

LEGAL NOTICE NO. 180

REPUBLIC OF TRINIDAD AND TOBAGO

THE 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 Act.

The Minister of Health signifies his approval in respect of the following new drugs listed hereunder:

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
VIRUCID 200 Tablets 200 mg	AEGIS Ltd.	Cyprus	Third Schedule
VIRUCID 400 Tablets 400 mg	do.	do.	do.
VIRUCID 800 Tablets 800 mg	do.	do.	do.
FLUCOZAL 150 Capsules 150 mg	do.	do.	do.
LASOPROL Capsules 30 mg	do.	do.	do.
SOTACOR Tablets 80 mg (Change in Packaging; Additional Source)	Bristol-Mayers Squibb	France	do.
TAXOL Injection 30 mg (6 mg/ml) (Additional Indication and Condition of Use)	Bristol Caribbean, Inc. Puerto Rico Subsidiary of Bristol-Mayers Squibb Company	USA	do.
TAXOL Injection 100 mg (6 mg/ml) (Additional Indication and Condition of Use)	do.	do.	do.
TAXOL Injection 300 mg (6 mg/ml) (Additional Indication and Condition of Use)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Micardis Tablets 40 mg	Boehringer Ingelheim Pharma KG for Boehringer Ingelheim International GmbH	Germany	Third Schedule
Micsardis Tablets 80 mg	do.	do.	do.
Cipro HC Otic Suspension	Bayer Corporation Distributed by ALCON LABORATORIES, INC.	USA	do.
Profasi 2000 Injection	Laboratories Serono S.A.	Switzerland	do.
Profasi 10000 Injection	do.	do.	do.
Priadel 400 mg Tablets (Change in Name of Manufacturer)	Synthelabo Groupe France for Lorex Synthelabo	England	do.
APO- METRONIDAZOLE Tablets 250 mg	APOTEX INC.	Canada	do.
Chondroitin Sulfate Caplets 360 mg	Jamieson Laboratories	do.	do.
DIPRIVAN 1% w/v INTRAVENOUS INFUSION 10 mg/ml Vial (Change in Label Packaging)	Fresenius Kabi AB, Sweden for Zeneca Limited	United Kingdom	do.
DIPRIVAN 1% w/v INTRAVENOUS INFUSION 10 mg/ml Ampoules (Change in Label Packaging)	do.	do.	do.
Arthrotec 50 Tablets	Searle, Morpeth England for G.D. Searle Inter- American Co.	USA	do.
Children's Advil Oral Suspension Grape Flavor (Change in Name, Label Packaging)	Whitehall-Robins Healthcare	do.	Freely
Anbesol Liquid Cool Mint	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
OXY Deep II Wash Liquid	SmithKline Beecham Costa Rica S.A.	Costa Rica	Freely
Baralgin "M" Drops (Change in Name of Manufacturer)	Hoechst Marion Roussel, S.A.	Guatemala	Third Schedule
Tritace 5 Tablets (Change in Name of Manufacturer, Formulation, Additional Source)	do.	do.	do.
Tritace 2.5 Tablets (Change in Name of Manufacturer, Formulation, Additional Source)	do.	do.	do.
DUROMINE CAPSULES 15 mg (Additional Source)	3M Pharmaceuticals Pty Ltd.	Australia	Controlled Drug
DUROMINE CAPSULES 30 mg (Additional Source)	do.	do.	do.
POSTINOR 2 Tablets (Change in Name— formerly Postinor Tablets)	GEDEON RICHTER Ltd.	Hungary	Third Schedule
Telviran 5% Cream	EGIS PHARMACEUTICALS LTD.	do.	do.
Telviran Tablets 200 mg	do.	do.	do.
Telviran Tablets 400 mg	do.	do.	do.
Qvar 50 Aerosol	3M Health Care Limited	England	do.
Qvar 100 Aerosol	do.	do.	do.
Paramettes 50+ COMPLETE Tablets	Wyeth-Ayerst Canada Inc., Canada Distributed by WHITEHALL- ROBINS INC.	Canada	Freely
Leucovorin Calcium Injection USP 50 mg in 5 ml	Pharmacia & Upjohn (Perth) Pty Limited	Australia	Third Schedule

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Leucovorin Calcium Injection USP 100 mg in 10 ml	Pharmacia & Upjohn (Perth) Pty Limited	Australia	Third Schedule
BRUFEN 400 Sugar Coated Tablets	QUIMICA KNOLL DE MEXICO S.A. DE C.V.	Mexico	do.
Ziagen Oral Solution 20 mg/ml	Glaxo Wellcome Operations	UK	do.
Ziagen Tablets 300 mg	do.	do.	do.
Zyrtec Tablets 10 mg	UCB S.A. PHARMA SECTOR	Belgium	do.
Seretide Diskus 50/100 mcg Powder for inhalation	Glaxo Wellcome Operations	England	do.
Seretide Diskus 50/500 mcg Powder for inhalation	do.	do.	do.
Seretide Diskus 50/250 mcg Powder for inhalation	do.	do.	do.
Anafranil 25 Tablets 25 mg (Additional Source, Change in Name of Manufacturer)	Novartis Farma S.p.A. Italy for Novartis Pharma AG	Switzerland	do.
Anafranil SR 75 Divitabs 75 mg (Additional Source, Change in Name of Manufacturer)	do.	do.	do.
Brinerdin Tablets (Additional Source, Change in Name of Manufacturer)	do.	do.	do.
Lioresal 10 Tablets 10 mg (Additional Source, Change in Name of Manufacturer)	do.	do.	do.
Ludiomil 75 Tablets 75 mg (Additional Source, Change in Name of Manufacturer)	Novartis Farmaceutica S.A. Spain for Novartis Pharma AG	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Leponex Tablets 25 mg (Additional Source, Change in Name of Manufacturer)	Novartis Pharmaceuticals UK Ltd. Great Britain for Novartis Pharma AG	Switzerland	Third Schedule
Leponex Tablets 100 mg (Additional Source, Change in Name of Manufacturer)	do.	do.	do.
Melleril Film-Coated Tablets 25 mg (Additional Source, Change in Name of Manufacturer)	do.	do.	do.
Melleril Film-Coated Tablets 50 mg (Additional Source, Change in Name of Manufacturer)	do.	do.	do.
Tegretol 2% Syrup (Additional Source, Change in Name of Manufacturer)	Novartis Pharma S.A., France for Novartis Pharma AG	do.	do.
Tegretol 200 Tablets 200 mg (Additional Source, Change in Name of Manufacturer)	Novartis Farma S.p.A. Italy for Novartis Pharma AG	do.	do.
Tegretol CR 200 Divitabs 200 mg (Additional Source, Change in Name of Manufacturer)	do.	do.	do.
Tegretol CR 400 Divitabs 400 mg (Additional Source, Change in Name of Manufacturer)	do.	do.	do.
Norprolac Tablets 75 mcg (Additional Source, Change in Name of Manufacturer)	Novartis Pharmaceuticals U K Ltd., Great Britain for Novartis Pharma AG	do.	do.
Norprolac Tablets 150 mcg (Additional Source, Change in Name of Manufacturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Norprolac Tablets 25/50 mcg (Additional Source, Change in Name of Manufacturer)	Novartis Pharmaceuticals UK Ltd., Great Britain for Novartis Pharma AG	Switzerland	Third Schedule
Saizen 4 Powder for Injection (Additional Source)	Laboratoires Serono S.A.	do.	do.
Strepsils Pain Relief Plus Lozenges	Crookes Healthcare Limited	England	Freely
Dequacaine Lozenges	do.	do.	do.
Buminate 5% Albumin (Human), USP, 5% Solution	Baxter Healthcare Corporation	USA	Third Schedule
0.45% Sodium Chloride Injection USP	do.	do.	do.
Albumoheel S Tablets	Biologische Heilmittel Heel GmbH	Germany	do.
Arteria-Heel Drops	do.	do.	do.
Bronchalis-Heel Tablets	do.	do.	do.
Diarrheel S Tablets	do.	do.	do.
Arsuraneel Tablets	do.	do.	do.
Gastricumeel Tablets	do.	do.	do.
Duodenoheel Tablets	do.	do.	do.
Syzygium compositum Drops	do.	do.	do.
Oculoheel Tablets	do.	do.	do.
Nervoheel N Tablets	do.	do.	do.
Luffeel Tablets	do.	do.	do.
Ginseng compositum Drops	do.	do.	do.
Klimakt-Heel Tablets	do.	do.	do.
Gynacoheel Drops	do.	do.	do.
Aletris-Heel Tablets	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Cisplatin "Ebewe" 10 mg Concentrate for preparation of infusion	EBEWE Arzneimittel Ges.m.b.H	Austria	Third Schedule
Dopamin "Ebewe" 200 mg Concentrate for preparing infusion	do.	do.	do.
Etoposid "Ebewe" 100 mg Concentrate for IV infusion	do.	do.	do.
Methotrexat "Ebewe" 10 mg Solution for injection and infusion	do.	do.	do.
Sadacoron 150 mg Solution for IV injection/infusion	do.	do.	do.
Tamoxifen "Ebewe" 20 mg Tablets	do.	do.	do.
Sedacoron 200 mg Tablets	do.	do.	do.
Tritace 2.5 HCT Tablets (Change in Name of Manufacturer)	Hoechst Marion Roussel, S.A.	Guatemala	do.
Baralgin "M" Injectable solution (Change in Name of Manufacturer)	do.	do.	do.
Daonil Tablets (Change in Name of Manufacturer)	do.	do.	do.
asenlix/DININTEL Capsules (Change in Name of Manufacturer)	do.	do.	do.
Lasix Injectable Solution (Change in Name of Manufacturer)	do.	do.	do.
Lasix Tablets (Change in Name of Manufacturer)	do.	do.	do.
Trental Solution for infusion (Change in Name of Manufacturer)	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Estracyt Capsules 140 mg	Pharmacia & Upjohn S.p.A., Italy for Pharmacia & Upjohn AB	Sweden	Third Schedule
Nephrosol Acetate Concentrate RS-223 Liquid	MINNTECH	USA	do.
MIOSTAT INTRAOCULAR SOLUTION	Alcon Laboratories Inc.	do.	do.
TARKA Sustained Release Film Coated Tablets	KNOLL AG Germany Distributed by QUIMICA KNOLL DE MEXICO S.A. DE C.V.	Mexico	do.
Ciproxina Infusion Solution 0.2 g	Bayer Germany Packaged by Bayer de El Salvador, S.A.	El Salvador	do.
Elequine 500 I.V. Minibag Injectable Solution	Abbott Laboratories, USA for Ortho Pharmaceutical Corporation and Mc Neil Pharmaceutical USA Packaged and distributed by CILAG DE MEXICO S.A. DE C.V.	Mexico	do.
Arthrotec 75 Tablets	Searle, Morpeth England for G.D. Searle Inter-American Co.	USA	do.
Micospec Cream	Carlisle Laboratories Ltd.	Barbados	do.
Micospec Powder	do.	do.	do.
NIFELONG SUSTAINED RELEASE TABLETS 20 mg	Dr. REDDY'S LABORATORIES LTD.	India	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
Metaplex Forte Injection	DCI PHARMACEUTICALS PVT. LTD. Marketed by INDOCO REMEDIES LTD.	India	Third Schedule
Amaryl 2.0 Tablets (Change in Name of Manufacturer)	Hoechst Marion Roussel, S.A.	Guatemala	do.
Amaryl 4.0 Tablets (Change in Name of Manufacturer)	do.	do.	do.
Batrafen Nail Lacquer (Change in Name of Manufacturer)	Hoechst AG, Germany Packaged by Hoechst Marion Roussel, S.A.	do.	do.
Frisium Tablets (Change in Name of Manufacturer)	Hoechst Marion Roussel, S.A.	do.	Controlled Drugs
Trental 400 Tablets (Change in Name of Manufacturer)	do.	do.	Third Schedule
Tritace 2.5 HCT Tablets (Additional Source)	Hoechst Marion Roussel, S.p.A. Italy Packed by Hoechst Marion Roussel, S.A.	do.	do.
Tritace 5 Tablets (Additional Source)	do.	do.	do.
Tritace 2.5 Tablets (Additional Source)	do.	do.	do.
Protease Saw Palmetto Complex Capsules	Jamieson Laboratories	Canada	do.
MENTAT SYRUP	THE HIMALAYA DRUG CO.	India	Freely
RUMALAYA TABLETS	do.	do.	do.
Liv. 52 SYRUP	do.	do.	Third Schedule
SEPTILIN TABLETS	do.	do.	Freely
SEPTILIN SYRUP	do.	do.	do.
GERIFORTE TABLETS	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
GERIFORTE SYRUP	THE HIMALAYA DRUG CO.	India	Freely
PILEX TABLETS	do.	do.	do.
CYSTONE TABLETS	do.	do.	Third Schedule
HERBOLAX CAPSULES	do.	do.	Freely
Westcan GLUCOSAMINE SULFATE 500 mg with DEVIL'S CLAW CAPLETS	Vita Health Company Ltd.	Canada	do.
BEST naturals Vitamin B Complex 50 Tablets	Arnet Pharmaceuticals U.S.A. Distributed by H & R MARKETERS LIMITED Trinidad	USA	do.
BEST naturals Vitamin C 100 mg with ROSEHIPS Tablets	do.	do.	do.
BEST naturals Lecithin 1200 mg Softgels	do.	do.	do.
HISTAL DC Syrup	Carlisle Laboratories Ltd.	Barbados	do.
Caltrate 600 PLUS Chewables Tablets Assorted Fruit Flavors	Lederle Laboratories Division Marketed by LEDERLE CONSUMER HEALTH	USA	do.
Caltrate PLUS Tablets	Lederle Laboratories Division Marketed by LEDERLE CONSUMER HEALTH DIVISION American Cyanamid Company	do.	do.
DICLOFENAC SODIUM INJECTION	LABORATE PHARMACEUTICAL (INDIA)	India	Third Schedule
ATROPINE INJECTION B.P. 1 mg/ml	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
AMINOPHYLLINE INJECTION B.P. 25 mg/ml	LABORATE PHARMACEUTICAL (INDIA)	India	Third Schedule
METOCLOPRAMIDE INJECTION B.P. 5 mg/ml	do.	do.	do.
VITAMIN B-COMPLEX INJECTION	do.	do.	do.
HYOSCINE BUTYL BROMINE INJECTION B.P. 10 mg/ml	do.	do.	do.
CHLORPHENIRAMINE INJECTION B.P. 10 mg/ml	do.	do.	do.
CYANOCOBALAMIN INJECTION B.P. 1000 mcg/ml	do.	do.	do.
HYDROCORTISONE SODIUM SUCCINATE INJECTION B.P. 100 mg	do.	do.	do.
Ferrol Mentholated Rub	Guyana Pharmaceutical Corporation Ltd.	Guyana	Freely
Qvar 100 Autohaler	3M Health Care Limited	England	Third Schedule
Qvar 50 Autohaler	do.	do.	do.
Combantrin Tablets 250 mg	Pfizer S.A.	Venezuela	Freely
<u>VETERINARY PRODUCTS</u>			
ENROSOL-S Oral Solution	Veterinary & Agricultural Products Mfg. Co. Ltd.	Jordan	do.
BIO-POX M FOWL POX VACCINE	TRI BIO LABORATORIES, INC.	USA	To Veterinarians or by Veterinary Prescription only
BIO-CAS + BRON MM NEWCASTLE- BRONCHITIS VACCINE	do.	do.	do.

<i>Trade Name and Form</i>	<i>Manufacturer</i>	<i>Country of Origin</i>	<i>Condition of Sale</i>
BIO-BURS 1 BURSAL DISEASE VACCINE	TRI BIO LABORATORIES INC.	U.S.A.	To Veterinarians or by Veterinary Prescription only
BIO-CAS B ₁ NEWCASTLE DISEASE VACCINE	do.	do.	do.
BURSAL DISEASE- MAREK'S DISEASE VACCINE Serotype 3, Live Virus Strains: IBDV- Lukert & MDV-FC-126 (HVT)	do.	do.	do.
MAREK'S DISEASE VACCINE Serotype 3, Live Virus Strains: FC 126 (HVT) BIOCEL-HVT	do.	do.	do.
MAREK'S DISEASE VACCINE Serotype 2 & 3, Live Virus Strains: SB-1 and FC 126 (HVT)	do.	do.	do.
Endovet Ces Tablets	REVETMEX, S.A. DE C.V.	Mexico	Freely
Endovet Polivitamin	do.	do.	To Veterinarians or by Veterinary Prescription only
Enrociline 10% Injection	do.	do.	do.
Benzamin B 12 Injection	do.	do.	do.
Disofen 3.75% Injection	do.	do.	do.
AVIMICOL Oral Suspension	PENTALAB	Venezuela	Freely

Dated this 17th day of July, 2000.

H. RAFEEQ
Minister of Health