



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. **2016-051**

03 JUN 2016

TO : GENERAL CONSUMING PUBLIC, FIELD REGULATORY OPERATIONS OFFICE OF THE FOOD AND DRUG ADMINISTRATION, LAW ENFORCEMENT AGENCIES, LOCAL GOVERNMENT UNITS AND COSMETIC RETAILERS

SUBJECT : Public Health Warning Against the Use of Unnotified Cosmetic Products

The 1987 Constitution of the Republic of the Philippines provided that "*The State shall protect and promote the right to health of the people and instill health consciousness among them.*" In line with this, Republic Act (RA) No. 3720 otherwise known as "Foods, Drugs and Devices, and Cosmetics Act," as amended by RA No. 9711, otherwise known as "Food and Drug Administration Act of 2009" has mandated the Food and Drug Administration (FDA) to ensure the safety, quality and efficacy of health products under its jurisdiction.

FDA, being the national regulatory authority covering cosmetic products, requires companies intending to manufacture, import, export, distribute, sell, offer for sale, transfer, promote and advertise cosmetic products to apply with the aforementioned agency, prior to carrying out said activities, for the following market authorizations, specifically (1) License to Operate (LTO) as Cosmetic Establishments and (2) Cosmetic Product Notification.

ASEAN Cosmetic Directive (ACD), adopted and implemented through the issuance of Administrative Orders (A.O.) 2005-0015 and 2005-0025, states in Article 1.3

"The company or person responsible for placing the cosmetic products in the market, shall notify the regulatory authority responsible for cosmetics (hereafter referred to as regulatory authority) of each Member State where the product will be marketed of the place of the manufacture or of initial importation before the product is placed in the market"

Thus, FDA hereby advises the general public not to purchase/use the following cosmetic products that have been collected from Region II and the National Capital

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines

Trunk Line +63 2 857 1900

Website: www.fda.gov.ph

Fax +63 2 807 0751

Email: info@fda.gov.ph



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System

www.tuv.com
ID 9105073396



Region (NCR). These products have not passed through the verification process of FDA thus have no valid cosmetic product notifications:

1. BSICA PERFUME CHARMING HAND WASHING GEL ROSE

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 1. BSICA Perfume Charming Hand Washing Gel Rose (Principal Display Panel)



Figure 2. BSICA Perfume Charming Hand Washing Gel Rose (Back)

2. BSICA PERFUME CHARMING HAND WASHING GEL TULIPS

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated

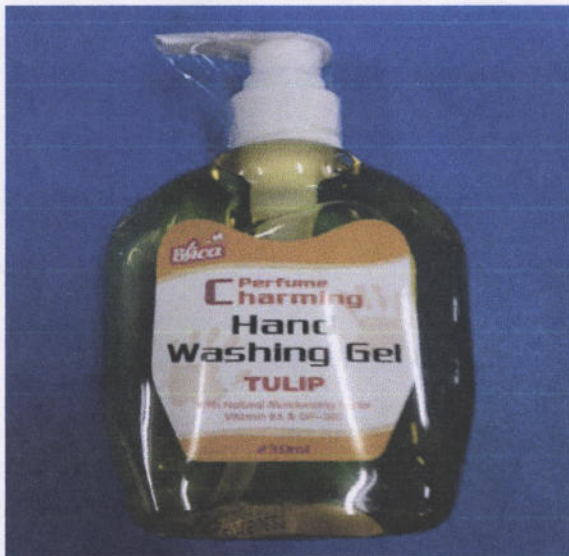


Figure 3. BSICA Perfume Charming Hand Washing Gel Tulip (Principal Display Panel)

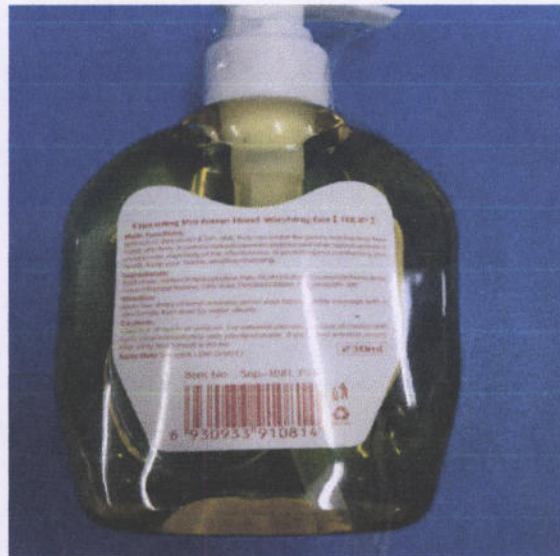


Figure 4. BSICA Perfume Charming Hand Washing Gel Tulip (Back)

3. BSICA PERFUME CHARMING HAND WASHING GEL LAVENDER

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 5. BSICA Perfume Charming Hand Washing Gel Lavender (Principal Display Panel)



Figure 6. BSICA Perfume Charming Hand Washing Gel Lavender (Back)

4. BSICA MOISTURIZING HAND WASHING GEL ALOE

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 7. BSICA Moisturizing Hand Washing Gel Aloe (Principal Display Panel)



Figure 8. BSICA Moisturizing Hand Washing Gel Aloe (Back)

5. BSICA MOISTURIZING HAND WASHING GEL JASMINE

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated

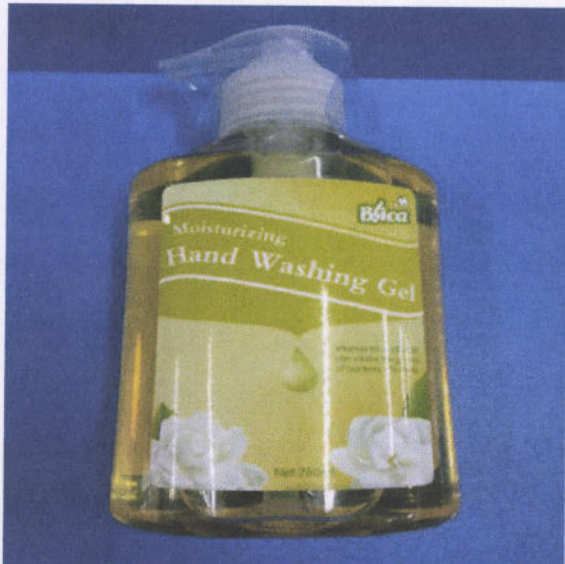


Figure 9. BSICA Moisturizing Hand Washing Gel Jasmine (Principal Display Panel)



Figure 10. BSICA Moisturizing Hand Washing Gel Jasmine (Back)

6. BSICA MOISTURIZING HAND WASHING GEL GREEN TEA

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 11. BSICA Moisturizing Hand Washing Gel Green Tea (Principal Display Panel)



Figure 12. BSICA Moisturizing Hand Washing Gel Green Tea (Back)

7. BSICA BODY LOTION ROSE

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 13. BSICA Body Lotion Rose (Principal Display Panel)



Figure 14. BSICA Body Lotion Rose (Back)

8. BSICA ANTIBACTERIAL HAND SANITIZER LAVENDER

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 15. BSICA Antibacterial Hand Sanitizer Lavender (Front, Hangtag)



Figure 16. BSICA Antibacterial Hand Sanitizer Lavender (Back, Hangtag)

9. BSICA ANTIBACTERIAL HAND SANITIZER ALOE

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 17. BSICA Antibacterial Hand Sanitizer Aloe (Front, Hangtag)



Figure 18. BSICA Antibacterial Hand Sanitizer Aloe (Back, Hangtag)

10. BSICA HAIR GEL B5

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 19. BSICA Hair Gel B5 (Principal Display Panel)



Figure 20. BSICA Hair Gel B5 (Back)

11. NYX HD STUDIO PHOTOGENIC FOUNDATION HDF 102 SOFT BEIGE

Manufacturer's Name: Not Indicated

Country of Manufacture: South Korea

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 21. NYX HD Studio Photogenic Foundation HDF 102 Soft Beige (Principal Display Panel)



Figure 22. NYX HD Studio Photogenic Foundation HDF 102 Soft Beige (Back)

12. E.L.F. LIPSTICK 7702 CLASSY

Manufacturer's Name: Not Indicated

Country of Manufacture: Covered by Price Tag

Local Company Responsible for Placing the Product in the Market: Sichel & Sichel Ent.

Address: 2602 CPTT Tower, 2210 Don Chino Rocas Ave., Makati



Figure 23. E.L.F. Lipstick 7702 Classy (Principal Display Panel)



Figure 24. E.L.F. Lipstick 7702 Classy (Back)

13. DEXE® HAIR COLOR SHAMPOO CHESTNUT BROWN

Manufacturer's Name: U-Top Technology Limitde (U.K.)

Country of Manufacture: United Kingdom (U.K.)

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 25. Dexe Hair Color Shampoo Chestnut Brown (Principal Display Panel)



Figure 26. Dexe Hair Color Shampoo Chestnut Brown (Back)

14. DEXE® BLACK HAIR SHAMPOO

Manufacturer's Name: Not Indicated

Country of Manufacture: Not Indicated

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated

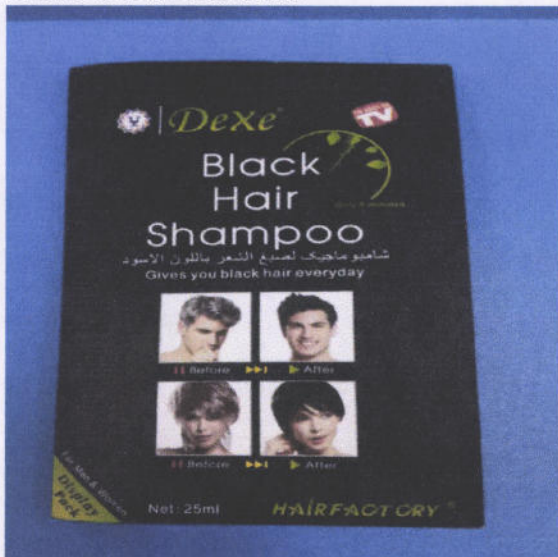


Figure 27. Dexe Black Hair Shampoo (Principal Display Panel)

15. DEXE® PERMANENT HAIR COLOR CREAM 1.00 BROWN BLACK

Manufacturer's Name: Dexe Group Inc. (U.K.)

Country of Manufacture: United Kingdom (U.K.)

Local Company Responsible for Placing the Product in the Market: Not Indicated

Address: Not Indicated



Figure 28. Dexe Permanent Hair Color Cream 1.00 Brown Black

The manufacture, importation, exportation, distribution, sale, offer for sale, transportation, promotion and/or advertisement of these cosmetic products are in direct violation of RA No. 9711.

Unnotified cosmetic products, not having been verified by FDA, pose potential health hazards to the consuming public. FDA cannot guarantee their quality and safety. The use of substandard and possibly adulterated cosmetic products may result to adverse reactions including but not limited to skin irritation, itchiness and anaphylactic shock. Thus, the public is advised to always verify if a cosmetic product has been notified with FDA before purchasing it. Consumers can do this by going to the FDA website (www.fda.gov.ph) and making use of the *Search* tab found in the upper right corner of the home page, as shown below:



Figure 29. FDA Website Homepage

The FDA Field Regulatory Operations Office (FROO) is ordered to monitor the market for the manufacture, importation, exportation, distribution, sale, offer for sale, transportation, promotion and/or advertisement of the abovementioned cosmetic products. FROO is further ordered to inventory and seal all of the aforesaid unnotified cosmetic products found in the Philippine market, and to effect/conduct seizure of the same in accordance with existing laws, rules and regulations.

All local government units and law enforcement agencies are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

All cosmetic retailers are warned against selling these violative cosmetic products.

The public is enjoined to assist FDA in monitoring the market and to report any suspicious promotional or marketing activities for cosmetic products and their availability in the market through any of the following channels:

1. FDA's e-report (www.fda.gov.ph)
Reports can be sent to FDA via the e-Report section found in the upper right corner of the FDA website. By clicking e-report, another page will appear where you will find the form that must be accomplished (refer to Figure 30).

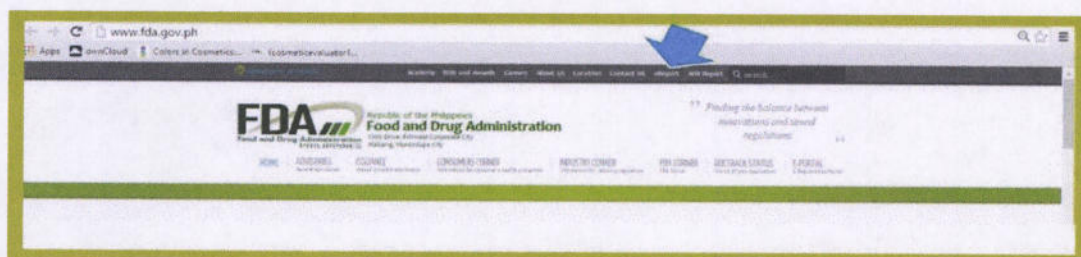


Figure 30. e-Report Section of the FDA Website

2. Send an email to report@fda.gov.ph
3. Contact the FDA Center for Cosmetics Regulation and Research (CCRR) Customer Service Hotline at (02) 857-1984.

Dissemination of the information to all is requested.

Maria Lourdes C. Santiago
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OIC, Director General