



31 August 2010

FDA CIRCULAR

No. ~~2010-015~~

SUBJECT: Declaring the Identified Products to be Imminently Injurious, Unsafe or Dangerous and Authorizing the FDA Inspectors to Seize Said Products from Public Sale or Distribution

The Food and Drug Administration (FDA) have found, through laboratory examination, that the samples of the following cosmetic products that were collected on separate occasions at various establishments/outlets identified as:

PRODUCT NAME	BRAND NAME	PREPARATION	MANUFACTURER /DISTRIBUTOR
St. Dalfour Beauty Whitening Cream	St. Dalfour	Cream	Tokyo, Japan
Beauty Girl Papaya & Hawthorn Essence (10 Double Whitening Speckles Removed Essence)	Beauty Girl	Cream	Yudantang International - Taiwan
Beauty Girl Ginseng & Green Cucumber (10 Double Whitening Speckles Removed)	Beauty Girl	Cream	Yudantang International - Taiwan
Beauty Girl Essence Aloe Pearl (10 Double Whitening Speckles Removed Essence)	Beauty Girl	Cream	Yudantang International - Taiwan
Beauty Girl Olive & Sheep Essence (10 Double Whitening Speckles Removed Essence)	Beauty Girl	Cream	Yudantang International - Taiwan

contain heavy metal (Mercury) exceeding the allowable limit of *1ppm*. These cosmetic products therefore pose imminent 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.

Accordingly, in the interest of protecting public health and safety and pursuant to Section 12 of Republic Act No. 9711, the Food and Drug Regulation Officers of this Office (both Central and those in the regions) are hereby ordered to seize immediately the above identified cosmetic products for custody from all outlets or establishments where they may be found. Likewise, the assistance of all local government units and consumers are sought in reporting all outlets found selling the above products.


NAZARITA T. TACANDONG, RPh, MPA
Acting Director IV

31 August 2010

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Beauty Girl Ginseng & Green Cucumber (10 Double Whitening Speckles Removed)	Beauty Girl	Cream	Yudantang International - Taiwan
Beauty Girl Essence Aloe Pearl (10 Double Whitening Speckles Removed Essence)	Beauty Girl	Cream	Yudantang International - Taiwan
Beauty Girl Olive & Sheep Essence (10 Double Whitening Speckles Removed Essence)	Beauty Girl	Cream	Yudantang International - Taiwan

contain heavy metal (Mercury) exceeding the allowable limit of *1ppm*. These cosmetic products therefore pose imminent 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.

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NAZARITA T. TACANDONG, RPh, MPA
Acting Director IV



Republic of the Philippines
DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Website: www.bfad.gov.ph



TEST REPORT

Laboratory No.: CP8 10-05-07-0770
Date: 31 May 2010

From LSD → Endorsed to PMS?

Test Item:	(Generic / INN/ Product Name / Dosage Strength/ Label Claim/ Amount of Active or Substance /Dosage Form/ Category / Type)		
	St. Dalfour Beauty Whitening Cream		
	Brand Name		
Registration No.:	DTI CR # 18151	Batch No:	N/I
		Lot No.:	N/I
Date Manufactured:	10/11/2009	Expiry Date/ Best Before Date :	09/11/2011
Manufacturer:	N/I	Address:	Tokyo, Japan
Repacker/ Address:	N/I	Importer/ Address:	N/I
Trader / Address:	N/I	Distributor/ Address:	N/I
Source/ Location:	Botica Fernandez		
Address:	Brgy. Cogon, Ormoc City, Leyte		
Date of Sampling:	11 March 2010	Collection Receipt Number:	N/I
Sampling plan:	N/I		
Environmental condition during sampling:	Temp (°C)	N/I	RH N/I
(explain details, if needed)			
Submitted/Requested by:	Vencula C. Alandra - FDRO II		
Address:	DOH-EV-8, Government Center, Candahug, Palo, Leyte		
No. of Test Items / Samples Received:	One box (1 Jar)		
Product Description (packaging type):	Transparent glass jar with dark blue screw cap in a blue box		
Date Test Item Received in LSD OC:	07 May 2010	Date(s) of Analysis:	17-28 May 2010

Test	Method(s)	Specification(s)	Result(s)	Remark(S)
Appearance	Visual Exam	-	Camel beige cream	-
Identification Test:				
Hydroquinone	COS-TP-2008-03	Negative	Negative	Passed
Tretinoin	COS-TP-2008-09	Negative	Negative	Passed
Assay:				
Mercury	COS-TP-2009-01	nmt 1 ppm	12,351.88 ppm	Failed

Detection Limit for Mercury - 0.24 ppb

Conclusion:

The sample submitted **does not conform** to the specification under the ASEAN Cosmetic Directive (ACD).

E. Angeles
EDEN B. ANGELES
Analyst

Attested by:

ML
MARIA LOURDES C. SANTIAGO, M.Sc., M.M.
Chief, Laboratory Services Division

Noted by:

NT
NAZARITA T. TACANDONG, R.Ph., M.P.A.
Acting Director IV

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TEST REPORT

Laboratory No:	CP 10-07-01-1039
Date:	29 July 2010

Cream	
Test Item:	(Generic / INN/ Product Name / Dosage Strength/ Label Claim/ Amount of Active or Substance /Dosage Form/ Category / Type) Beauty Girl Papaya & Hawthorn Essence (10 Double Whitening Speckles Removed Essence)
Brand Name	
Registration No.:	N/I
Batch No:	N/I
Lot No.:	N/I
Date Manufactured:	2009/11/08
Expiry Date/ Best Before Date:	2012/11/08
Manufacturer:	Yudantang International
Address:	TAIWAN
Repacker/ Address:	N/I
Importer/ Address:	N/I
Trader / Address:	N/I
Distributor/ Address:	N/I
Source/ Location:	Excel Chinese Drugstore
Address:	Roxerfan Commercial Bldg., #158 Quirino Ave., Redemtorist, Baclaran, Parañaque City
Date of Sampling:	28 June 2010
Collection Receipt Number:	N/I
Sampling plan:	Enforcement/ to implement FDA Circular No. 2010-002, 2010-004, 2010-011
Environmental condition during sampling:	Temp (°C) N/I RH N/I
(explain details, if needed) Room Temperature	
Submitted/Requested by:	Marissa C. Fajardo- FDRO II
Address:	FDA, Regulation Division I, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City
No. of Test Items / Samples Received:	2 boxes x 2 jars x 18g
Product Description (packaging type):	Transparent jar with violet screw cap in a box
Date Test Item Received in LSD OC:	01 July 2010
Date(s) of Analysis:	26 to 27 July 2010

Test	Method(s)	Specification(s)	Result(s)	Remark(s)
Appearance	Visual Exam	-	a) Beige cream: b) Yellow cream	- -
Assay Mercury	COS-TP-2009-01	nmt 1 ppm	a) 50.12 ppm b) 7,397.58 ppm	Failed Failed

Detection Limit for Hg: 0.24 ppb

Conclusion:

The sample submitted **does not conform** to the specification under the ASEAN Cosmetic Directive (ACD).

LUZ N. PAGARAN
Analyst

Attested by:

MARIA LOURDES C. SANTIAGO, M.Sc., M.M.
Chief, Laboratory Services Division

Noted by:

NAZARITA T. TACANDONG, RPh, MPA
Acting Director

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TEST REPORT

Laboratory No:	CP 10-07-01-1035
Date:	26 July 2010

Test Item:	Whitening Cream (Generic / INN/ Product Name / Dosage Strength/ Label Claim/ Amount of Active or Substance /Dosage Form/ Category / Type)		
	Beauty Girl Ginseng & Green Cucumber(10 Double Whitening Speckles Removed)		
Registration No.:	N/I	Batch No:	N/I
Date Manufactured:	2010/04/25	Lot No.:	N/I
Manufacturer:	Yudantang International	Expiry Date/ Best Before Date :	2013/04/25
Address:	TAIWAN		
Repacker/ Address:	N/I	Importer/ Address:	N/I
Trader / Address:	N/I	Distributor/ Address:	N/I
Source/ Location:	Benson Chinese Drugstore		
Address:	892 C.M. Recto Ave., Binondo, Manila		
Date of Sampling:	28 June 2010	Collection Receipt Number:	N/I
Sampling plan:	Enforcement/ to implement FDA Circular No. 2010-002, 2010-004, 2010-011		
Environmental condition during sampling:	Temp (°C)	N/I	RH N/I
(explain details, if needed) Room Temperature			
Submitted/Requested by:	Marissa C. Fajardo- FDRO II		
Address:	FDA, Regulation Division 1, Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City		
No. of Test Items / Samples Received:	2 boxes x (2 jars x 18g)		
Product Description (packaging type):	Transparent jar with violet screw cap in a box		
Date Test Item Received in LSD OC:	01 July 2010	Date(s) of Analysis:	15 and 16 July 2010

Test	Method(s)	Specification(s)	Result(s)	Remark(s)
Appearance	Visual Exam	-	a) Beige cream b) Yellow cream	-
Assay: Mercury	COS-TP-2009-01	nmt 1 ppm	a) 1.71 ppm b) 5,953.74 ppm	Failed Failed

Detection Limit: Mercury – 0.24 ppb

Conclusion:

The sample submitted **does not conform** to the specification under the ASEAN Cosmetic Directive (ACD).

LUZ/N. PAGARAN
Analyst

Attested by:

MARIA LOURDES C. SANTIAGO, M.Sc., M.M.
Chief, Laboratory Services Division

Noted by:

NAZARITA T. TACANDONG, R.Ph., M.P.A.
Acting Director IV

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TEST REPORT

Laboratory No:	CP 10-07-01-1037
Date:	26 July 2010

Test Item:	Whitening Cream (Generic / INN/ Product Name / Dosage Strength/ Label Claim/ Amount of Active or Substance / Dosage Form/ Category / Type) Beauty Girl Essence Aloe Pearl (10 Double Whitening Speckles Removed Essence)				
Registration No.:	N/I	Batch No:	N/I	Lot No.:	N/I
Date Manufactured:	2009/11/18	Expiry Date/ Best Before Date :	2012/11/18		
Manufacturer:	Yudantang International	Address:	TAIWAN		
Repacker/ Address:	N/I	Importer/ Address:	N/I		
Trader / Address:	N/I	Distributor/ Address:	N/I		
Source/ Location:	Benson Chinese Drugstore				
Address:	892 C.M. Recto Ave., Binondo, Manila				
Date of Sampling:	28 June 2010	Collection Receipt Number:	N/I		
Sampling plan:	Enforcement/ to implement FDA Circular No. 2010-002, 2010-004, 2010-011				
Environmental condition during sampling:	Temp (°C)	N/I	RH	N/I	
(explain details, if needed) Room Temperature					
Submitted/Requested by:	Marissa C. Fajardo- FDRO II				
Address:	FDA, Regulation Division 1 Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City				
No. of Test Items / Samples Received:	2 boxes x 2 jars X 18g				
Product Description (packaging type):	Transparent jar with maroon screw cap in a box				
Date Test Item Received in LSD OC:	01 July 2010	Date(s) of Analysis:	15 and 16 July 2010		

Test	Method(s)	Specification(s)	Result(s)	Remark(s)
Appearance	Visual Exam	-	a) Beige cream b) Yellow cream	-
Assay: Mercury	COS-TP-2009-01	nmt 1 ppm	a) 1.72 ppm b) 5.983.98 ppm	Failed Failed

Detection Limit: Mercury – 0.24 ppb

Conclusion:

The sample submitted **does not conform** to the specification under the ASEAN Cosmetic Directive (ACD).

Signature
LUZ N. PAGARAN
Analyst

Attested by:

Signature
MARIA LOURDES C. SANTIAGO, M.Sc., M.M.
Chief, Laboratory Services Division

Noted by:

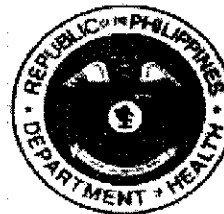
Signature
NAZARITA T. TACANDONG, R.Ph., M.P.A.
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TEST REPORT

Laboratory No:	CP 10-07-01-1034
Date:	26 July 2010

Test Item:	Whitening Cream (Generic / INN / Product Name / Dosage Strength / Label Claim / Amount of Active or Substance / Dosage Form / Category / Type) Beauty Girl Olive & Sheep Essence (10 Double Whitening Speckles Removed Essence)				
Registration No.:	N/I	Batch No.:	N/I	Lot No.:	N/I
Date Manufactured:	2010/02/18	Expiry Date / Best Before Date:	2013/02/18		
Manufacturer:	Yudantang International	Address:	TAIWAN		
Repacker / Address:	N/I	Importer / Address:	N/I		
Trader / Address:	N/I	Distributor / Address:	N/I		
Source / Location:	Benson Chinese Drugstore				
Address:	892 C.M. Recto Ave., Binondo, Manila				
Date of Sampling:	28 June 2010	Collection Receipt Number:	N/I		
Sampling plan:	Enforcement/ to implement FDA Circular No. 2010-002, 2010-004, 2010-011				
Environmental condition during sampling:	Temp (°C)	N/I	RH	N/I	
(explain details, if needed) Room Temperature					
Submitted/Requested by:	Marissa C. Fajardo- FDRO II				
Address:	FDA, Regulation Division 1 Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City				
No. of Test Items / Samples Received:	2 boxes x (jars x 18g)				
Product Description (packaging type):	Transparent jar with violet screw cap in a box				
Date Test Item Received in LSD OC:	01 July 2010	Date(s) of Analysis:	15 and 16 July 2010		

Test	Method(s)	Specification(s)	Result(s)	Remark(s)
Appearance	Visual Exam	-	a) Beige cream b) Yellow cream	-
Assay: Mercury	COS-TP-2009-01	nmt 1 ppm	a) 36.50 ppm b) 7,401.20 ppm	Failed Failed

Detection Limit: Mercury – 0.24 ppb

Conclusion:

The sample submitted **does not conform** to the specification under the ASEAN Cosmetic Directive (ACD).

Luiz N. Pagaran
LUZ N. PAGARAN
Analyst

Attested by:

Maria Lourdes C. Santiago
MARIA LOURDES C. SANTIAGO, M.Sc., M.M.
Chief, Laboratory Services Division

Noted by:

Nazarita T. Tacandong
NAZARITA T. TACANDONG, R.Ph., M.P.A.
Acting Director IV

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