrafen Nail Lacquer (Change<br>of Name of Manufacturer<br>and Change of Artwork Design)   | sanofi-aventis<br>Deutschland GmbH        | Germany           | do.               |
| Cordarone Solution for Injec-<br>tion 150 mg/3 ml-Ampoule<br>(Change of Name of Market-<br>ing Authorisation Holder<br>and Change of Artwork<br>Design) | Sanofi Winthrop<br>Industrie              | France            | do.               |
| Dinintel Capsules 30 mg<br>(Additional Source)  | sanofi-aventis de<br>México, S.A. de C.V. | Mexico            | do.               |
| Maalox Plus Antacid+Anti-Gas<br>Oral Suspension-Cherry<br>Flavored (Change of Name<br>of Manufacturer and Change<br>of Artwork Design)                  | do.                                       | do.               | Freely            |
| Maalox Plus Antacid+Anti-Gas<br>Oral Suspension-Mint Flav-<br>ored (Change of Name of<br>Manufacturer and Change<br>of Artwork Design)                  | do.                                       | do.               | do.               |
| Albendazole MK 400 mg/10 mL<br>Suspension (Change of Art-<br>work Design)   | Corporación Bonima<br>S.A. de C.V.        | El Salvador       | do.               |
| Evista Film-Coated Tablets<br>60 mg (Change of Artwork<br>Design)   | Lilly S.A.                                | Spain             | Third Schedule    |
| Cymbalta Hard Gastro-Resistant<br>Capsules 30 mg (Change of<br>Packaging)   | do.                                       | do.               | do.               |
| Cymbalta Hard Gastro-Resistant<br>Capsules 60 mg (Change of<br>Packaging)   | do.                                       | do.               | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Caltrate 600 + D Tablets<br>(Additional Source and Re-<br>duced Size + Mass of Tablet) | Marketed by:<br>Wyeth Consumer<br>Health Care USA<br>(Product of USA)  | USA               | Freely            |
| Mebucaine Lozenges (Additional<br>Source)  | Manufactured by:<br>Novartis Farmacéutic:<br>S.A. de C.V. for Novart<br>Consumer Health S.A<br>Switzerlend                                 | is                | do.               |
| Cozaar Tablets 50 mg (Change<br>of Packaging Site)                                     | Manufactured by:<br>Merck Sharp & Dohm<br>De México, S.A. DE C.<br>México<br>Packaged by:<br>Merck Sharp & Dohm<br>De México, S.A. DE C.   | V.<br>ne          | Third Schedule    |
| Cozaar Tablets 100 mg (Change<br>of Packaging Site)                                    | Manufactured by:<br>Merck Sharp & Dohm<br>Limited, United Kingdo<br>Packaged by:<br>Merck Sharp & Dohm<br>De México, S.A. DE C.            | m<br>ne           | do.               |
| Stocrin Tablets 600 mg (Change<br>of Packaging Site)                                   | Manufactured by:<br>Merck Sharp & Dohm<br>(Australia) Pty Ltd.<br>Australia<br>Packaged by:<br>Merck Sharp & Dohm<br>De México, S.A. DE C. | ne                | do.               |
| (Change of Packaging Site)   | Manufactured by:<br>Merck Sharp & Dohm<br>Limited England<br>Packaged by:<br>Merck Sharp & Dohm<br>De México, S.A. DE C.                   | ne                | do.               |
| Hepsera Tablets 10 mg<br>(Additional Source)   | GlaxoSmithKline<br>(Tianjin) Co., Ltd.   | China             | do.               |
| Paxil CR Controlled Release<br>Tablets 12.5 mg (Additional<br>Source)                  | GlaxoSmithKline Inc.   | Canada            | do.               |
| Paxil CR Controlled Release<br>Tablets 25 mg (Additional<br>Source)                    | do.  | do.               | do.               |
| Ziagen Coated Tablets 300 mg<br>(Addition of scored line in<br>Tablet)                 | Glaxo Operations UK<br>Limited<br>Trading as:<br>Glaxo Wellcome<br>Operations  | United Kingdom    | do.               |

| Trade Name and Form  | Manufacturer   | Country of Origin      | Condition of Sale |
|--|--|------------------------|-------------------|
| Rivotril Tablets 2 mg (Change<br>of Artwork Design)  | Made for:<br>F. Hoffmann-La Roche<br>Ltd., Switzerland by<br>Roche Farma SA  |                        | Controlled Drug   |
| Kytril Film-Coated Tablets 1 mg<br>(Change of Artwork Design)                                    |  | Switzerland            | Third Schedule    |
| Pulmozyme Solution for Inha-<br>lation 2500U. (2.5 mg) 2.5 ml<br>(Change of Artwork Design)      | F. Hoffmann-La Roche   |                        | do.               |
| Tamiflu Capsules 75 mg<br>(Extension of Indication)  | Made for:<br>F. Hoffmann-La Roche<br>Ltd., Switzerland by<br>CENEXI SAS  |                        | do.               |
| Dilantin-125 Oral Suspension<br>USP (Change of<br>Manufacturing Site)                            | Pharmacia & Upjohn<br>Company  | USA                    | do.               |
| Effexor XR Extended-Release<br>Capsules 37.5 mg (Additional<br>Manufacturer and Bulk<br>Release) | Manufactured by:<br>Wyeth Medica Ireland<br>Ireland<br>Packaged by:<br>Wyeth Pharmaceuticals<br>Company                            |                        | do.               |
| Effexor XR Extended-Release<br>Capsules 75 mg (Additional<br>Manufacturer and Bulk<br>Release)   | do.  | do.                    | do.               |
| Effexor XR Extended-Release<br>Capsules 150 mg (Additional<br>Manufacturer and Bulk<br>Release)  | do.  | do.                    | do.               |
| Norprolac Tablets 25 mcg<br>(Change of Name of<br>Manufacturer)                                  | Manufactured &<br>Packaged by: Jelfa<br>Pharmaceutical<br>Company SA<br>Marketing Authorisation<br>Holder: Ferring GmbH<br>Germany |                        | do.               |
| Norprolac Tablets 75 mcg<br>(Change of Name of<br>Manufacturer)                                  | do.  | do.                    | do.               |
| Salve Antiseptic Liquid<br>(Change of Packaging and<br>Change of Artwork Design)                 | Genethics Pharma-<br>ceuticals Ltd.  | Trinidad and<br>Tobago | Freely            |

| Trade Name and Form  | Manufacturer   | Country of Origin | Condition of Sale |
|--|--|-------------------|-------------------|
| Faslodex Solution for Injec-<br>tion in a Pre-Filled Syringe<br>250 mg/5 ml (Change of Art-<br>work Design and Change of<br>Packaging) | Manufactured and Prim-<br>ary Packed by: Vetter<br>Pharma-Fertigung<br>GmbH & Co. KG,<br>Germany<br>Secondary Packed by:<br>AstraZeneca, UK<br>Limited | United Kingdom    | Third Schedule    |
| Crestor Tablets 40 mg<br>(Additional Indication)   | Manufactured by:<br>IPR Pharmeceuticals<br>Inc., Puerto Rico<br>Packaged by:<br>AstraZeneca UK<br>Limited  | do.               | do.               |
| Nexium Film-Coated Tablets<br>20 mg (Change of Artwork<br>Design)  | Manufactured by:<br>AstraZeneca AB<br>Sweden<br>Packed and Distributed<br>by: AstraZeneca<br>S.A. de C.V.  | Mexico            | do.               |
| Nexium Film-Coated Tablets<br>40 mg (Change of Artwork<br>Design)  | do.  | do.               | do.               |
| Exforge Film-Coated Tablets<br>5 mg/80 mg (Additional<br>Source)   | Manufactured by:<br>Novartis Farmacéutica<br>S.A. for Novartis<br>Pharma AG<br>Switzerland   | Spain             | do.               |
| Exforge Film-Coated Tablets<br>5 mg/160 mg (Additional<br>Source)  | do.  | do.               | do.               |
| Tegretol 200 Tablets 200 mg<br>(Additional Source)   | Manufactured by:<br>Novartis Pharmaceuticals<br>UK Ltd. for Novartis<br>Pharma AG, Switzerland   | Great Britain     | do.               |
| Glivec Film-Coated Tablets<br>100 mg (Additional Indication)   | Novartis Pharma Stein AG   | Switzerland       | do.               |
| Glivec Film-Coated Tablets<br>400 mg (Additional Indication)   | do.  | do.               | do.               |
| Novolin 70/30 Penfill Injection<br>(Change of Artwork Design<br>and Change of Packaging)   | Novo Nordisk A/S   | Denmark           | do.               |
| Levemir Penfill Solution for<br>Injection in a Cartridge<br>100U/ml (Change of Form-<br>ulation)                                       | do.  | do.               | do.               |
| Novolin N Suspension for Injec-<br>tion (Change of Artwork Design<br>and Change of Packaging)  | do.  | do.               | do.               |

| Trade Name and Form  | Manufacturer (  | Country of Origin | Condition of Sale |
|--|---|-------------------|-------------------|
| Novolin 70/30 Suspension for<br>Injection (Change of Artwork<br>Design, Change of Packaging<br>and Change of In-Use Time)            |   | Denmark           | Third Schedule    |
| Levemir FlexPen Solution<br>for Injection in a Pre-Filled<br>Pen 100U/ml (Change of<br>Formulation)                                  | do.   | do.               | do.               |
| Novolin R Penfill Solution for<br>Injection in a Cartridge<br>100IU/ml (Change of Primary<br>Packaging and Change of<br>In-Use Time) | do.   | do.               | do.               |
| Novolin R Solution for Injection<br>(Change of Artwork Design,<br>Change of Packaging and<br>Change of In-Use Time)                  | do.   | do.               | do.               |
| NovoRapid Penfill Solution<br>for Injection in a Cartridge<br>100U/ml (Change of Art-<br>work Design)                                | do.   | do.               | do.               |
| Fluorescite 10% injection USP<br>(Change of Manufacturer)  | Alcon Laboratories<br>Inc.  | USA               | do.               |
| Atrovent HFA Metered Aerosol<br>20µg/metered dose (Change<br>of Name of Product and<br>Change of Artwork Design)                     | Distributed by:<br>Boehringer Ingelhein<br>(Canada) Ltd.  | Canada<br>1       | do.               |
| Buscopan Tablets 10 mg<br>(Change of Packaging)  | do.   | do.               | do.               |
| Micardis Tablets 40 mg<br>(Additional Source and<br>Additional Indication)   | do.   | do.               | do.               |
| Micardis Tablets 80 mg<br>(Additional Source and<br>Additional Indication)   | do.   | do.               | do.               |
| Arasid-1000 Injection 1000 mg/<br>10 mL-Single Use Vial<br>(Change of Artwork Design)  | Intas Pharmacueticals<br>Ltd.   | India             | do.               |
| Zomet Tablets IP 500 mg<br>(Change of Packaging)   | do.   | do.               | do.               |
| Avodart Soft Capsules 0.5 mg<br>(Change of Name of Manu-<br>facturer and Change of<br>Packaging Site)                                | Made by:<br>Catalent France Beir<br>heim S.A. France<br>Packed by:<br>Catalent Germany<br>Schorndorf GmbH | Germany<br>1-     | do.               |

| Trade Name and Form   | Manufacturer (  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Eltroxin Tablets 100 mcg<br>(Change of Name of Manu-<br>facturer and Change of<br>Artwork Design)   | Aspen Bad Oldesloe<br>GmbH  | Germany           | Third Schedule    |
| Panadol Advance Film-Coated<br>Tablets 500 mg (Change of<br>Packaging Site)   | Manufactured by:<br>GlaxoSmithKline<br>Dungarvan Ltd.<br>Ireland<br>Packed by:<br>GlaxoSmithKline<br>Panamá, S.A. | Panama            | Freely            |
| Cipro-Denk 500 Film-Coated<br>Tablets (Change of Manufac-<br>turer and Change of Surface)<br>of Tablet)   | Manufactured by:<br>Allphamed PHARBI<br>Arzneimittel GmbH<br>for DENK PHARMA<br>GmbH & Co. KG<br>Germany          |                   | Third Schedule    |
| Robitussin DM Cough & Chest<br>Congestion Syrup-Alcohol<br>and Sugar-Free Non-Drowsy<br>(Change of Manufacturer,<br>Change of Name of Product<br>and Change of Artwork<br>Design) | Richmond Division of<br>Wyeth   | USA               | Freely            |
| Camptosar Injection 100 mg/5 mL<br>(Change of Manufacturer,<br>Change of Packaging and<br>Change of Artwork Design)   | Pfizer (Perth) Pty Limited  | Australia         | Third Schedule    |
| Fragmin Solution for Injection<br>100,000IU/4 ml Multidose<br>Vial (Change of Manufacturer)   | Pfizer Manufacturing<br>Belgium NV  | Belgium           | do.               |
| Dilantin Extended Oral Capsules<br>100 mg (Change of Manu-<br>facturer and Change of<br>Artwork Design)   | Pfizer Pharmaceuticals<br>LLC   | USA               | do.               |
| Norditropin Nordilet Solution<br>for Injection in a Pre-Filled<br>Pen 5 mg/1.5 ml (Change of<br>Dosing Regimen)   | Norvo Nordisk A/S   | Denmark           | do.               |
| Advanced Listerine with<br>Tartar Protection Antiseptic<br>Mouthwash<br>Artic Mint <sup>™</sup> (Change of<br>Artwork Design)   | Distributed by:<br>Johnson & Johnson<br>Healthcare Product<br>DIVISION OF<br>McNEIL PPC, Inc.<br>(Product of USA) | USA<br>s          | do.               |
| FreshBurst Listerine Anti-<br>septic Mouthwash (Change<br>of Artwork Design)  | do.   | do.               | do.               |
| Listerine Antiseptic Mouth-<br>wash (Change of Artwork<br>Design)   | do.   | do.               | do.               |

| Trade Name and Form   | Manufacturer  | Country of Origin | Condition of Sale |
|---|---|-------------------|-------------------|
| Cool Mint Listerine Antiseptic<br>Mouthwash (Change of<br>Artwork Design)   | Distributed by:<br>Johnson & Johnson<br>Healthcare Product<br>DIVISION OF<br>McNEIL PPC, Inc.<br>(Product of USA)               |                   | Freely            |
| Diprivan 10 mg/ml (1%)<br>Emulsion for Injection or<br>Infusion-Pre-Filled Syringe<br>(Change of Name of<br>Manufacturer) | Manufactured by:<br>Corden Pharma Sp/<br>Italy<br>Packed by:<br>AstraZeneca UK Lt<br>for AstraZeneca UK<br>Ltd., United Kingdon | A<br>.d.<br>X     | n Third Schedule  |
| Diprivan 10 mg/ml (1%)<br>Emulsion for Injection or<br>Infusion-Vial (Change of<br>Name of Manufacturer)                  | do.   | do.               | do.               |
| Diprivan 10 mg/ml (1%)<br>Emulsion for Injection or<br>Infusion-Ampoules (Change<br>of Name of Manufacturer)              | do.   | do.               | do.               |
| Lamisil Tablets 250 mg<br>(Additional Source)   | Novartis Biociencias<br>S.A.  | Brazil            | do.               |
| Trental Film-Coated Tablets<br>400 mg (Additional Source)   | sanofi-aventis de Méxicó<br>S.A. de C.V.  | Mexico            | do.               |
| Lasix Injectable Solution<br>20 mg/2 mL (Additional Source)   | do.   | do.               | do.               |
| Allegra Film-Coated Tablets<br>120 mg (Additional Packager)   | Manufactured by:<br>sanofi-aventis<br>U.S. LLC., USA<br>Packaged by:<br>sanofi-aventis<br>Farmacêutica LTDA                     | Brazil            | do.               |
| Allegra Film-Coated Tablets<br>180 mg (Additional Packager)   | do.   | do.               | do.               |
| Allegra D Extended Release<br>Film-Coated Tablets 60 mg/<br>120 mg (Additional Packager)                                  | do.   | do.               | do.               |
| Tritace Tablets 2.5 mg<br>(Change of Manufacturer)  | sanofi-aventis de México<br>S.A. de C.V.  | ) Mexico          | do.               |
| Tritace Tablets 5 mg<br>(Change of Manufacturer)  | do.   | do.               | do.               |
| Tritace Tablets 10 mg<br>(Change of Manufacturer)   | do.   | do.               | do.               |
| Piportil L4 Solution for<br>Injection 25 mg/1 mL<br>(Change of Manufacturer)  | sanofi-aventis<br>Farmacêutica Ltda.  | Brazil            | do.               |

| Trade Name and Form   | Manufacturer   | Country of Origin | Condition of Sale         |
|---|--|-------------------|---------------------------|
| Nyolol Ophthalmic Gel 0.1%<br>(Change of Manufacturer<br>and Change of Storage<br>Condition)  | Manufactured by:<br>Excelvision AG, for<br>Novartis Pharma AG<br>Switzerland |                   | Third Schedule            |
| Ferrol DM Orange Flavoured<br>Liquid (Alcohol Free) (Sugar<br>Free) (Change of Name of<br>Manufacturer)                                 | New GPC INC.   | Guyana            | Freely                    |
| Ferrol Children's Elixir Straw-<br>berry Flavoured Liquid—<br>Alcohol free (Change of<br>Name of Manufacturer)                          | do.  | do.               | do.                       |
| Rogers' Beef Iron and Wine<br>Liquid Tonic (Change of<br>Name of Manufacturer)  | do.  | do.               | do.                       |
| Mustarcreme Ointment<br>(Change of Name of Manu-<br>facturer)   | do.  | do.               | do.                       |
| Alcosulph Cream (Change<br>of Name of Manufacturer)   | do.  | do.               | do.                       |
| Ferrol Expectorant Cherry<br>Flavoured Liquid (Change<br>of Name of Manufacturer)   | do.  | do.               | do.                       |
| Canadian Healing Oil<br>(Change of Name of Manu-<br>facturer)   | do.  | do.               | do.                       |
| Novolin N Penfill Suspension<br>for Injection in a Cartridge-<br>100IU/ml (Change of Primary<br>Packaging and Change of<br>In-Use Time) | Novo Nordisk A/S   | Denmark           | Third Schedule            |
| PanGraf 5.0 Capsules 5.0 mg   | Panacea Biotec Ltd.  | India             | do.                       |
| Wingora 50 Film-Coated<br>Tablets   | Meyer Healthcare<br>Pvt. Ltd.  | do.               | do.                       |
| Now C-1000 with Rose Hips<br>Sustained Release Tablets  | Now Foods  | USA               | Freely                    |
| Now CoQ10 with Hawthorn<br>Berry Vcaps 100 mg   | do.  | do.               | do.                       |
| Natrol Easy-C Regenerating<br>Complex with Bioflavonoids<br>Vegetarian Capsules   | Natrol, Inc.   | do.               | do.                       |
| Nature's Plus Liquid C 1000 mg<br>with Lemon Bioflavonoids<br>Natural Orange Flavour  | Natural Organics<br>Laboratories, Inc.                                       | do.               | do.                       |
| Bitter Melon Capsules<br>(Change of Name of Product<br>and Change of Artwork Design)  | The Himalaya Drug<br>Company   | India             | Freely (Pharmacy<br>ONLY) |

| Trade Name and Form  | Manufacturer                 | Country of Origin | Condition of Sale         |
|--|------------------------------|-------------------|---------------------------|
| Holy Basil Capsules<br>(Change of Name of Product<br>and Change of Artwork Design) | The Himalaya Drug<br>Company | India             | Freely (Pharmacy<br>ONLY) |
| Arjuna Capsules (Change of<br>Artwork Design)                                      | do.                          | do.               | do.                       |
| Ashwagandha Capsules<br>(Change of Artwork Design)                                 | do.                          | do.               | do.                       |
| Gymnema Capsules<br>(Change of Name of Product<br>and Change of Artwork<br>Design) | do.                          | do.               | do.                       |
| Mucuna Capsules<br>(Change of Name of Product<br>and Change of Artwork<br>Design)  | do.                          | do.               | do.                       |
| Amla Capsules<br>(Change of Name of Product<br>and Change of Artwork<br>Design)    | do.                          | do.               | Freely                    |
| Neem Capsules<br>(Change of Artwork Design)  | do.                          | do.               | Freely (Pharmacy<br>ONLY) |
| Guduchi Capsules<br>(Change of Artwork Design)                                     | do.                          | do.               | do.                       |
| Triphala Capsules<br>(Change of Artwork Design)                                    | do.                          | do.               | Freely                    |
| Bacopa Capsules<br>(Change of Name of Product<br>and Change of Artwork<br>Design)  | do.                          | do.               | Freely (Pharmacy<br>ONLY) |
| Tumeric Capsules<br>(Change of Name of Product<br>and Change of Artwork<br>Design) | do.                          | do.               | Freely                    |

Dated this 19th day of August, 2011.

F. KHAN Minister of Health

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