

Enforcement Report - Week of September 30, 2020

Class I Drugs Event

Event ID:

86199

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

08/06/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/18/2020

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

Incredible Products, SA de CV
Calle Castellanos Y Tapia 921 Col. Santa Maria
Guadalajara Mexico

Distribution Pattern:

CA and GA

Associated Products

Product Description:

Incredible Products Gelbac T Antibacterial Hand Gel (ethyl alcohol 80%), Kills 99.9% bacteria and germs, a) 4.2 Oz./125 mL bottle, NDC: 71761-000-00, UPC: 7502278002555, Distributed by Pacific Coast Global Inc. Chula Vista, CA 91911, Made in Mexico b) 33.8 Oz./1 L, UPC: 7502278002586, Made in Mexico By Incredible Products S.A. de C.V. alle Castellanos y Tapia 921, Oblatos, 44350 Guadalajara, Jal, MX.

Product Quantity:**Reason for Recall:**

Chemical Contamination: Product contains methanol as an active ingredient and is sub-potent for ethanol.

Recall Number:

D-1587-2020

Code Information:

Lot #: 001, Exp. 04/2023

Class I Drugs Event

Event ID:

86377

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/01/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/24/2020

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

The Protein Shoppe
101 E Interstate 2
Pharr TX United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Red-E Tablet, Proprietary Blend 3000 mg**, packaged in 1-count plastic bag stapled with cardboard labeling.

Product Quantity:

21,511 tablets

Reason for Recall:

Marketed Without An Approved NDA/ANDA: product found to be tainted with sildenafil, an FDA approved drug for the treatment of male erectile dysfunction, making this an unapproved drug fro which the safety and efficacy have not been established and therefore subject to recall.

Recall Number:

D-1595-2020

Code Information:

All lots.

Class I Drugs Event

Event ID:

86390

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/03/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/18/2020

Initial Firm Notification of Consignee or Public:

Press Release

Recalling Firm:

CORGIOMED LLC

1775 Tysons Blvd Ste 500

Mc Lean VA United States

Distribution Pattern:

NC and MD

Associated Products

Product Description:

Leafree Instant Hand Sanitizer Aloe Vera (ethyl alcohol 70% v/v), Kills 99.99% Germs, EDIBLE ALCOHOL, a) 100 mL bottles, UPC code 6970495860325, b) 300 mL bottles, UPC code 6970495860318, and c) 500 mL bottles, UPC code 6970495860301, Exclusively Distributed by: Corgiomed LLC, McLean, VA 22102, USA, Made in China.

Product Quantity:

28900 bottles

Reason for Recall:

Marketed without an Approved NDA/ANDA; product labeled as Edible Alcohol rendering the product an unapproved new drug and misbranded.

Recall Number:

D-1586-2020

Code Information:

Lot # 2020A3010, Exp 05/30/2022

Class II Drugs Event

Event ID:

86388

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/03/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:
09/24/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
AJR TRADING LLC
814 Ponce De Leon Blvd Ste 218
Coral Gables FL United States

Distribution Pattern:
Distributed in Florida

Associated Products

Product Description:
bio aaa Alcohol en Gel Antibacterial, Alcohol al 70% Cont. Neto 480 ml bottle, Hecho en Mexico por: AAA Cosmetica S.A. DE C.V. Recursos Hidraulicos No. 1 Secc. A, Col La Loma Zona Industrial, Tlalnepantla de Baz C.P. 54060 Edo. Mexico. UPC 7 502272 12108 5

Product Quantity:
2000 bottles

Reason for Recall:
CGMP Deviations: Product manufactured in a facility where methanol was found in other distributed lots of product.

Recall Number:
D-1620-2020

Code Information:
Lot: 20DF8307 Exp. 04/2022

Class II Drugs Event

Event ID:
86394

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/02/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Repackaged tablets sold to three physicians located in CA and GA.

Associated Products

Product Description:
Nature-Throid, 1/2 Grain, 32.5 mg (Thyroid U.S.P. 1/2 gr. (32.5 mg)/Liothyronine (T3) 4.5mcg/Levothyroxine (T4) 19mcg, 100-count tablets, Rx Only, Mfg: RLC Labs; Cave Creek, AZ, Preferred Pharmaceuticals, Inc. NDC 68788-9283-01

Product Quantity:

Reason for Recall:
CGMP Deviations

Recall Number:
D-1621-2020

Code Information:
Lot #: L2717G, Exp. Date: 12/31/2020; Lot #: B2618A, Exp. Date: 12/21/2020; Lot #: C1419P, Exp. Date: 2/28/2021

Product Description:
Nature-Throid, 3/4 Grain (48.75 mg) Thyroid U.S.P. 3/4 gr. (48.75 mg)/Liothyronine (T3) 6.75mcg/Levothyroxine (T4) 28.5mcg, 90-count tablets, Rx

Only, Mfg: RLC Labs; Cave Creek, AZ, Preferred Pharmaceuticals, Inc. NDC 68788-6860-09

Product Quantity:**Reason for Recall:**

CGMP Deviations

Recall Number:

D-1622-2020

Code Information:

Lot #: B2618E, Exp. Date: 2/28/2021

Product Description:

Nature-Throid, 1 Grain, 65 mg (Thyroid U.S.P. 1 gr. (65mg)/Liothyronine (T3) 9mcg/Levothyroxine (T4) 38mcg, packaged in a) 90-count bottles (NDC 68788-7604-09), b) 100-count tablets (NDC 68788-7604-01), Rx Only, Mfg: RLC Labs; Cave Creek, AZ, Preferred Pharmaceuticals, Inc.

Product Quantity:**Reason for Recall:**

CGMP Deviations

Recall Number:

D-1623-2020

Code Information:

a) Lot #: A0220Q, Exp. Date: 10/31/2020; b) Lot #: K15171, Exp. Date: 10/31/2020

Product Description:

Nature-Throid, 1.5 Grain, (97.5 mg), (Thyroid U.S.P. 1.5 gr. (97.5mg)/Liothyronine (T3) 13.5mcg/Levothyroxine (T4) 57mcg, 90-count bottles, Rx Only, Mfg: RLC Labs; Cave Creek, AZ, Preferred Pharmaceuticals, Inc. NDC 68788-7605-09

Product Quantity:**Reason for Recall:**

CGMP Deviations

Recall Number:

D-1624-2020

Code Information:

a) Lot #: A0220R, Exp. Date: 2/28/2021

Class II Drugs Event

Event ID:

86429

Status:

Ongoing

Recall Initiation Date:

09/16/2020

Center Classification Date:

09/23/2020

Recalling Firm:

Perrigo Company PLC
515 Eastern Ave
Allegan MI United States

Distribution Pattern:

Nationwide in the U.S.

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Albuterol Sulfate Inhalation Aerosol, 90 mcg per actuation, 200 metered inhalations, Manufactured by: Catalent Pharma Solutions, 160 N Pharma Drive, Morrisville, NC 27560, Distributed by: Perrigo, Allegan, MI 49010 NDC 45802-088-01

Product Quantity:

7,775,813 metered dose inhalers

Reason for Recall:

Defective Delivery System: Sustained trend of failure to dispense complaints.

Recall Number:

D-1594-2020

Code Information:

18MC-052, 18MC-055, 18MC-056, 18MC-057, 18MC-058, 18MC-060, EXP 09/2020; 18MC-061, 18MC-062, 18MC-064, 18MC-065, 18MC-066, 18MC-068, 18MC-069, 18MC-070, 18MC-071, 18MC-072, 18MC-073, 18MC-074 EXP 10/2020; 18MC-075, 18MC-076, 18MC-077, 18MC-078, 18MC-079, 18MC-080, 18MC-081, 18MC-082, 18MC-083, 18MC-084, 18MC-085 EXP 11/2020; 18MC-095, 18MC-096, 18MC-097, 18MC-098, 18MC-099 EXP 12/2020; 19MC-001, 19MC-002, 19MC-003, 19MC-004 EXP 1/2021; 19MC-005, 19MC-006, 19MC-007, 19MC-008, 19MC-009, 19MC-010, 19MC-011, 19MC-012, 19MC-013, 19MC-014, 19MC-015 EXP 2/2021; 19MC-020, 19MC-041, 19MC-042, 19MC-043, 19MC-044, 19MC-045 EXP 4/2021; 19MC-046, 19MC-047, 19MC-048, 19MC-049, 19MC-050, 19MC-051, 19MC-052 EXP 5/2021; 19MC-053, 19MC-054, 19MC-055, 19MC-056, 19MC-057, 19MC-059, 19MC-060 EXP 6/2021; 19MC-061, 19MC-062, 19MC-063, 19MC-064, 19MC-065, 19MC-066, 19MC-067, 19MC-068, 19MC-069, 19MC-070, 19MC-083, 19MC-084, 19MC-085 EXP 7/2021; 19MC-087, 19MC-088, 19MC-090, 19MC-091, 19MC-092, 19MC-093, 19MC-094, 19MC-095, 19MC-096, 19MC-097, 19MC-098, 19MC-099 EXP 8/2021; 19MC-101, 19MC-102, 19MC-103, 19MC-104, 19MC-107, 19MC-108, 19MC-109, 19MC-110, 19MC-112, 19MC-113 EXP 9/2021; 20MC-014, 20MC-015, 20MC-016, 20MC-017, 20MC-020, 20MC-021, 20MC-072 EXP 3/2022; 20MC-022, 20MC-023, 20MC-024, 20MC-029, 20MC-030, 20MC-032, 20MC-034, 20MC-035, 20MC-036, 20MC-037, 20MC-038, 20MC-039, 20MC-040, 20MC-041, 20MC-042, 20MC-043, 20MC-044 EXP 4/2022; 20MC-045, 20MC-046, 20MC-047, 20MC-048, 20MC-049, 20MC-050, 20MC-051, 20MC-052, 20MC-053, 20MC-054, 20MC-061, 20MC-062, 20MC-063, 20MC-064, 20MC-065, 20MC-066, 20MC-067, 20MC-068 EXP 5/2022; 20MC-069, 20MC-070, 20MC-078, 20MC-079, 20MC-080, 20MC-081, 20MC-083, 20MC-084 EXP 6/2022