US FDA Health, Beauty And Wellness Recalls

FDA RECALL ANNOUNCED AUG. 22
King Bio Inc. expanded its voluntary recall of Dr. King's brand products on Aug. 22, announcing 32 additional products accounting for a total of 74 lots, after some manufactured between August 2017 and April 2018 tested positive for microbial contamination.
Product name/package size/UPC/lots; (SCRX: SafeCare Rx For Professional Use Only)
DK Attention & Learning Enhance, 2 oz. bottle; 357955501527; 050216G, 070816C, 092617F
Chicken Pox Symptom Relief, 2 oz. bottle; 357955602521; 021216K, 062716D
Children's Appetite & Weight, 2 oz. bottle; 357955551720; 080916M, 091316D, 050516E, 072516E
Children's Appetite Enhance, 2 oz. bottle; 357955531821; 020117F, 060216E, 080916B, 092415F
Children's Cough Relief, 2 oz. bottle; 357955514527; 021216J, 030916T, 092815E
Children's Fever Reliever; 2 oz. bottle; 357955515920; 021216H, 052616H, 102815C, 120816A
Children's Growth & Development; 2 oz. bottle; 357955514220; 050516E, 072516E
DK Newborn Tonic; 2 oz. bottle; 357955511427; 063016K, 112315F
DK Nosebleed Relief; 2 oz. bottle; 357955514022; 050516H, 080916J
TonsilPlex; 2 oz. bottle; 357955501725; 041416K, 061616D
Children's Ear Relief Formula; 2 oz. bottle; 357955531524; 072516G,112315B,050216P
DK Teething; 2 oz. bottle; 357955501824; 020717B, 110716C, 080317D, 111617E, 020118F
DK Colic Relief; 2 oz. bottle; 357955515821; 092017A, 020118H
Tummy Aches; 2 oz. bottle; 357955514626; 050516D, 072216Q, 021918B
Kids Multi- Strain Flu Relief; 2 oz. bottle; 357955042228; 071316A, 071316A, 111015B, 112015A
Kids Stress & Anxiety; 2 oz. bottle; 357955042327; 070516E, 081016G
Kids Sleep Aid; 2 oz. bottle; 357955042426; 063016D, 081016F
Kids Bed Wetting (NP); 2 oz. bottle; 357955501220; 111717C, 101615B
Kids Candida; 4 oz. bottle; 357955332244; 011416G, 011917R, 081016E, 092815AA, 041518H
Kids Attention & Learning (SCRX); 2 oz. bottle; 357955001522; 121617A, 032316C, 091216A

Bed Wetting Prevention (SCRX); 2 oz. bottle 357955001225 102216B	
Chicken Pox Symptom Relief (SCRX); 2 oz. bottle; 357955782520; 042616D	
Childrens Cough (SCRX); 2 oz. bottle; 35795501452; 091015B; 120616B	
Children's Ear Formula (SCRX); 2 oz. bottle; 357955075721; 032316B	
Children's Fever Reliever (SCRX); 2 oz. bottle; 357955015925; 082516A, 102015F	
Children's Growth & Development (SCRX); 2 oz. bottle; 357955014225; 020917A, 062716E	
Colic Relief (SCRX); 2 oz. bottle; 357955015826; 111717E	
Newborn Tonic (SCRX); 2 oz. bottle; 357955011422; 110915H	
Teething (SCRX); 2 oz. bottle; 357955501824; 032216C	
Tummy Aches (SCRX); 2 oz. bottle; 357955014621; 022316F	
Children's Appetite & Weight (SCRX); 2 oz. bottle; 357955251729; 102016J	
Children's Appetite Enhancer (SCRX); 2 oz. bottle; 357955031826; 022316G	
FDA RECALLS CLASSIFIED THROUGH AUG. 22	
AUG. 22: FOOD-CLASS III	
1) FP0392, Confidence, Glucosamine Plus, with White Willow Bark & Boswella, 90 Extended Release Tablets, UPC# 8 10891 02253 7; 2) FP0292 Confidence Nitro-Cross 60s, UPC# 8 92483 00155 7; 3) FP0692, Confidence, Prenatal Multi-V + DHA, 90 tablets per bottle, UPC# 8 10891 02056 4; 4) FP0391 Confidence, Glucosamine Plus, With Hyaluronic Acid + Curcumin & Boswellia, 60 Extended Release Tablets, UPC: 8 92483 00106 9.	
Code: 1) Lot# 010216 Lot# 070816 Lot# 090117 Lot# 100817; 2) Lot# 070616; 3) Lot# 110516; 4) Lot# 030616.	
Manufacturer:	Confidence Inc./Confidence U.S.A. Inc., Port Washington, NY
Recalled by:	Confidence U.S.A by letter on July 26, 2018; classified by FDA on Aug. 13; voluntary recall is ongoing.
Distribution:	US nationwide; 5,650 bottles in US distribution (total for all products).
Reason:	Product contains undeclared ingredients, Hydroxypropyl Methylcellulose (HPMC), Titanium Dioxide, Polyethylene Glycol 400 and 800 (PEG), Triacetin.
Recall numbers:	F-1813-2018 through F-1816-2018
FOOD-CLASS II	

BulkSupplements.com Glucosamine Sulfate Potassium; 100 grams, 250 grams, 500 grams, 1 kilogram; Stand up zipper pouch bags. Directions: As a dietary supplement, take 1000 mg (scant 1/4 tsp) up to three time daily, or as directed by a physician. Distributed exclusively by: Bulk Supplements.com 7511 Eastgate Road Henderson, NV 89011.	
Code: Lot: 121D1214, Exp: 12/13/18; Lot: 121E0629, Exp: 06/28/19.	
Manufacturer:	Hard Eight Nutrition LLC, Henderson, NV
Recalled by:	Hard Eight Nutrition by email on Aug. 6, 2018; classified by FDA on Aug. 15; voluntary recall is ongoing.
Distribution:	Worldwide sales from website and Amazon. Foreign distribution to: Australia, Austria, Canada, Czech Republic, Denmark, Finland, France, Germany, Iceland, Isle of Man, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, South Africa, Sweden, Switzerland, The Philippines, United Kingdom; 2,100 units.
Reason:	FDA inspection found two lots of supplements that did not declare shellfish as an ingredient on the product label; shellfish is properly declared on website.
Recall numbers:	F-1827-2018
COSMETIC: CLASS II	
1) Avalon Organics Refreshing Lemon Bath & Shower Gel 12 fl. oz. (AV35185) UPC# 6 54749 35185 7; 2) Avalon Organics Nourishing Lavender Bath & Shower Gel 32 fl. oz. (AV35196) UPC# 6 54749 35196 3.	
Code: 1) Lot 8081, 2) Lot 8167.	
Manufacturer:	The Hain Celestial Group, Inc. - Worldwide HQ, New Hyde Park, NY
Recalled by:	Hain Celestial Group by email on July 25, 2018; classified by FDA on Aug. 14; voluntary recall is ongoing.
Distribution:	U.S. distribution to the following: CA, KS, NJ, CO, WI, IN, TX, WA, GA, OR, NY. No foreign distribution; 1,158 total units.
Reason:	Elevated levels of microbiological counts.
Recall numbers:	F-1824-2018, F-1825-2018
DRUG-CLASS II	
alba BOTANICA Sensitive Sheer Shield Sunscreen Fragrance Free spf 50+ , 85 g 3 oz tube. Manufactured by: The Haine Celestial Group, Inc. Lake Success, NY, UPC 7 24742 00438 5.	
Code: Lot code 8041.	
Manufacturer:	The Hain Celestial Group, Inc. - Worldwide HQ, New Hyde Park, NY

Recalled by:	Hain Celestial Group by letter on July 25, 2018; classified by FDA on Aug. 14; voluntary recall is ongoing.
Distribution:	Product was distributed to one distributor in California who may have distributed the product further within the US; 1,098 tubes.
Reason:	Microbial Contamination of a Non-Sterile Product.
Recall numbers:	D-1078-2018
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.	