# Enforcement Report - Week of June 10, 2020

## Class I Drugs Event

**Event ID:**
85721

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/22/2020

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/08/2020

**Initial Firm Notification of Consignee or Public:**
Press Release

**Recalling Firm:**
Acella Pharmaceuticals, LLC
1880 Mcfarland Pkwy Ste 110-B
Alpharetta GA United States

**Distribution Pattern:**
Distributed Nationwide in the US and Puerto Rico

## Associated Products

**Product Description:**
NP Thyroid 30, Thyroid Tablets, USP, 1/2 grain (30 mg), 100-count bottles, Rx Only, Manufactured For: Acella Pharmaceuticals, LLC, Alpharetta, GA 30005, NDC 42192-329-01.

**Product Quantity:**
112,140 bottles

**Reason for Recall:**
Superpotent Drug.

**Recall Number:**
D-1298-2020

**Code Information:**
Lots: M329H18-1, Exp. JUL-2020; M329J18-1, M329J18-2, M329J18-3 Exp. AUG-2020; M329M18-2 Exp. NOV-2020, M329A19-1 Exp. DEC-2020.

**Product Description:**
NP Thyroid 60, Thyroid Tablets, USP, 1 grain (60 mg), 100-count bottles, Rx Only, Manufactured For: Acella Pharmaceuticals, LLC, Alpharetta, GA 30005, NDC 42192-330-01.

**Product Quantity:**
29,304 bottles

**Reason for Recall:**
Superpotent Drug.

**Recall Number:**
D-1299-2020

**Code Information:**
Lots: M330J18-2A, M330J18-3 Exp. AUG-2020

**Product Description:**
NP Thyroid 90, Thyroid Tablets, USP, 1 & 1/2 grain (90 mg), 100-count bottles, Rx Only, Manufactured For: Acella Pharmaceuticals, LLC, Alpharetta, GA 30005, NDC 42192-331-01.

**Product Quantity:**
49,128 bottles

**Reason for Recall:**
Superpotent Drug.

**Recall Number:**
D-1300-2020

**Code Information:**
Lots: M331G18-1 Exp. JUN-2020, M331J18-1, M331J18-2, Exp. AUG-2020, M331M18-1, M331M18-2 Exp. NOV-2020

## Class II Drugs Event

**Event ID:**
85704

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/15/2020

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/01/2020

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
TRIOVA PHARMACEUTICALS LLC
115 W 3rd St Ste 720
Tulsa OK United States

**Distribution Pattern:**
U.S.A. Nationwide

## Associated Products

**Product Description:**
Estriol USP Micronized 5 G, Rx only, Triova 115 W 3rd Street Suite 720 Tulsa, OK 74103, NDC 71092-9977-02

**Product Quantity:**
210 grams

**Reason for Recall:**
Failed impurities/ degradation specifications: Out of specification for organic impurities.

**Recall Number:**
D-1284-2020

**Code Information:**
Lot #:17010401181119190927, EXP 12/2020, 17010401181119190927252001 22, EXP.12/2020

## Class II Drugs Event

**Event ID:**
85712

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/22/2020

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/04/2020

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

**Distribution Pattern:**
Nationwide within the United State and Puerto Rico.

## Associated Products

**Product Description:**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets ( Mixed Amphetamine Salts Product), 5 mg, 100 count bottles, Rx Only, Teva Pharmaceuticals USA, INC. North Wales, PA 19454, NDC 0555-0971-02

**Product Quantity:**
33,280 bottles

**Reason for Recall:**
Some bottles may contain mixed strengths of the product.

**Recall Number:**
D-1285-2020

**Code Information:**
Lot #: 42614718, Exp. date 02/2021

**Product Description:**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets ( Mixed Amphetamine Salts Product), 15 mg, 100 count bottles, Rx Only, Teva Pharmaceuticals USA, INC. North Wales, PA 19454, NDC 0555-0777-02

**Product Quantity:**
41,348 bottles

**Reason for Recall:**
Some bottles may contain mixed strengths of the product.

**Recall Number:**
D-1286-2020

**Code Information:**
Lot #: 42617008, Exp. date 10/2021

**Product Description:**
Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets ( Mixed Amphetamine Salts Product), 20 mg, 100 count bottles, Rx Only, Teva Pharmaceuticals USA, INC. North Wales, PA 19454, NDC 0555-0973-02

**Product Quantity:**
84,209 bottles

**Reason for Recall:**
Some bottles may contain mixed strengths of the product.

**Recall Number:**
D-1287-2020

**Code Information:**
Lot #: 42617891, exp. date 01/2022

## Class II Drugs Event

**Event ID:**
85757

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/22/2020

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/04/2020

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
The Harvard Drug Group
17177 N Laurel Park Dr Ste 233
Livonia MI United States

**Distribution Pattern:**
Nationwide within the United States

## Associated Products

**Product Description:**
Doxycycline Hyclate Tablets, USP, 100 mg, packaged in a) 3x10 unit dose cartons (NDC 0904-0430-04) and b) 5 x 10 unit dose carton (NDC 0904-0430-06), Mfd. by: West-Ward Pharmaceutical Corp., Eatontown, NJ 07724; Distributed by: Major Pharmaceuticals, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152.

**Product Quantity:**
16,443 cartons

**Reason for Recall:**
Failed Dissolution Specification: The dissolution test at the 24 month time point (end of shelf life) yielded an out-of-specification result.

**Recall Number:**
D-1288-2020

**Code Information:**
Lot #: a) R00828D, Exp. date 08/2020, b) R00732D, Exp. date 05/2020; R00783D, Exp. date 06/2020; R00827D, Exp. date 08/2020

## Class III Drugs Event

**Event ID:**
85783

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/28/2020

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**
06/04/2020

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
AVKARE Inc.
615 N 1st St
Pulaski TN United States

**Distribution Pattern:**
Nationwide in the U.S.

## Associated Products

**Product Description:**
Lamotrigine Tablets, USP, 150 mg, Rx Only, a) 60 count Bottle, NDC 42291-368-60, b) 500 count Bottle, NDC 42291-368-50, Manufactured for: AvKARE, Inc. Pulaski, TN 38478.

**Product Quantity:**
4124 bottles

**Reason for Recall:**
Presence of Foreign Substance consistent with granules from desiccant packs used during storage

**Recall Number:**
D-1289-2020

**Code Information:**
Lot #: a) 25634, b) 25633; Exp. 09/30/2021

## Not Yet Classified Drugs Event

**Event ID:**
85644

**Product Type:**
Drugs

**Status:**
Ongoing

**Date Terminated:**

**Recall Initiation Date:**
05/11/2020

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Center Classification Date:**

**Initial Firm Notification of Consignee or Public:**
Letter

**Recalling Firm:**
Torrent Pharma Inc.
150 Allen Rd Ste 102
Basking Ridge NJ United States

**Distribution Pattern:**
USA Nationwide and Puerto Rico

## Associated Products

**Product Description:**
Carbamazepine Tablets, USP 200 mg, packaged in a 500-count bottle, Rx only, Manufactured by: Torrent Pharmaceuticals Ltd, Bharuch 392130, India; Manufactured for: Torrent Pharma Inc., Basking Ridge, NJ 07920, NDC 13668-268-05

**Product Quantity:**
6228 Bottles

**Reason for Recall:**
Failed Dissolution Specifications

**Recall Number:**

**Code Information:**
Lot #: 4FF4F001, Exp 1/2023