Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 JUN 2017

FDA ADVISORY
No. 2017-192-A

PARA: **SA LAHAT NG *HEALTHCARE PROFESSIONALS* AT SA PUBLIKO**

PAKSA: **Babala sa Publiko Tungkol sa Pagbili at Paggamit ng mga Hindi Rehistradong Gamot na:**

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)**

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng mga hindi rehistradong gamot.

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng *Food and Drug Administration* (FDA) na ang mga nasabing gamot ay hindi dumaan sa proseso ng rehistrasyon ng ahensya at hindi nabigyan ng kaukulang awtorisasyon tulad ng *Certificate of Product Registration* (CPR).

Alinsunod sa *Republic Act No.* 9711, o ang *Food and Drug Administration Act of 2009*, ang paggawa, pag-angkat, pagbenta, pamamahagi, paglipat, promosyon, pagpapatalastas o *sponsorship* ng produktong pangkalusugan nang walang kaukulang awtorisasyon mula sa FDA ay ipinagbabawal.

Gayundin, dahil ang mga hindi rehistradong produktong ito ay hindi dumaan sa proseso ng pagsusuri at pageeksamin ng FDA, hindi masisiguro ng ahensya ang

kalidad at kaligtasan ng mga ito. Ang mga nasabing iligal na produkto ay maaaring magdulot ng panganib sa kalusugan ng mga gagamit nito.

Ang publiko ay pinapaalalahanang huwag bumili ng mga nasabing iligal na produkto at maging maingat laban sa mga gamot na maaaring hindi rehistrado sa FDA. Ugaliing tingnan kung ang gamot ay rehistrado sa FDA bago bilhin, sa pamamagitan ng paggamit ng *Search feature* ng FDA *website* sa www.fda.gov.ph. Maaari ring tingnan ang FDA *Registration number* sa *label* ng produkto.

Ang lahat ng establisyamento at/o entidad ay binabalaang huwag mamahagi ng mga nasabing iligal na produkto hanggang ang mga ito ay mabigyan ng kaukulang awtorisasyon, sapagkat kaukulang parusa ay mahigpit na ipatutupad.

Hinihiling sa lahat ng *Local Government Units* (LGUs) at *Law Enforcement Agencies* (LEAs) na tiyaking ang mga produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

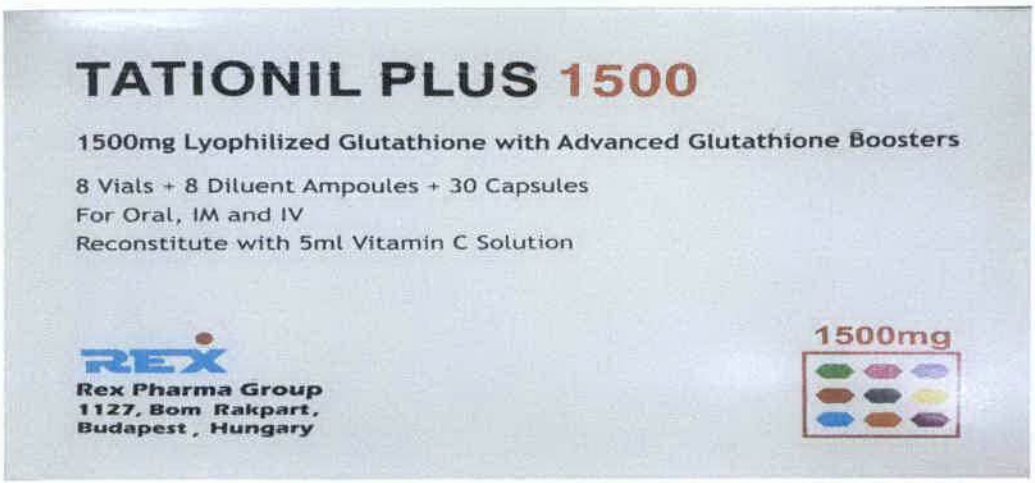
Para sa karagdagang impormasyon at katanungan, maaaring mag-*email* sa **info@fda.gov.ph**. Upang mag-*report* ng patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong gamot, mag-*email* sa **report@fda.gov.ph**, o mag-*report* gamit ang aming *online reporting facility*, ***eReport***, sa **www.fda.gov.ph**. Maaari ring tumawag sa *Center for Drug Regulation and Research* (CDRR) sa numerong **(02) 809-5596**. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-*report* agad sa FDA gamit ang *link* na ito: **www.fda.gov.ph/adr-report-new** at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.

NELA CHARADE G. PUNO, RPh
Director General

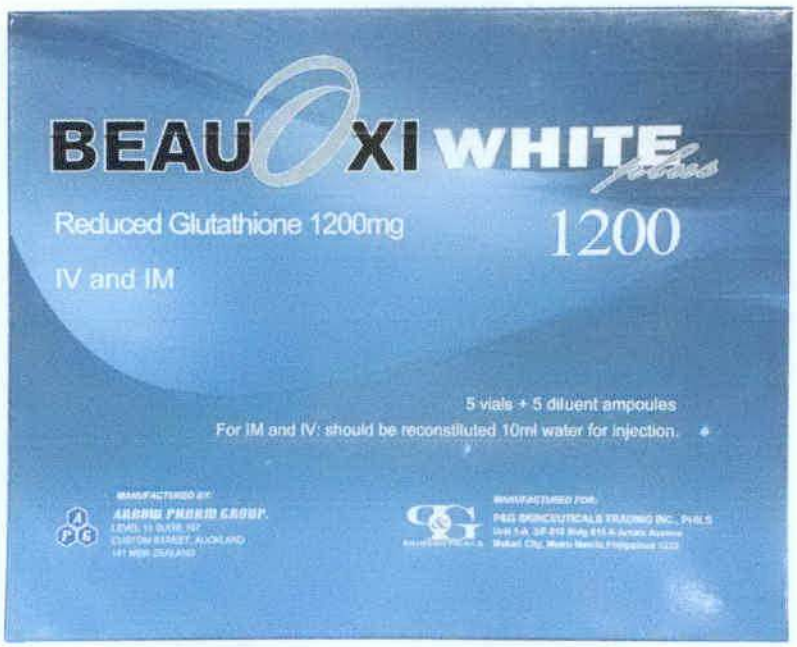
DTN: 20170606151531

ANNEX
Details on the Unregistered Drug Products



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

Larawan 1. Hindi rehistradong gamot

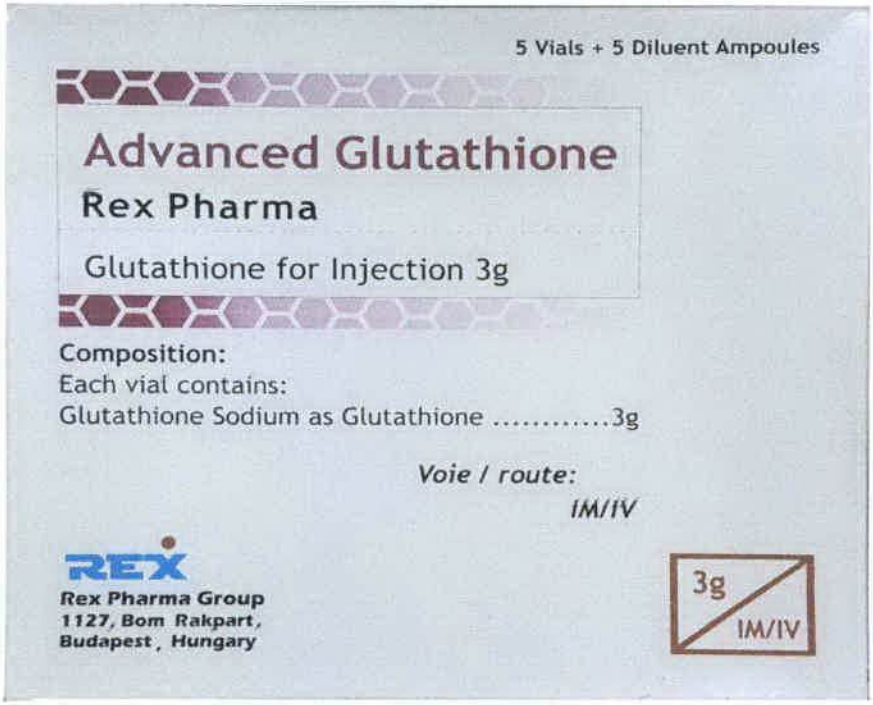


Beauoxi White plus 1200
Manufactured by Arrow Pharm Group – Level 11 Suite 167 Custom Street, Auckland 141 New Zealand
Manufactured for P&G Skinceuticals Trading Inc., Phils. – Unit 1-A 3/F 818 Bldg 818 A Arnaiz Avenue Makati City, Metro Manila Philippines 1223

Larawan 2. Hindi rehistradong gamot

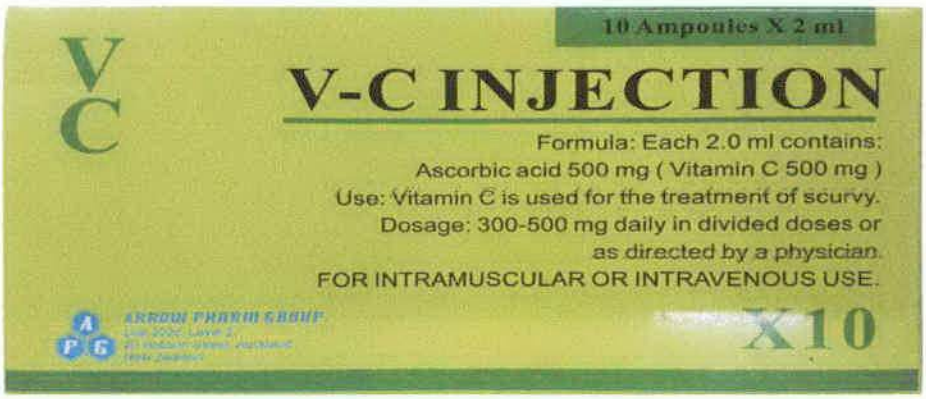
Tationil 600 mg / 4 mL
Teofarma s.r.l. =via F.lli Cervi, 8 = 27010 Valle Salimbene (PV)

Larawan 3. Hindi rehistradong gamot



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

Larawan 4. Hindi rehistradong gamot



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

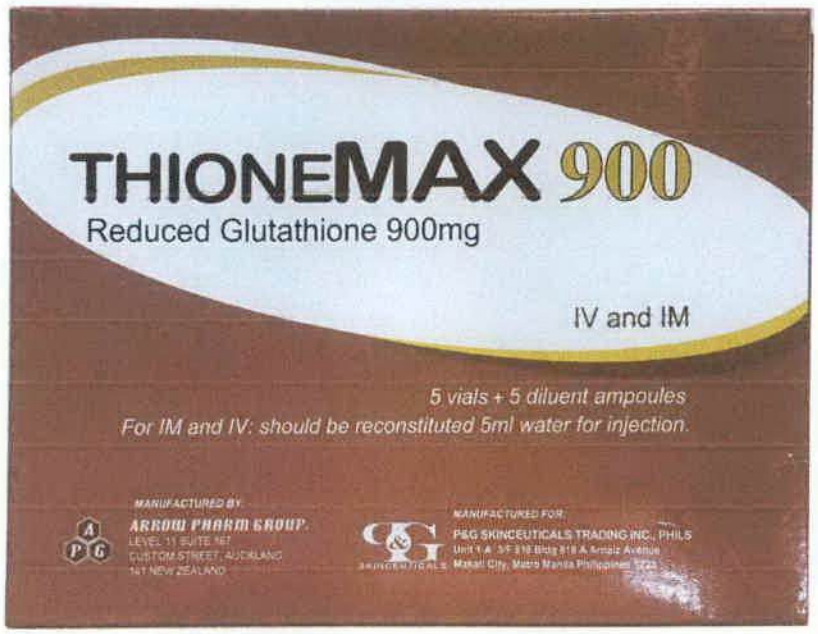
Larawan 5. Hindi rehistradong gamot

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

Larawan 6. Hindi rehistradong gamot

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

Larawan 7. Hindi rehistradong gamot

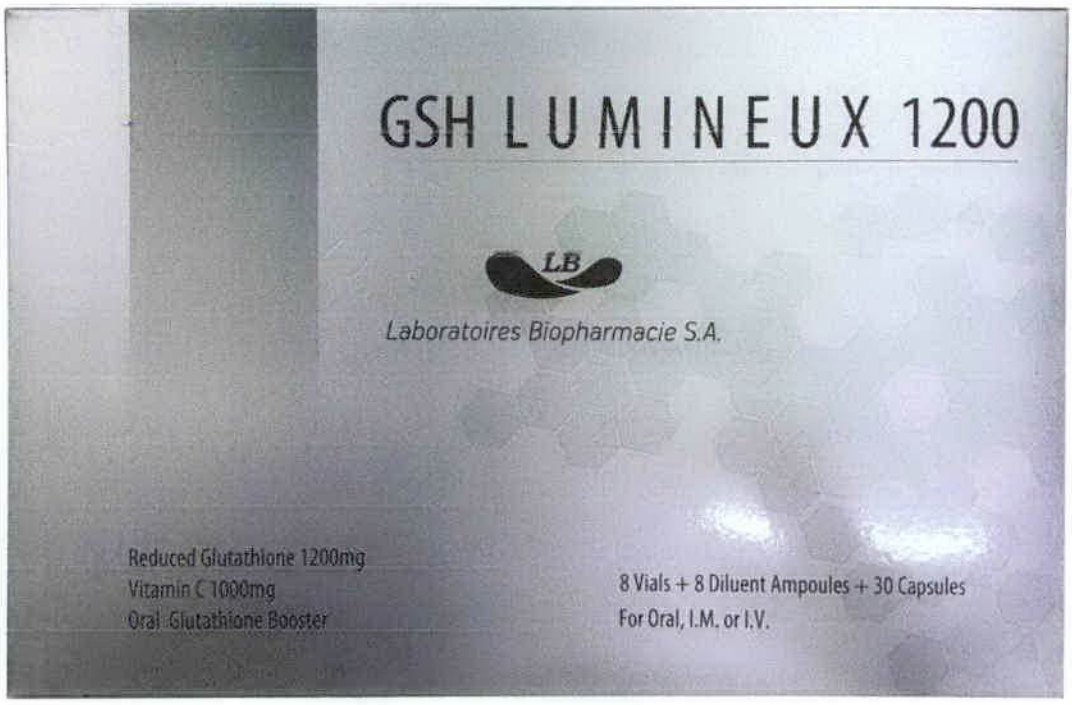


Thionemax 900
Manufactured by Arrow Pharm Group – Level 11 Suite 167, Custom Street, Auckland, 141 New Zealand
Manufactured for P&G Skinceuticals Trading Inc., Phils. – Unit 1-A, 3/F 818 Bldg 818 A Arnaiz Avenue, Makati City, Metro Manila Philippines 1223

Larawan 8. Hindi rehistradong gamot

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

Larawan 9. Hindi rehistradong gamot

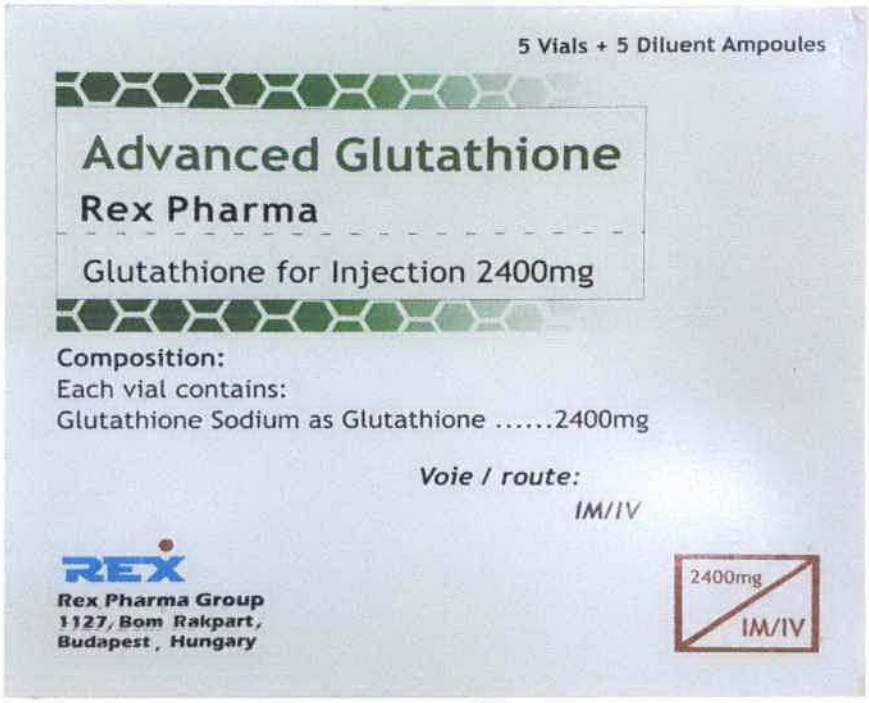


GSH LUMINEUX 1200
LB Laboratoires Biopharmacie S.A. – 37, Boulevard Saint-Marcel, 75013 Paris, France

Larawan 10. Hindi rehistradong gamot

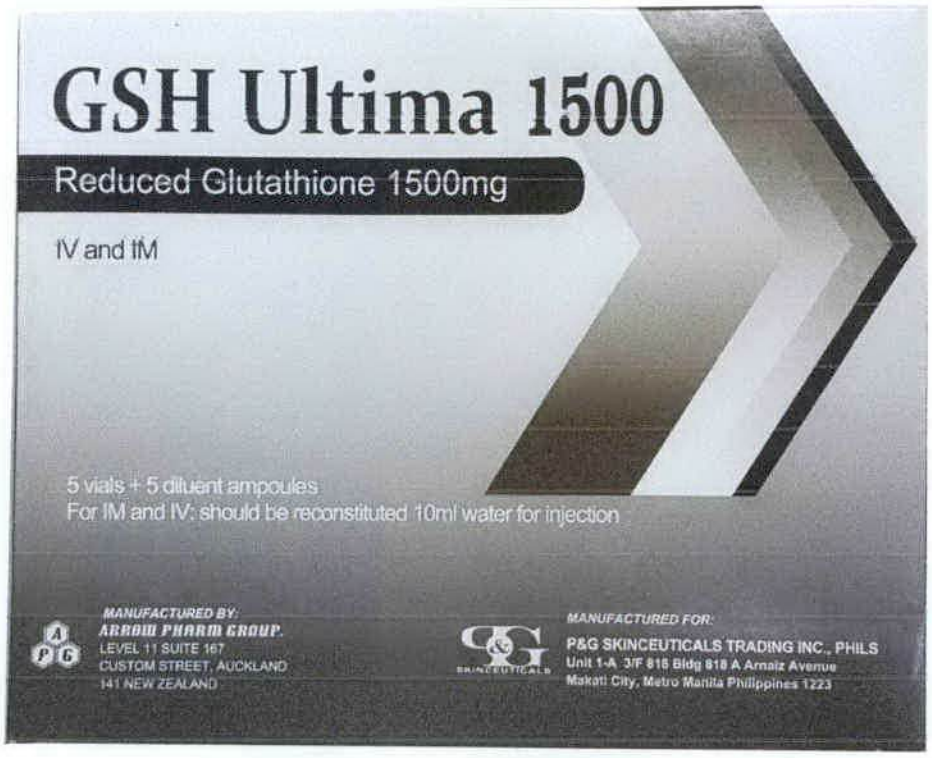
Tioredox 4.8 g Powder for Solution for infusion
Biomedica Foscama Group S.p.A.

Larawan 11. Hindi rehistradong gamot



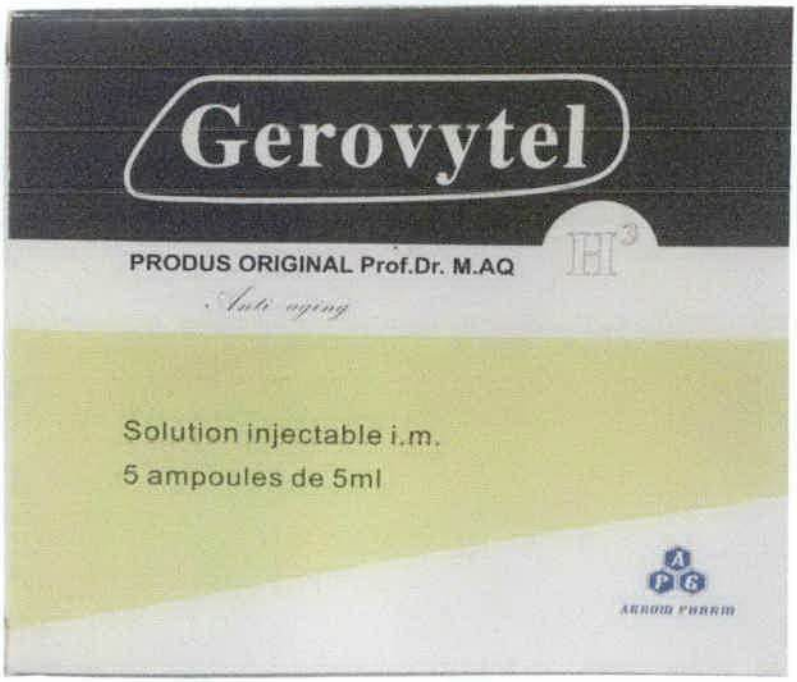
Advanced Glutathione, Glutathione for Injection 2400 mg
Rex Pharma Group – 1127, Bom Rakpart, Budapest, Hungary

Larawan 12. Hindi rehistradong gamot



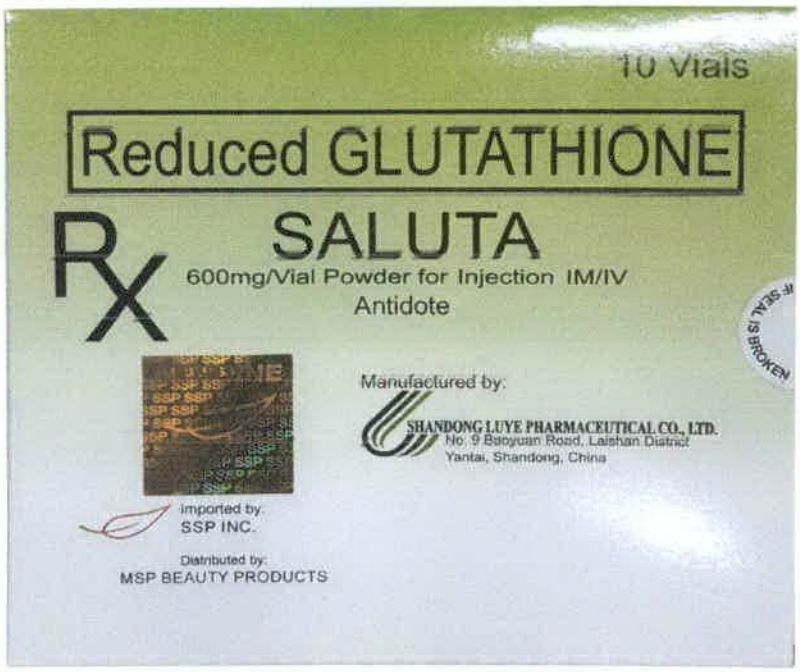
GSH Ultima 1500, Reduced Glutathione 1500 mg
Manufactured by Arrow Pharm Group – Level 11 Suite 167 Custom Street, Auckland 141 New Zealand
Manufactured for P&G Skinceuticals Trading Inc., Phils. – Unit 1-A 3/F 818 Bldg. 818 A Arnaiz Avenue, Makati City, Metro Manila Philippines 1223

Larawan 13. Hindi rehistradong gamot



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

Larawan 14. Hindi rehistradong gamot



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

Larawan 15. Hindi rehistradong gamot

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

Larawan 16. Hindi rehistradong gamot