



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



30 JUN 2017

FDA ADVISORY
No. **2017-192**

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:

1. Tationil Plus 1500
2. Beauoxi White plus 1200
3. Tationil 600 mg / 4 mL
4. Advanced Glutathione Rex Pharma 3 g
5. V-C Injection
6. GSH DermaForte 1500
7. Placenta Lucchini Fresh Cell Therapy
8. Thionemax 900
9. Laennec Inj. Placenta Extract (Human)
10. GSH Lumineux 1200
11. Tioredox 4.8 g
12. Advanced Glutathione Rex Pharma 2,400 mg
13. GSH Ultima 1500
14. Gerovytel
15. Reduced Glutathione (Saluta) 600 mg/Vial Powder for Injection IM/IV
16. Reduced Glutathione / Hydrolyzed Collagen, 1200 mg / 200 mg Vial Powder for Injection (Lyophilized Powder) (Tatiomax)

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products.

Food and Drug Administration (FDA) post-marketing surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the agency and have not been issued with proper authorization in the form of Certificate of Product Registration.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

Accordingly, since these unregistered drug products have not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety.



The use of such violative products may pose potential health hazards to the consuming public.

In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against drug products that might not be duly registered with the FDA. Always check if a drug product has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until it have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via report@fda.gov.ph, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. You may also call the Center for Drug Regulation and Research at telephone number (02) 809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General

DTN: 20170606151530

ANNEX
Details on the Unregistered Drug Products

TATIONIL PLUS 1500

1500mg Lyophilized Glutathione with Advanced Glutathione Boosters

8 Vials + 8 Diluent Ampoules + 30 Capsules

For Oral, IM and IV

Reconstitute with 5ml Vitamin C Solution



Rex Pharma Group
1127, Bom Rakpart,
Budapest, Hungary

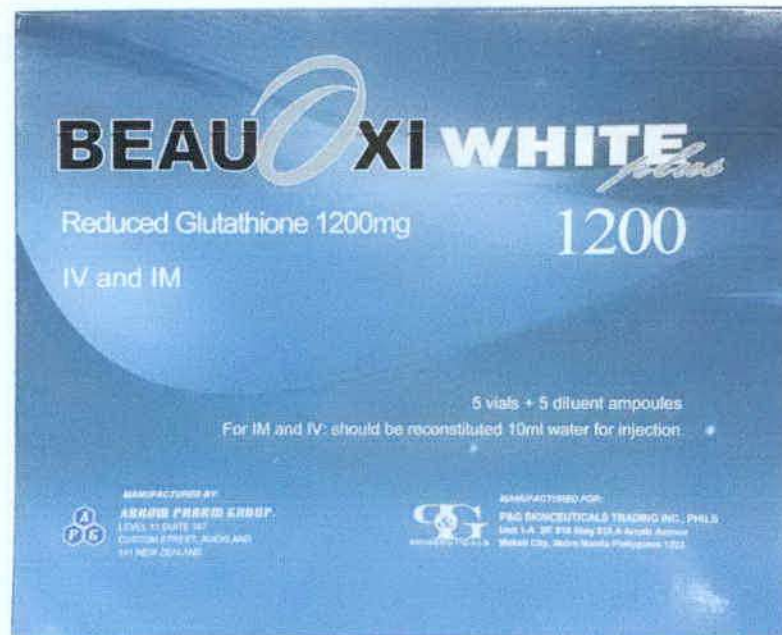


1500mg



Tationil Plus 1500
Rex Pharma Group – 1127, Bom Rakpart, Budapest, Hungary

Figure 1. Unregistered Drug Product



Beauoxi White plus 1200

Manufactured by Arrow Pharm Group – Level 11 Suite 167 Custom Street, Auckland 141 New Zealand

Manufactured for P&G Skinceuticals Trading Inc., Phils. – Unit 1-A 3/F 818 Bldg 818 A Arnaiz Avenue Makati City, Metro Manila Philippines 1223

Figure 2. Unregistered Drug Product

**Tationil® 600 mg/4 ml
polvere e solvente
per soluzione iniettabile**

glutathione

i.m./e.v.

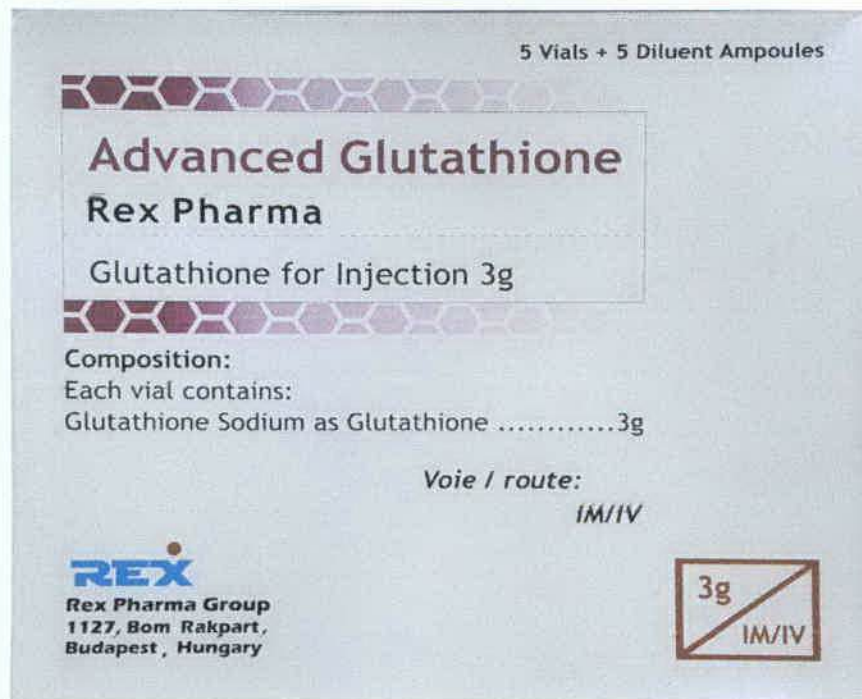
10 flaconcini polvere +
10 fiale solvente 4 ml



Tationil 600 mg / 4 mL

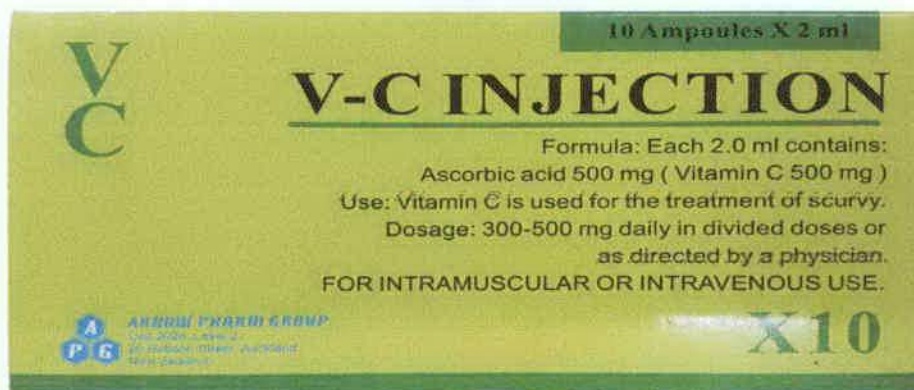
Teofarma s.r.l. = via F.lli Cervi, 8 = 27010 Valle Salimbene (PV)

Figure 3. Unregistered Drug Product



Advanced Glutathione, Glutathione for Injection 3 g
Rex Pharma Group – 1127, Bom Rakpart, Budapest, Hungary

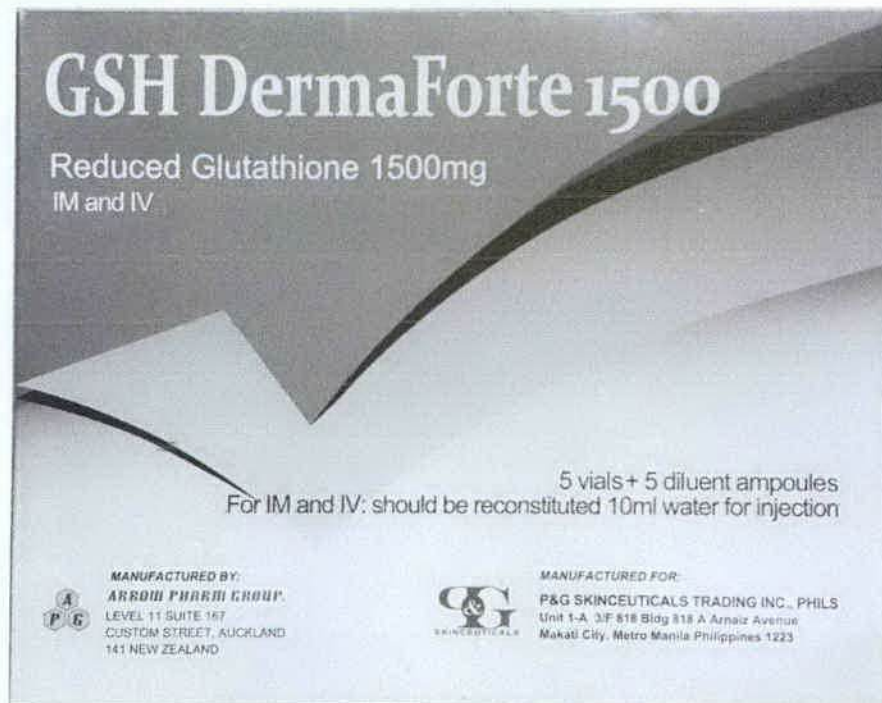
Figure 4. Unregistered Drug Product



V-C Injection

Arrow Pharm Group – Unit 202d, Level 2, 20 Hobson Street, Auckland, New Zealand

Figure 5. Unregistered Drug Product



GSH DermaForte 1500

Manufactured by Arrow Pharm Group – Level 11 Suite 167 Custom Street, Auckland 141 New Zealand

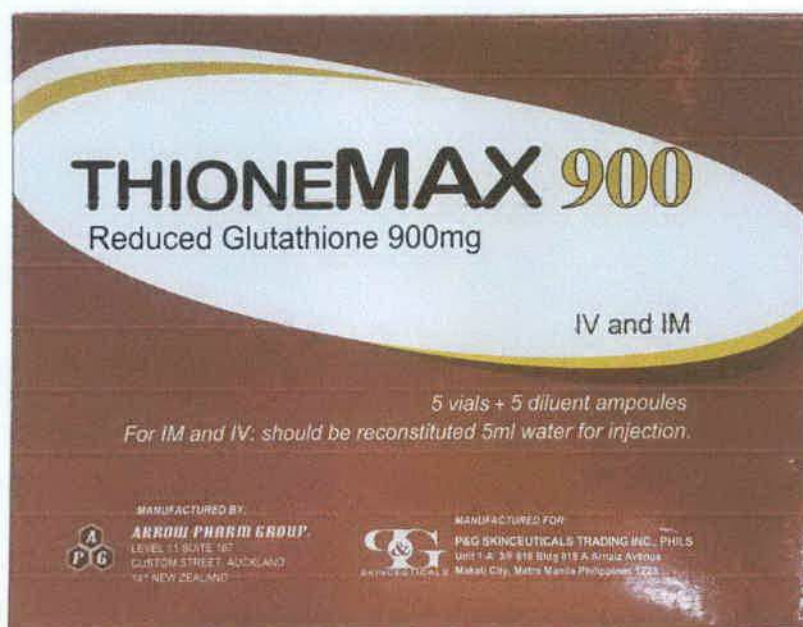
Manufactured for P&G Skinceuticals Trading Inc., Phils – Unit 1-A 3/F 818 A Arnaiz Avenue Makati City, Metro Manila Philippines 1223

Figure 6. Unregistered Drug Product



Placenta Lucchini Fresh Cell Therapy
Laboratoire Lucchini S.A. Geneva (Suisse)
Distributed by Farmacie Petrone – S.A. Geneva (Suisse)

Figure 7. Unregistered Drug Product



Thionemax 900

Manufactured by Arrow Pharm Group – Level 11 Suite 167, Custom Street, Auckland, 141 New Zealand

Manufactured for P&G Skinceuticals Trading Inc., Phils. – Unit 1-A, 3/F 818 Bldg 818 A Arnaiz Avenue, Makati City, Metro Manila Philippines 1223

Figure 8. Unregistered Drug Product



Placental Extract (Human) Laennec Inj.

Manufactured by GCJBP Corp. – 156-50 Naesong-ri, Geumwang-eup, Eumsung-gun, Chungbuk, Korea

Distributed by Japan Bio Products Co., Ltd. – 1-44-1 Tomigaya, Shibuya-Ku, Tokyo, Japan

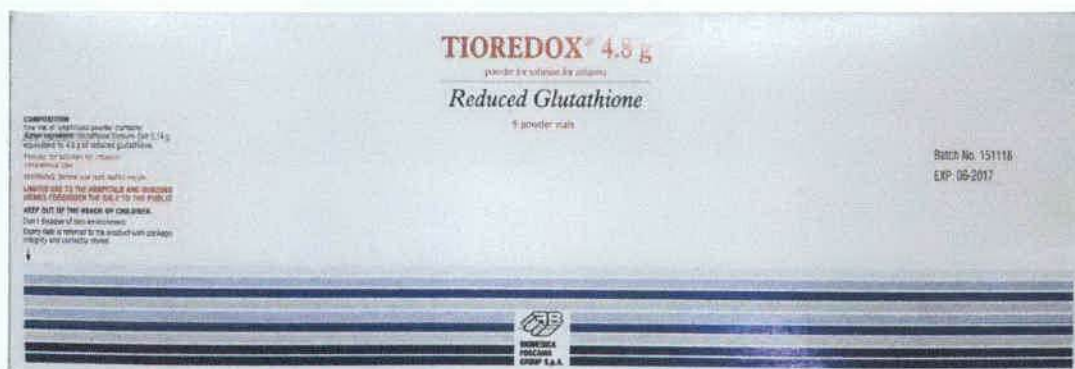
Figure 9. Unregistered Drug Product



GSH LUMINEUX 1200

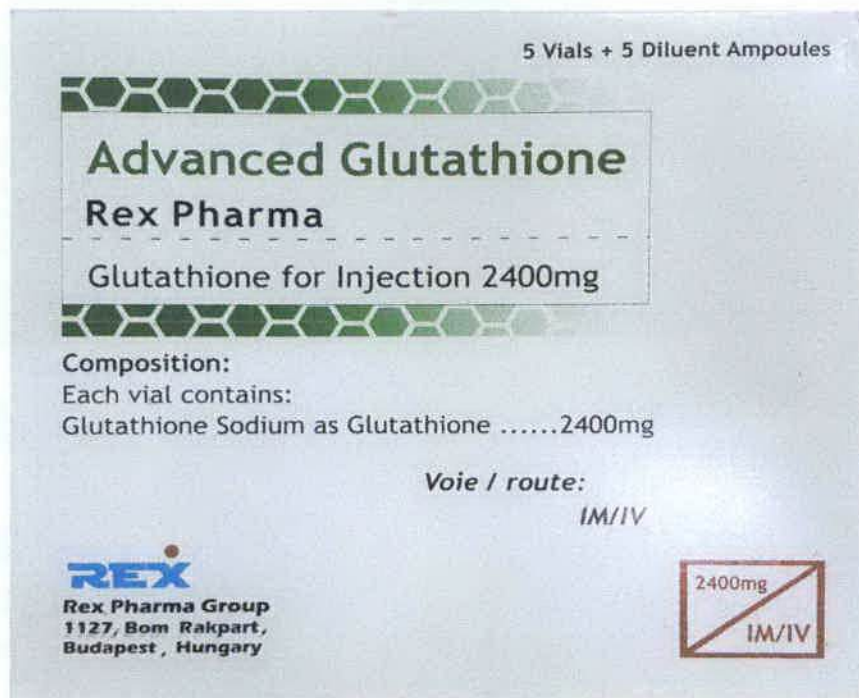
LB Laboratoires Biopharmacie S.A. = 37, Boulevard Saint-Marcel, 75013 Paris, France

Figure 10. Unregistered Drug Product



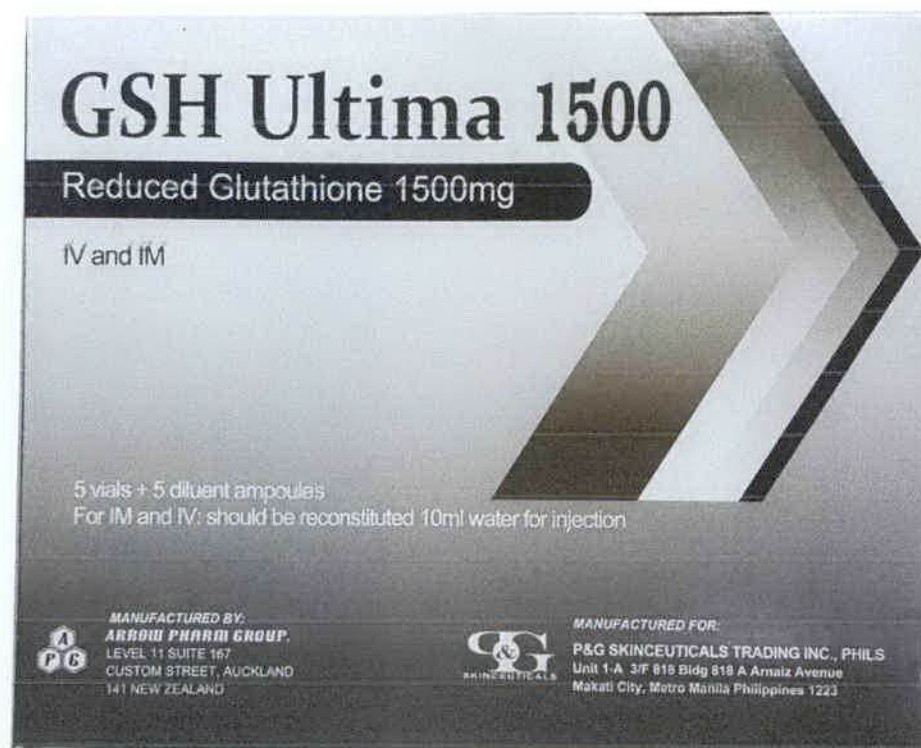
Tioredox 4.8 g Powder for Solution for infusion
 Biomedica Foscama Group S.p.A.

Figure 11. Unregistered Drug Product



Advanced Glutathione, Glutathione for Injection 2400 mg
Rex Pharma Group – 1127, Bom Rakpart, Budapest, Hungary

Figure 12. Unregistered Drug Product



GSH Ultima 1500, Reduced Glutathione 1500 mg

Manufactured by Arrow Pharm Group – Level 11 Suite 167 Custom Street, Auckland 141 New Zealand

Manufactured for P&G Skinceuticals Trading Inc., Phils. – Unit 1-A 3/F 818 Bldg. 818 A Arnaiz Avenue, Makati City, Metro Manila Philippines 1223

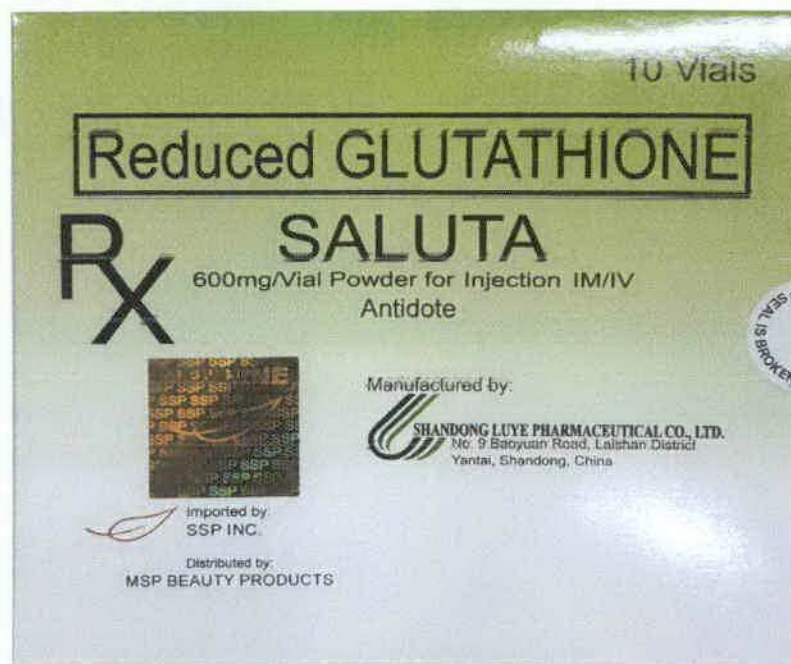
Figure 13. Unregistered Drug Product



Gerovytel

Arrow Pharm Group – Level 11 Suite 167 Custom Street Auckland 141, New Zealand

Figure 14. Unregistered Drug Product



Reduced Glutathione (Saluta) 600 mg / Vial Powder for Injection IM/IV
 Manufactured by Shandong Luye Pharmaceutical Co., Ltd. – No. 9 Baoyuan Road,
 Laishan District, Yantai, Shandong, China
 Imported by SSP Inc.
 Distributed by MSP Beauty Products

Figure 15, Unregistered Drug Product



**Reduced Glutathione + Hydrolyzed Collagen (Tatiomax) 1200 mg / 200 mg
Powder for Injection
Made in Japan**

Figure 16. Unregistered Drug Product