Health, Beauty And Wellness Product Recalls 3 July, 2019

FDA RECALLS CLASSIFIED THROUGH 10 JULY, 2019

3 JULY: DRUG-CLASS II

(FDA's 10 July update did not include any OTC drugs, cosmetics or dietary supplements.)

1) Acetaminophen Children's Liquid, 160 mg/5 mL, 4 oz bottle, NDC 52959-0309-04; **2)** Diphenhydramine HCL Liquid, 12.5 mg/5 mL, 4 oz bottle, NDC 52959-0123-03 (both labeled as Manufactured by Torrent Pharma, Inc., Levittown, PA 19057).

Code: 1) Lot #: ACL75M, Exp. 02/20; ACL76M, Exp. 08/19; ACL77M, Exp. 05/20; 2) Lot #: DHI56M, Exp. 12/19.

Manufacturer:	H J Harkins Company Inc dba Pharma Pac, Grover Beach, CA
Recalled by:	Pharma Pac by undisclosed on June 24, 2019; classified by FDA on 27 June; voluntary recall is ongoing.
Distribution:	Nationwide within US; 1) 40 bottles, 2) 12 bottles.
Reason:	Microbial Contamination of Non-sterile Products: Potential product contamination with Burkholderia cepacia (B.cepacia) and Ralstonia pickettii (R. pickettii).
Recall numbers:	D-1429-2019, D-1430-2019

COMSETIC-CLASS II

City Color Cosmetics Contour Effects Palette 2 Contour, Bronze, Highlight; Net Wt. 5.7 grams x 3 powders totaling to 17.1 grams. Item number CCF 0006A Coutour: Ingredients: Talc, Mica, Mineral Oil (Paraffinum Liquidum) Phenoxyethanol, Ethyhlexlglycerin, Tocopheryl Acetate, Tocopheral, Iron Oxides (CI77491, CI 77482, CI 77499) Bronze: Ingredients: Talc, Mica, Mineral Oil (Paraffinum Liquidum), Petrolatum, Methylparaben, Propylparaben, Tocopheryl, Acetate, Tocopherol, Iron Oxides (CI 77491, CI 77492, CI 77499) Highlight: Ingredients: Talc, Mica, Petrolatum, Mineral Oil (Parraffinum Liquidum), Polybutene, Methylparaben, Propylparaben, Tocopheryl Acetate, Tocopheral, Iron Oxides (CI 77491, CI 77492), Titanium Dioxide (ci 77891) UPC: 8 49136 01436 5 Distributed by Beauty Plus Global, Inc. Ontario, CA Made in PRC.

Code: Batch # S1603002/PD-C1179.

Manufacturer:	Beauty Plus Global Inc., Ontario, CA
Recalled by:	Beauty Plus Global by letter on 30 May , 2019; classified by FDA on 26 June; voluntary recall terminated on 1 July.
Distribution:	Florida, Mexico and Australia as on website; 917 pieces.
Reason:	FDA sampled product and found mineral particles that are consistent with chrysotile and tremolite asbestos

Recall numbers: F-1492-2019

COSMETIC-CLASS II

skyn ICELAND Solutions for Stressed Skin Micellar Cleansing Water WITH ARCTIC ALGAE 155 mL / 5.24 US fl oz UPC: 8 55275 00710 6.

Code: Lot codes: MD18DBD, M19BDA, M18BDB.

Manufacturer:	Skyn Iceland, New York, NY
Recalled by:	Skyn Iceland by two or more of email, fax, letter, press release, telephone or visit on 15 May, 2019; classified by FDA on 25 June; voluntary recall is ongoing.
Distribution:	Nationwide US and Canada, GB, DE, TH, NL, RU, AU, IS, DK, SG, CN; 2557 units US and 2611 units ex-US.
Reason:	Micellar Cleansing Water was found to contain Burkholderia Cepacia.
Recall numbers:	F-1491-2019

FOOD-CLASS II

GlutaDose 400 mg Antioxidant & Immune Detox 30 day supply Dietary Supplement Oral Solution Citric Flavor.

Code: 30 units of 10ml vials per carton Lot 90013 EXP 03/2021.

Manufacturer:	BioDose Pharma LLC, Sunrise, FL
Recalled by:	BioDose Pharma by email on 15 May, 2019; classified by FDA on 24 June; voluntary recall is ongoing.
Distribution:	US consignees only; 2231 cases (30 vials per case).
Reason:	Product has potential to be contaminated with Bacillus cepacia.
Recall numbers:	F-1487-2019

EDITORS' NOTE: Tabulation prepared from information provided by FDA. The agency has three classes of recalls. Class I - violative product poses reasonable probability of serious adverse health consequences or death; Class II - violative product may cause temporary or medically reversible adverse health consequences; probability of serious consequences remote; Class III - violative product not likely to cause adverse health consequences.