Health, Beauty And Wellness Product Recalls

FDA RECALLS CLASSIFIED FROM SEPT. 5 THROUGH OCT. 3	
SEPT. 5: FOOD-CLASS II	
equate High Performance Protein Shake: Chocolate, Naturally & Artificially Flavored, ready to drink; 11 FL OZ (325 mL), sold in 12 pack case: Case UPC: 6 81131 01580 6 Distributed by: Wal-Mart, Inc. Bentonville, AR.	
Code: Lot L180980D, Lot L180990D: 03/01/2019 and 04/01/2019.	
Manufacturer:	California Natural Products, Lathrop, CA
Recalled by:	California Natural Products by email on July 20, 2018; classified by FDA on Aug. 27; voluntary recall is ongoing.
Distribution:	FL, CO, VA, PA, NY. MI, TX, NC, AR, WI, AL, CA, OH, OR, LA, KY, UT, DE; 7,244 cases.
Reason:	Reports of off odor and off taste in Equate High Performance Protein Shake Chocolate led to recall of two lots of the product.
Recall numbers:	F-1907-2018
SEPT 12: FOOD-CLASS III	
Virt Gard and **Virt Nate** tablets; number of units per package: 100 Tablets Package Type: 100 Tablets/Bottle.	
Code: Lot# M187380 Expiration Date: 1/2019 Lot# M192410 Expiration Date: 6/2019 Lot# M192410A Expiration Date: 6/2019; Lot# M187380 Expiration Date: 1/2019 Lot# M192410 Expiration Date: 6/2019 Lot# M192410A Expiration Date: 6/2019.	
Manufacturer:	Virtus Pharmaceuticals LLC, Newtown, PA
Recalled by:	Virtus Pharmaceuticals by letter on Aug. 3, 2018; classified by FDA on Sept 4; voluntary recall is ongoing.
Distribution:	Virt Nate: Arizona, Colorado, Illinois, Indiana, Michigan, Minnesota, Missouri, Mississippi, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, Texas, Virginia, Vermont and Wisconsin. Virt Gard: Arizona, California, Colorado, Florida, Georgia, Iowa, Illinois, Kentucky, Massachusetts, Michigan, Missouri, Mississippi, North Carolina, New Jersey, New York, Ohio, Pennsylvania, South Carolina, Texas, Virginia and West Virginia; 11,926 bottles total.
Reason:	Virtus Pharmaceuticals has decided to initiate a recall of Virt-Nate Tablets and Virt Gard Tablets because product labels do not reflect the correct amount of Dietary Folate Equivalents (DFEs) calculated based on the product formulation.

Recall numbers:	F-1933-2018
SEPT. 19 DRUG-CLASS I	
1) ompulsin, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle; **2) Neuroveen**, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle; **3) Thyroveev**, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle; **4) Respitrol**, Homeopathic (OTC Medicine), 2 fl oz (59 mL) per bottle;(all labeled as: Mftd for: HelloLife, Inc. 4635 40th St SE, Grand Rapids, MI 49512. NDC: 49726-003-02).	
Code: 1) Lot: CO/030717B, exp 7/2019; 2) Lot: NV/030717D, exp 7/2019; 3) Lot: TV/030717F, exp 7/2019; 4) Lot: RE/030717E, exp 7/2019.	
Manufacturer:	Hellolife Inc., Grand Rapids, MI
Recalled by:	Hellolife by letter on Aug. 23, 2018; classified by FDA on Sept. 17; voluntary recall is ongoing.
Distribution:	Nationwide USA, Algeria Australia Belgium Brazil Bulgaria Canada Colombia Croatia Cyprus Czech Republic Denmark Dominican Republic Ecuador Estonia French Polynesia Greece Guadeloupe Guam Hong Kong Hungary India Ireland Israel Italy Latvia Lithuania Martinique Mexico Monaco Netherlands New Zealand Norway Peru Poland Portugal Romania Russia Russian Federation Saudi Arabia Senegal Serbia Slovakia Slovakia (Slovak Republic) Slovenia Swaziland Sweden Switzerland Taiwan Turkey United Kingdom; 1) 989 bottles; 2) 4,358 bottles; 3) 370 bottles; 4) 1,869 bottles.
Reason:	Microbial Contamination of Non Sterile Products; Products contaminated with microoganisms, including but not limited to Staphylococcus saprophyticus and Burkholderia cepacian.
Recall numbers:	D-1200-2018 through D-1203-2018
SEPT. 26 DRUG-CLASS II	
1) Skin Irritation & Itch Response Homeopathic Formula, 2 FL. OZ. (59.2 mL) per amber glass oral spray bottle, NDC 58066-7002-7; **2) Sinus Response Homeopathic Formula**, 2 FL. OZ. (59.2 mL) per amber glass oral spray bottle, NDC 58066-7013-7; **3) Sore Throat & Laryngitis Response Homeopathic Formula**, 2 FL. OZ. (59.2 mL) per amber glass oral spray bottle, NDC 58066-7014-7; **4) Diarrhea Response Homeopathic Formula**, 2 FL. OZ. (59.2 mL) per amber glass oral spray bottle, NDC 58066-7022-7; **5) Muscle & Joint Pain Relief Homeopathic Formula**, 2 FL. OZ. (59.2 mL) per amber glass oral spray bottle, NDC 58066-7041-7; **6) Allergy & Hay Fever Relief Homeopathic Formula**, 2 FL. OZ. (59.2 mL) per amber glass oral spray bottle, NDC 58066-7011-7; **7) Colds & Flu Response Homeopathic Formula**, 2 FL. OZ. (59.2 mL) per amber glass oral spray bottle, NDC 58066-7012-7; **8) Arthritis Pain Relief Homeopathic Formula**, 2 FL. OZ. (59.2 mL) per amber glass oral spray bottle, NDC 58066-7042-7; (All labeled as: Distributed by Beaumont Bio-Med, Inc., Waukon, IA 52172).	
Code: 1) Lot: 091515C, Exp 09/2018; 050118S, Exp 05/2021; 2) Lot: 100316A, Exp 10/2019; 3) Lot: 100316G, Exp 10/2019; 050118R, Exp 05/2021; 4) Lot: 090915A, Exp 09/2018; 5) Lot: 012916F, Exp 01/2019; 6) Lot: 050216X, Exp 05/2019; 7) Lot: 042816C, Exp 04/2019; 112317K, Exp 11/2020; 8) Lot: 012916E, Exp 01/2019.	

Manufacturer:	Beaumont Bio-med, Inc. Waukon, IA
Recalled by:	Beaumont Bio-med by letter on Aug. 31, 2018; classified by FDA on Sept. 17; voluntary recall is ongoing.
Distribution:	Nationwide in the US; 1) 192 bottles; 2) 90 bottles; 3) 420 bottles; 4) 160 bottles; 5) 109 bottles; 6) 124 bottles; 7) 314 bottles; 8) 140 bottles.
Reason:	CGMP Deviations: products manufactured by contract manufacturer under conditions that could result in possible microbial contamination.
Recall numbers:	D-1192-2018 through D-1199-2018.
FOOD-CLASS III	
1) **FP0191, Confidence**, Bone-Lock WITHGENISTEIN AND CHLOROPHYLL, A Dietary Supplement, 60 tablets per bottle, UPC: 8 92483 00145 8; 2) **FP0392, For-Men-10**, All Natural Formula to Overall Men's Health, A Dietary Supplement, 60 Tablets, UPC: 8 92483 00139 7.	
Code: 1) Lot# 090616, 2) Lot# 020116.	
Manufacturer:	Confidence Inc./Confidence U.S.A. Inc., Port Washington, NY
Recalled by:	Confidence U.S.A. by letter on Sept. 4, 2018; classified by FDA on Sept. 21; voluntary recall is ongoing.
Distribution:	NY, MI, TN, FL, IL, WI, NJ, MD, TX, CA, VA, LA, MS, WA, SC, OH, NV, NE, PA, HI; 1) 538 bottles; 2) 2,016 bottles.
Reason:	Product contains undeclared ingredients, Hydroxypropyl Methylcellulose (HPMC), Titanium Dioxide, Polyethylene Glycol (PEG).
Recall numbers:	F-1971-2018, F-1972-2018
OCT. 3: FOOD-CLASS I	
1) Powerful Red Vein Bali Premium Kratom, Zakah Life Dietary Supplement, Mitragyn Speciosa, packaged in 1) 90 capsules, 500 mg per capsules bottles, or 2) 3.52 oz // 100 grams of Kratom bags; 2) **Super Green Maeng Da Premium Kratom**, Zakah Life Dietary Supplement, Mitragyn Speciosa, packaged in 1) 90 capsules, 500 mg per capsules bottles, or 2) 3.52 oz // 100 grams of Kratom bags; 3**) Top Shelf White Maeng Da Premium Kratom**, Zakah Life Dietary Supplement, Mitragyn Speciosa, packaged in 1) 90 capsules, 500 mg per capsules bottles, or 2) 3.52 oz // 100 grams of Kratom bags. (All labeled as: Distributed by Zakah Life LLC Ankeny IA.	
Code: 1) SG010118, Exp: 06/2023; 2) SG50118, Exp: 06/2023; 3) TS050118, Exp: 06/2023.	
Manufacturer:	Zakah Life LLC, Ankeny, IA
Recalled by:	Zakah Life by telephone on Aug. 3, 2018; classified by FDA on Sept. 25; voluntary recall is ongoing.

Distribution:	4 Distributed to consumers and retailers in Colorado, Illinois, Iowa, and Nebraska; 1) 30 100g bags and 12 bottles and 8.4 kg of capsules; 2) 6 100g bags and 12 bottles and 8.4 kg of capsules; 3) 10 100g bags.
Reason:	The firm distributes dietary supplements which contain Mitragyna speciosa (kratom) a dietary ingredient with inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Also, based on FDA sample positive sample results, the red and green strains are potentiallycontaminated with Salmonella.
Recall numbers:	F-1982-2018 through F-1984-2018.
COSMETIC-CLASS III	
Family wellness Cornstarch baby powder retail unit 14oz. plastic bottle. 6 retail bottles per wholesale case.	
Code: Lot#18142THW.	
Manufacturer:	Thorton Industries, Morris, IL
Recalled by:	Thorton Industries by email on Aug. 22, 2018; classified by FDA on Sept. 27; voluntary recall is ongoing.
Distribution:	Nationwide at Family Dollar stores; 28,650 retail units.
Reason:	Product has incorrect ingredient declaration, states contains talc but does not, also incorrect Distributed by.
Recall numbers:	F-1990-2018
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.	