



FDA ADVISORY
No. **2018-214**

02 JUL 2018

TO: GENERAL CONSUMING PUBLIC

**SUBJECT: Public Health Warning Against the Use of Unnotified
Cosmetic Products (Batch 11)**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unnotified cosmetic products whose particulars/details are provided in the attached annex:

1. VAPORISING RUB MANGOSTEEN
2. SAM-SAMMI SPF 35+++ SUNBLOCK FACE CREAM
3. SAM-SAMMI MERIAM CEBO DE MACHO
4. ROYALE BEAUTY® L-GLUTAPOWERR® FACIAL SOAP
5. FAIRY SKIN GLOWING FACIAL SET:
 - A. FAIRY SKIN FACIAL TONER
 - B. FAIRY SKIN BLEACHING SOAP
 - C. FAIRY SKIN WHITENING CREAM
 - D. FAIRY SKIN SUNBLOCK CREAM SPF 45
6. LOVIA PROFESSIONAL PREMIUM HAIR COLOUR CREAM (NATURAL BLACK 2.0)
7. MYCHOICE® BUBBLE SCRUB SHOWER SALT HIGH CONCENTRATE (CUCUMBER) 2-IN-1 REFRESHING
8. MYCHOICE® RED CROWN CREAM PUFF (5)
9. EPIELLE™ HAIR COLOR DARK BROWN
10. PERSONAL CARE VITAMIN E SKIN OIL 1500 IU
11. EAD SUNSCREEN BROAD SPECTRUM LOTION SPF15
12. SANTEE® USA MAGIC SKIN BEAUTIFIER BB SPF20 (6)
13. MYCHOICE® ANTI-ACNE FACIAL FOAM
14. HENGFANG® CUSHIOM CARESSE (NO. 9047)
15. ASHLEY SHINE HAIR COLOR SPRAY CHESTNUT RED
16. INFINITE BEAUTY SKIN AND BEYOND RADIANCE SERUM
17. BEAUTY LUSH SKIN ESSENTIALS PERFECT FIRING SOAP
18. MYUNGIN FARMSTAY GRAPE STEM CELL TONER
19. GEVEMIA TRI&1™ PROFESSIONAL HAIR COLOUR (H819 GRAPE-PURPLE)
20. BEAUTY HOST PAPAYA WHITENING PEELING GEL
21. HIMALAYA® HERBALS PROTECTING NEEM & TURMERIC SOAP
22. LACTO CARROT SOAP WITH LACTOBACILLUS PAFI
23. NEW YAKI BABY SOAP BLOSSOMS
24. COSMETIC BUFFET REJUVENATING SET KIT 1:
 - A. COSMETIC BUFFET BLEACHING CREAM
 - B. COSMETIC BUFFET REJUVENATING TONER



- C. COSMETIC BUFFET KOJIC ACID SOAP**
D. COSMETIC BUFFET DAY CREAM
- 25. JARFUL OF GOODNESS CHOCO SOAP**
 - 26. JARFUL OF GOODNESS GENTLE CLAY & CHARCOAL SOAP**
 - 27. JARFUL OF GOODNESS PURE CASTILE ALL-NATURAL SOAP**
 - 28. BAZ'A GALAXDOR MAKEUP CLEANSING WIPES**
 - 29. ULTRA COMSOFT WET WIPES (MANGO)**
 - 30. ULTRA COMSOFT WET WIPES (GREEN APPLE)**
 - 31. HP HILTON PACKARD 5 IN 1 ACTION WIPES (YELLOW)**
 - 32. ULTRA SOFT SENSITIVE COMSOFT WITH ALOE VERA BABY WIPES**
 - 33. DONG BANG® 123 KID'S BABY WIPES**
 - 34. MB MISS BEAUTY MAKE-UP KIT (MB6464) (1)**
 - 35. ADS FASHION BLUSHER (A8408) (3)**
 - 36. LADY BELLE SKIN ENHANCERS BY OSEUR LADY BELLE NIGHT TIME CRÈME**
 - 37. MERIAM GLUTA CREAM LOTION CHERRY BLOSSOM SCENT**
 - 38. LP MIRACLE CREAM WITH ARGAN AND VITAMIN SPF 55**
 - 39. SUNBLOCK CREAM SPF 30**
 - 40. WELLCHECK™ VALUESCENT™ EXTRA STRENGTH WITH VITAMIN E**

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned cosmetic products have not gone through the verification process of the agency and have not been issued the proper authorization in the form of acknowledged cosmetic notifications. 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, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization from FDA is prohibited.

Accordingly, because unnotified cosmetic products have not gone through the verification process of the FDA, the agency cannot guarantee their quality and safety. The use of such violative products may pose potential health hazards to the consuming public.

Potential hazards may come from ingredients that are not allowed to be part of a cosmetic product or from the contamination of heavy metals such as mercury especially in whitening cosmetic products. The use of substandard and possibly adulterated cosmetic products may result to adverse reactions including but not limited to skin irritation, itchiness, anaphylactic shock and organ failure.

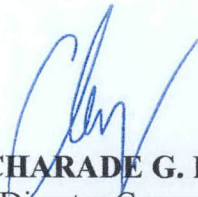
In light of the above, the public is advised not to purchase the aforementioned violative products. Moreover, the public is also advised to be vigilant against cosmetic products that might not be duly notified with FDA. Always check if a cosmetic product has been notified with FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph.

All concerned establishments are warned not to distribute the above-identified violative cosmetic products until they have already been covered by the appropriate authorization (cosmetic notification), 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 the above unnotified cosmetic products, utilize our online reporting facility, **eReport**, at www.fda.gov.ph/ereport, or e-mail us via report@fda.gov.ph, or call us at the Center for Cosmetics Regulation and Research (CCRR) hotline **(02) 857-1900 local 8113 or 8107**.

Dissemination of the information to all concerned is requested.


NELA CHARADE G. PUNO, RPh
Director General

DTN 20180619155257




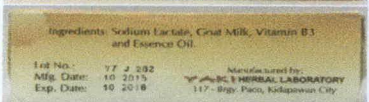


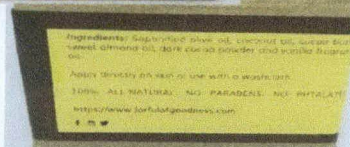
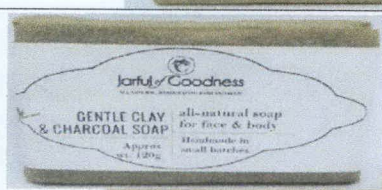
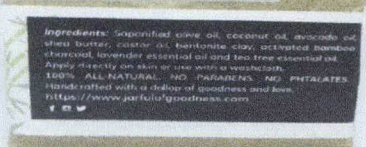

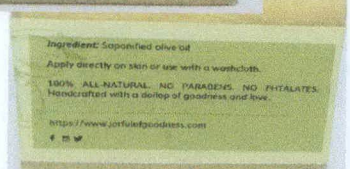
ANNEX
Details of the Unnotified Cosmetic Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1 VAPORISING RUB MANGOSTEEN	Local Company Responsible for Placing the Product in the Market: Sam-Sammi Herbal Products Address: Odiongan, Romblon Country of Manufacture: Philippines	
2 SAM-SAMMI SPF 35+++ SUNBLOCK FACE CREAM	Local Company Responsible for Placing the Product in the Market: Sam-Sammi Herbal Products Address: Odiongan, Romblon Country of Manufacture: Philippines	
3 SAM-SAMMI MERIAM CEBO DE MACHO	Local Company Responsible for Placing the Product in the Market: Sam-Sammi Herbal Products Address: Odiongan, Romblon Country of Manufacture: Philippines	
4 ROYALE BEAUTY® L- GLUTAPOWER® FACIAL SOAP	Local Company Responsible for Placing the Product in the Market: Royale Business Club International, Inc.® Address: Royale Centre 1363A Quezon Avenue, West Triangle, Quezon City, Philippines 1104 Country of Manufacture: Philippines	
5 FAIRY SKIN GLOWING FACIAL SET:	Local Company Responsible for Placing the Product in the Market: Fairy Skin Address: Not Indicated Country of Manufacture: Philippines	
A. FAIRY SKIN FACIAL TONER		
B. FAIRY SKIN BLEACHING SOAP		
C. FAIRY SKIN WHITENING CREAM		
D. FAIRY SKIN SUNBLOCK CREAM SPF 45		

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
6	LOVIA PROFESSIONAL PREMIUM HAIR COLOUR CREAM (NATURAL BLACK 2.0)	Local Company Responsible for Placing the Product in the Market: BestCare Global Marketing Inc. Address: Makati, Philippines Country of Manufacture: P.R.C.	
7	MYCHOICE® BUBBLE SCRUB SHOWER SALT HIGH CONCENTRATE (CUCUMBER) 2-IN-1 REFRESHING	Local Company Responsible for Placing the Product in the Market: Prime Asia Consolidated Products Corporation Address: Not Indicated Country of Manufacture: Thailand	
8	MYCHOICE® RED CROWN CREAM PUFF (5)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Thailand	
9	EPIELLE™ HAIR COLOR DARK BROWN	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Korea	
10	PERSONAL CARE VITAMIN E SKIN OIL 1500 IU	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: India	
11	EAD SUNSCREEN BROAD SPECTRUM LOTION SPF15	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: United Arab Emirates	



PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
12 SANTEE® USA MAGIC SKIN BEAUTIFIER BB SPF20 (6)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: P.R.C.	
13 MYCHOICE® ANTI-ACNE FACIAL FOAM	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Thailand	
14 HENGFANG® CUSHIOM CARESSE (NO. 9047)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
15 ASHLEY SHINE HAIR COLOR SPRAY CHESTNUT RED	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: China	
16 INFINITE BEAUTY SKIN AND BEYOND RADIANCE SERUM	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Philippines	
17 BEAUTY LUSH SKIN ESSENTIALS PERFECT FIRING SOAP	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Philippines	

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
18	MYUNGIN FARMSTAY GRAPE STEM CELL TONER	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Korea	
19	GEVEMIA TRI&1™ PROFESSIONAL HAIR COLOUR (H819 GRAPE-PURPLE)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
20	BEAUTY HOST PAPAYA WHITENING PEELING GEL	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: China	
21	HIMALAYA® HERBALS PROTECTING NEEM & TURMERIC SOAP	Local Company Responsible for Placing the Product in the Market: Transfarma Philippines, Inc. Address: 24/F Philippine AXA Life Center, 1286 Sen. Gil Puyat Avenue cor. Tindalo St., Makati, 1200, Philippines Country of Manufacture: India	
22	LACTO CARROT SOAP WITH LACTOBACILLUS PAFI	Local Company Responsible for Placing the Product in the Market: Lactocom Marketing Address: Not Indicated Country of Manufacture: Philippines	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
23 NEW YAKI BABY SOAP BLOSSOMS	<p>Local Company Responsible for Placing the Product in the Market: Yaki Herbal Laboratory</p> <p>Address: 117-Brgy. Paco, Kidapawan City</p> <p>Country of Manufacture: Not Indicated</p>	 
24 COSMETIC BUFFET REJUVENATING SET KIT 1:	<p>Local Company Responsible for Placing the Product in the Market: Cosmetic Buffet Skin Essential Products Enterprise</p> <p>Address: AJEA Building Muzon National Road Taytay Rizal 1920</p> <p>Country of Manufacture: Not Indicated</p>	
25 JARFUL OF GOODNESS CHOCO SOAP	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	 
26 JARFUL OF GOODNESS GENTLE CLAY & CHARCOAL SOAP	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	 
27 JARFUL OF GOODNESS PURE CASTILE ALL-NATURAL SOAP	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	 

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
28	BAZ'A GALAXDOR MAKEUP CLEANSING WIPES	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: China	
29	ULTRA COMSOFT WET WIPES (MANGO)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
30	ULTRA COMSOFT WET WIPES (GREEN APPLE)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
31	HP HILTON PACKARD 5 IN 1 ACTION WIPES (YELLOW)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: P.R.C.	
32	ULTRA SOFT SENSITIVE COMSOFT WITH ALOE VERA BABY WIPES	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	

33	PRODUCT NAME DONG BANG® 123 KID'S BABY WIPES	PRODUCT DETAILS Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: China	PRODUCT IMAGE/S 
34	MB MISS BEAUTY MAKE-UP KIT (MB6464) (1)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: Not Indicated	
35	ADS FASHION BLUSHER (A8408) (3)	Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated Country of Manufacture: China	
36	LADY BELLE SKIN ENHANCERS BY OSEUR LADY BELLE NIGHT TIME CRÈME	Local Company Responsible for Placing the Product in the Market: Hermon International Marketing Address: Not Indicated Country of Manufacture: Not Indicated	
37	MERIAM GLUTA CREAM LOTION CHERRY BLOSSOM SCENT	Local Company Responsible for Placing the Product in the Market: Sam-Sammi Herbal Products Address: Odiongán, Romblon Country of Manufacture: Philippines	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
<p>38 LP MIRACLE CREAM WITH ARGAN AND VITAMIN SPF 55</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	
<p>39 SUNBLOCK CREAM SPF 30</p>	<p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p>	
<p>40 WELLCHECK™ VALUESCENT™ EXTRA STRENGTH WITH VITAMIN E</p>	<p>Local Company Responsible for Placing the Product in the Market: Aldrtz Corporation</p> <p>Address: 23 Lacson Ext., Corner Alijis Road, Bacolod City, Philippines, 6100</p> <p>Country of Manufacture: Philippines</p>	