



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2016-133**

15 NOV 2016

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. **Glutax 6GS Ultra Whitening**
2. **Glutax 9g Contengono EGF**
3. **Glutax 15G Nano Revitalise-SD**
4. **Glutax Glutathione 600GS Ultrafiltration**
5. **Glutax 200GS Diamond Bright**
6. **Glutathione (Saluta) 600 mg/Vial Reduced Glutathione Powder for Injection**
7. **Reduced Glutathione (Saluta) 1800 mg/Vial Powder for Injection IM/IV Antidote**
8. **Reduced Glutathione + Vitamin C (Tatiomax) 2.8 g Powder for Injection (Lyophilized Powder) I.M./I.V. Antidote**
9. **Glutathione + Hydrolyzed Collagen + Vitamin C (Tatiomax Plus) 1200 mg / 200 mg / 500 mg/5 mL Lyophilized Powder for IM or IV injection**
10. **Glutathione (Tad) 2500 mg / 25 mL Lyophilized Powder for Injection I.M. / I.V. Antidote**
11. **Reduced L-Glutathione (Reiki) 1200 mg I.V. / I.M.**
12. **Vitamin C Injection 500 mg / 2mL ampoule I.M. / I.V.**
13. **Vitamin C + Collagen (Laroscobine Platinum) Solution Injectable I.V.**
14. **Reduced Glutathione for Injection 2400 mg + Vitamin C 1000 mg / 5mL with Collagen 200 mg (Gluta Pro) I.M. / I.V.**
15. **Reduced Glutathione (ProWhite) 1800 mg / Vial Powder for Injection IM/IV Antidote**
16. **Reduced Glutathione (STS) 1.2 g Powder for Injection I.M. / I.V.**

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

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned drug products. These pose potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.



In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act. No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the products identified above. Anyone found selling the said products will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that these products are not sold or offered for sale in their localities or area of jurisdiction.

Consumers are advised to purchase their medications only from FDA-licensed establishments. In addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Please look for the FDA Registration number on the product label. Be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

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 you may call the telephone number (02)807-8275. 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: 20160825161149

ANNEX
Details on the Unregistered Drug Products



GLUTAX 6GS
Ultra Whitening

Ascorbic Acid 1000mg
Alpha Lipoic Acid 300mg
Collagen Extract 400mg
Vitamin E 400mg

Pro-Vitamina B3 300mg
Pro-Vitamina B5 200mg
Pro-Vitamina B6 100mg

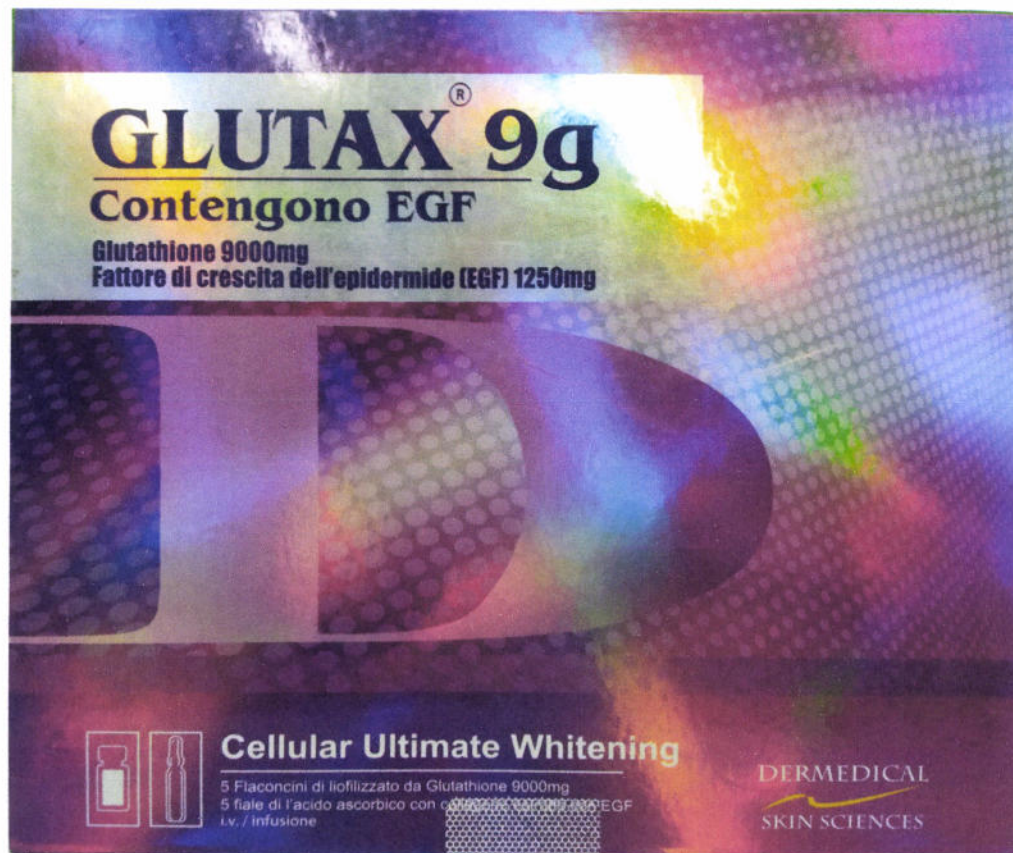
Salicylic Acid 500mg
Epidermal Growth Factor 200mg

PROVEN

DERMEDICAL SKIN SCIENCES

Glutax 6GS Ultra Whitening
Dermedical Skin Sciences – Via K. Marx, 18, Noverasco di Opera, MI, 20090, Italy

Figure 1. Unregistered Drug Product



Glutax 9g Contengono EGF

Dermedical Skin Sciences – Via K. Marx, 18, Noverasco di Opera, MI, 20090, Italy

Figure 2. Unregistered Drug Product

GLUTAX[®] 15G

Nano Revitalise-SD

L'acido ascorbico 2500mg
Collagene estratto 500mg
Vitamin E 400mg
Pro-Vitamin B3 350mg
Pro-Vitamin B5 350mg

Nano Glutathione 15000mg
Acido alfa lipoico 500mg
Marine Plant Stem Cell 500mg
Nano Licorice Extract 350mg
Kojic Acid 500mg

DERMEDICAL
SKIN SCIENCES

Composizione
5 flaconi di 15ml
L'acido ascorbico 2500mg
Collagene estratto 500mg
Vitamin E 400mg
Pro-Vitamin B3 350mg
Pro-Vitamin B5 350mg

5 flaconcini di
Nano Glutathione 15000mg
Acido alfa lipoico 500mg

5 flaconcini di
Marine Plant Stem Cell 500mg

5 flaconcini di
Nano Licorice Extract 350mg
Kojic Acid 500mg

Glutax 15G Nano Revitalise-SD
Dermedical Skin Sciences – Via K. Marx, 18, Noverasco di Opera, MI, 20090, Italy

Figure 3. Unregistered Drug Product

Page 5 of 18



Glutax Glutathione 600GS Ultrafiltration

Dermedical Skin Sciences – Via K. Marx, 18, Noverasco di Opera, MI, 20090, Italy

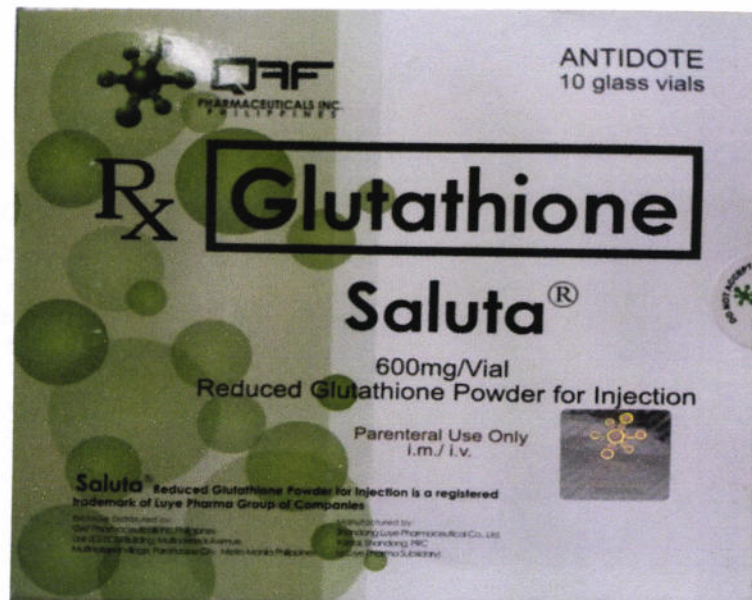
Figure 4. Unregistered Drug Product



Glutax 200GS Diamond Bright

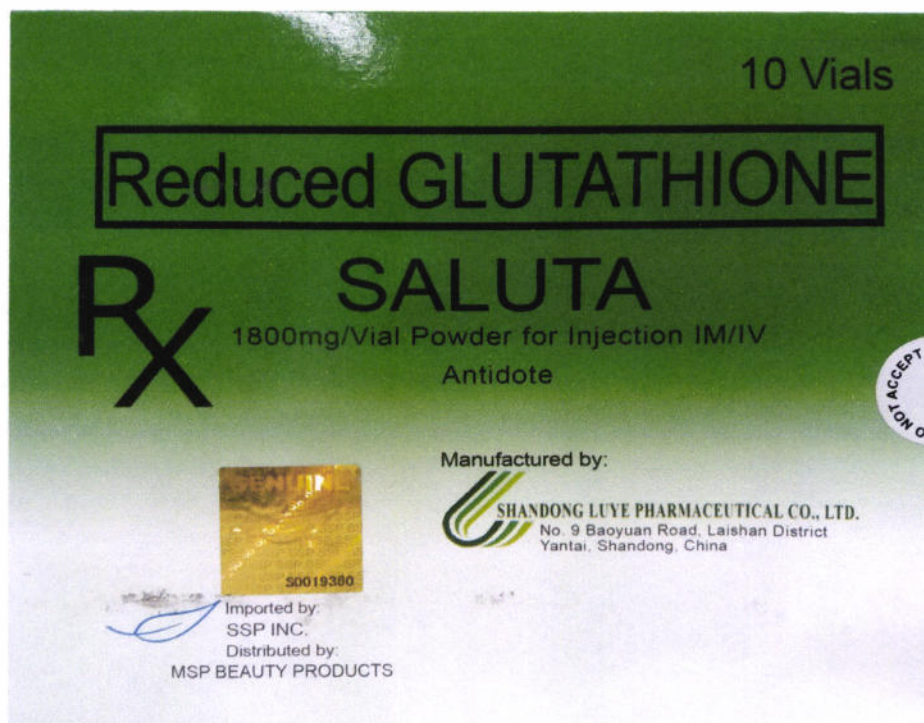
Dermedical Skin Sciences – Via K. Marx, 18, Noverasco di Opera, MI, 20090, Italy

Figure 5. Unregistered Drug Product



Glutathione (Saluta) 600 mg/Vial Reduced Glutathione Powder for Injection
 Manufactured by Shandong Luye Pharmaceutical Co., Ltd. – Yantai, Shandong, PRC
 (a Luye Pharma Subsidiary)
 Exclusive Distributed by QAF Pharmaceuticals Inc. Philippines – Unit 202 ECG
 Building, Multinational Avenue, Multinational Village, Parañaque City, Metro Manila
 Philippines (LTO expired last 04 March 2011)

Figure 6. Unregistered Drug Product



Reduced Glutathione (Saluta) 1800 mg/Vial Powder for Injection IM/IV Antidote

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 (LTO expired last 11 May 2011)

Figure 7. Unregistered Drug Product



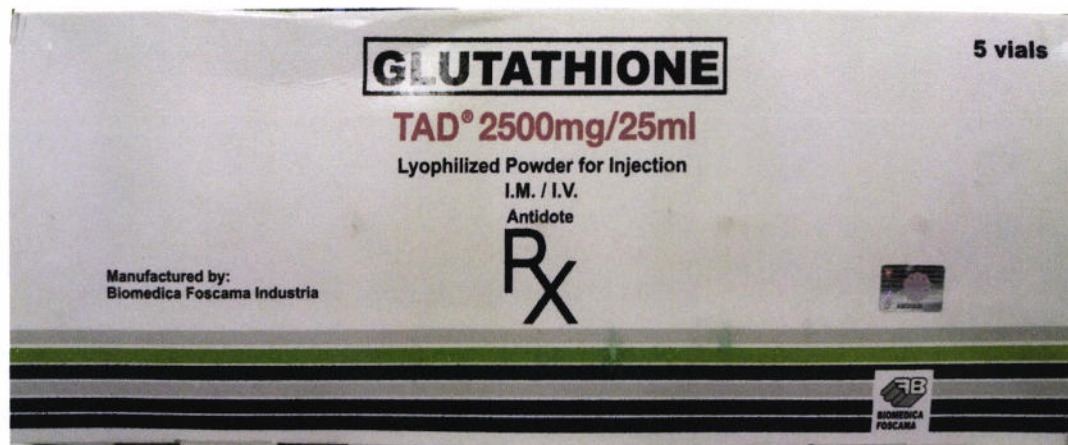
**Reduced Glutathione + Vitamin C (Tatiomax) 2.8 g Powder for Injection
(Lyophilized Powder) I.M./I.V. Antidote**
Made in Japan

Figure 8. Unregistered Drug Product



Glutathione + Hydrolyzed Collagen + Vitamin C (Tatiomax Plus) 1200 mg / 200 mg / 500 mg/5 mL Lyophilized Powder for IM or IV injection
Imported and Distributed by T/M Pharma Co.

Figure 9. Unregistered Drug Product



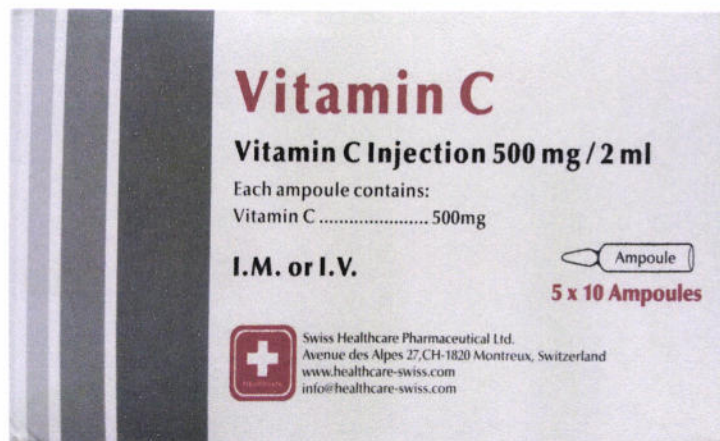
Glutathione (Tad) 2500 mg / 25 mL Lyophilized Powder for Injection I.M. / I.V. Antidote
 Manufactured by Biomedica Foscama Industria

Figure 10. Unregistered Drug Product



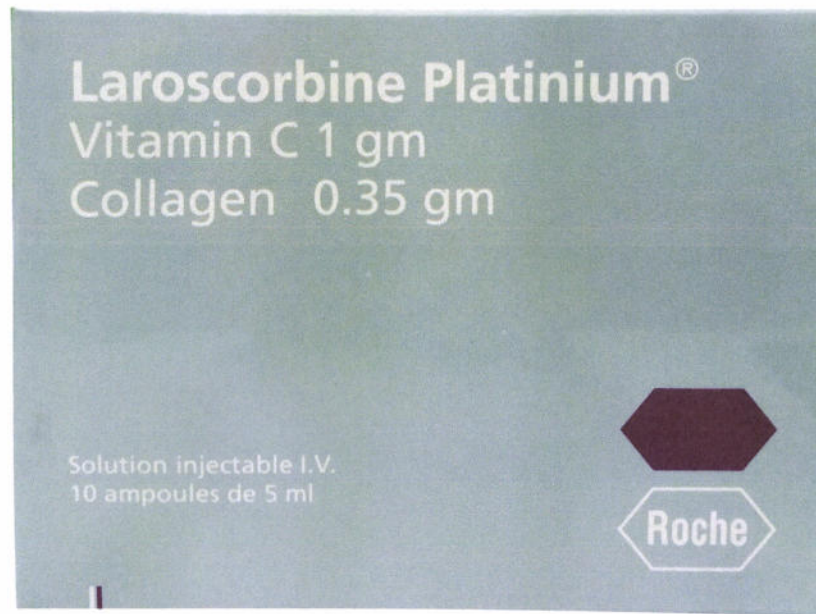
Reduced L-Glutathione (Reiki) 1200 mg I.V. / I.M.
Reiki International Ltd. Japan

Figure 11. Unregistered Drug Product



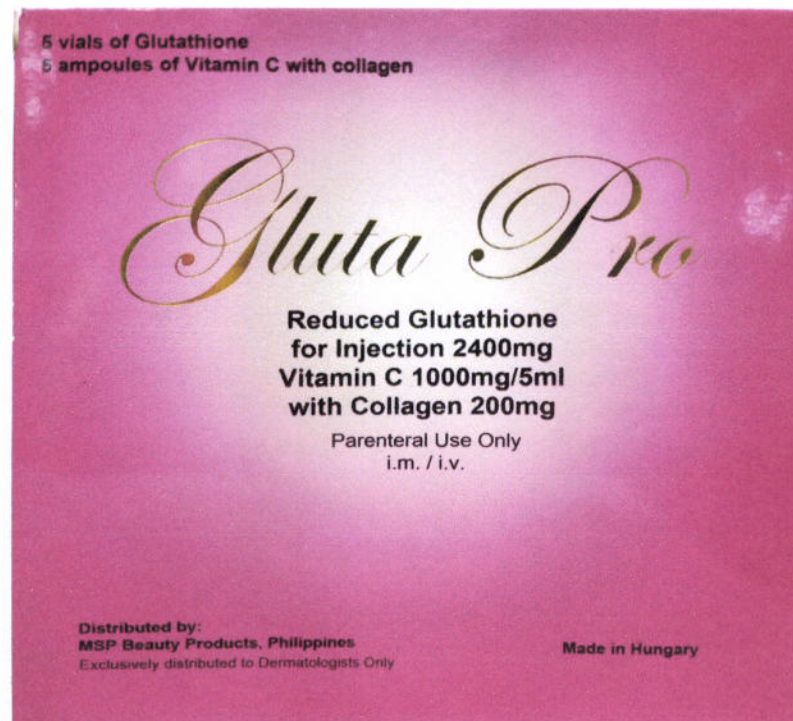
Vitamin C Injection 500 mg / 2mL ampoule I.M. / I.V.
 Swiss Healthcare Pharmaceutical Ltd. – Avenue des Alpes 27, CH-1820 Montreux, Switzerland

Figure 12. Unregistered Drug Product



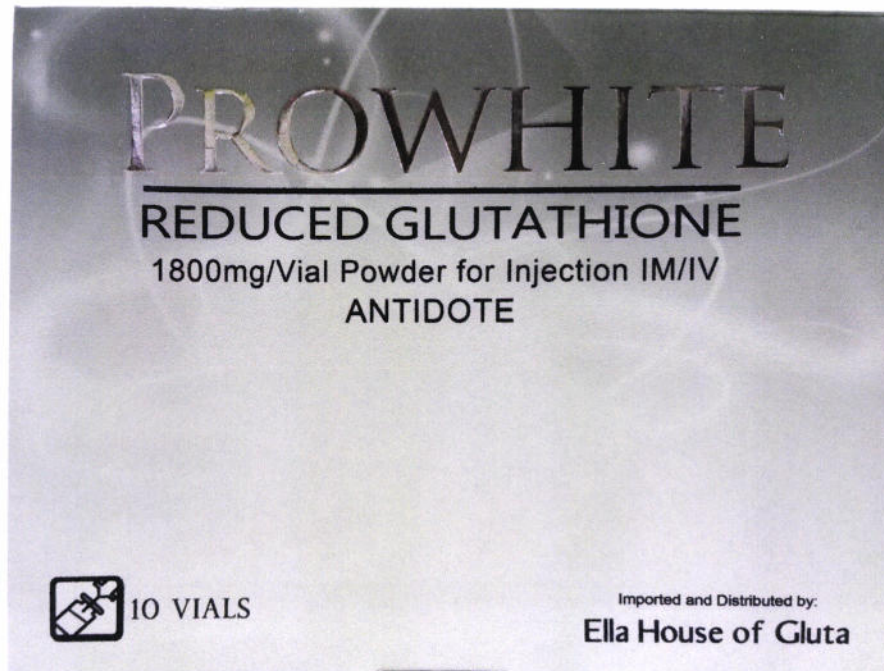
Vitamin C + Collagen (Laroscorbine Platinium) Solution Injectable I.V.
Laboratoires ROCHE NICHOLAS S.A.

Figure 13. Unregistered Drug Product



**Reduced Glutathione for Injection 2400 mg + Vitamin C 1000 mg / 5mL with
Collagen 200 mg (Gluta Pro) I.M. / I.V.**
Distributed by MSP Beauty Products, Philippines (LTO expired last 11 May 2011)

Figure 14. Unregistered Drug Product

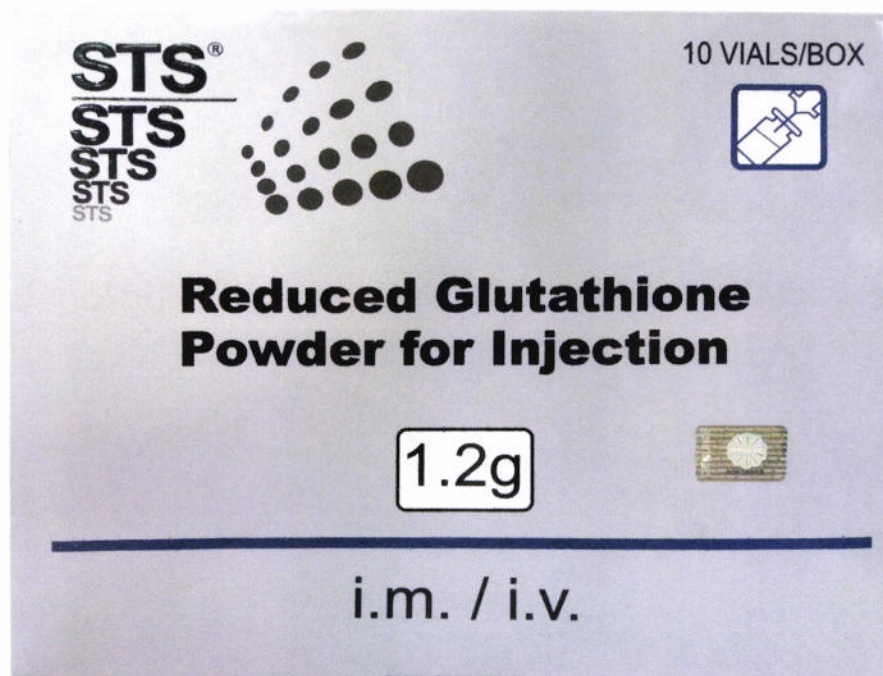


Reduced Glutathione (ProWhite) 1800 mg / Vial Powder for Injection IM/IV Antidote

Imported and Distributed by Ella House of Gluta (no LTO)

Exclusively Distributed by MSP Beauty Products (LTO expired last 11 May 2011)

Figure 15. Unregistered Drug Product



Reduced Glutathione (STS) 1.2 g Powder for Injection I.M. / I.V.
Manufacturer: Kunming Jida Pharmaceutical Co., Ltd.
Exclusively Distributed by: MSP Beauty Products (LTO expired last 11 May 2011)

Figure 16. Unregistered Drug Product