

Michael R. Pence Governor William C. VanNess II, MD State Health Commissioner

DATE:

April 30, 2014

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

Laurie Kidwell, RRT Supervisor

Food Protection Program

SUBJECT:

Flawless Beauty and Skin – RECALL [Drug]

AFFECTED

PRODUCT:

Roche Laroscrobine Platinum, Relumins Advanced Glutathione, QAF Pharmaceuticals

Inc. Philippines Saluta Glutathione Rx, Tatiomax Reduced Glutathione + Hydrolyzed

Collagen, TP Drug Laboratories Vitamin C, and Rx Sterile Water for Injection

SUMMARY:

Unclassified Recall; The recall has been initiated because the products are currently

unapproved drugs in the US.

The recalled products are listed below:

NAME	STRENGTH	UPC	LOT/BATCH #	EXP.D ATE
Roche Laroscrobine Platinum	1gm Vitamin C + 0.35gm Collagen	*3421357*	F040	08- 2016
Tatiomax Reduced Glutathione + Hydrolyzed Collagen	1200mg Reduced Glutathione + 200mg Reduced Collagen	4973430081576	UB302	5-12- 15
Saluta Glutathione Rx	600mg Glutathione	6920425209014	201302275	1/20/15
			201308384	10/19/2 015
Relumins Advanced Glutathione	1500mg Glutathione + 500mg Vitamin C	700175760302	130616	2016.0 6
TP Drug Laboratories Vitamin C	500mg	8853533000533	556273	25/9/16
			556219	2/8/16



NAME	STRENGTH	UPC	LOT/BATCH #	EXP.D ATE
Rx Sterile Water for Injection	N/A		16U421	08- 2016
		4800573016219	16U423	09- 2016
			16U394	04- 2016
TP Drug Laboratories Vitamin C	N/A	N/A	Reg.No.:	N/A
		are I was also de	1A1557/30	

The recalled lots were distributed in the US to wholesale, retail & Internet customers.

SUGGESTED

ACTION:

For consumer inquiry only. Consumers with questions regarding this recall can contact Flawless Beauty and Skin by +1-917-831-5948 or sweetsuzzy@flawlessbeautyandskin.com on Monday-Friday, 9:30AM-5:30 PM, EST.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Flawless Beauty and Skin Issues Voluntary USA Recall of Unapproved Drugs

Contact:

Consumer: 1-917-831-5948

sweetsuzzy@flawlessbeautyandskin.com

Media: Jack Gindi 1-917-653-3856

FOR IMMEDIATE RELEASE —April 29, 2014 – Asbury Park, NJ, Flawless Beauty and Skin is voluntarily recalling eleven (11) lots of Roche Laroscrobine Platinum, Relumins Advanced Glutathione, QAF Pharmaceuticals Inc. Philippines Saluta Glutathione Rx, Tatiomax Reduced Glutathione + Hydrolyzed Collagen, TP Drug Laboratories Vitamin C, and Rx Sterile Water for Injection to the retail and consumer level. These products are currently unapproved drugs in the US.

These products claim to treat scurvy, degenerative brain and liver diseases, alcoholic liver disease, and serve as antidotes to various drugs. The label claims may result in patients not seeking proper medical treatment. Furthermore, the fact that these products may be administered intramuscularly or intravenously, heightens the risk associated with unknown quality, safety, or efficacy. To date, Flawless Beauty and Skin has not received any reports of adverse events related to this recall.

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Rx Sterile Water for Injection	N/A	4800573016219	16U423	09-2016
			16U394	04-2016
TP Drug Laboratories Vitamin C	N/A	N/A	Reg.No.:	
			1A1557/30	N/A

Flawless Beauty and Skin is notifying its distributors and customers by sending recall letters and is arranging for return of all recalled products. Consumers, distributors & retailers that have the products which are being recalled should stop using & return to Flawless Beauty and Skin.

Consumers with questions regarding this recall can contact Flawless Beauty and Skin by +1-917-831-5948 or sweetsuzzy@flawlessbeautyandskin.com on Monday-Friday, 9:30AM – 5:30 PM, EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report Online: www.fda.gov/medwatch/report.html

 Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.html or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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