Class II Drugs Event

Event ID:
77064
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/19/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/07/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Qualgen
14844 Bristol Park Blvd
Edmond OK United States
Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Estradiol 25 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF, in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only. Rx Only ,Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC 69761-025-01,
Product Quantity:
1,153 pellets.
Reason for Recall:
CGMP deviations- Lack of Quality Assurance
Recall Number:
D-0889-2017
Code Information:
Lot # C031; Exp. 03/2/18 Lot # B077; Exp. 08/10/17 Lot # B040; Exp. 05/16/17

Product Description:
Estradiol 22 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF, in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC 69761-022-01
Product Quantity:
1,666 pellets.
Reason for Recall:
CGMP deviations- Lack of Quality Assurance
Recall Number:
D-0890-2017
Code Information:
Lot # B128; Exp. 11/1/17 Lot # B075; Exp. 08/3/17

Product Description:
Estradiol 20 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count and 12 count bottles, Sterile Office Use Only, For Subcutaneous Use Only Rx Only, Manufactured by Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC: 69761-020-01
Product Quantity:
4,468 pellets.
Reason for Recall:
CGMP deviations- Lack of Quality Assurance
Recall Number:
D-0891-2017
Code Information:
Lot# C022; Exp. 08/21/17 Lot# B143; Exp. 11/22/17 Lot# B104; Exp. 09/27/17 Lot# B073; Exp. 08/1/17 Lot# B052; Exp. 06/13/17

Product Description:
Estradiol 18 mg pellet , 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, Subcutaneous Use Only, Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC: 69761-018-01.
Product Quantity:
6,361 pellets.
Reason for Recall:
CGMP deviations- Lack of Quality Assurance
Recall Number:
D-0892-2017
Code Information:
Lot# C018; Exp. 08/2/17 Lot# B151; Exp. 12/7/17 Lot# B108; Exp. 10/3/17 Lot# B095; Exp. 09/12/17 Lot# B062; Exp. 07/6/17 Lot# B035; Exp. 05/2/17 Lot# B133; Exp. 11/4/17

Product Description:
Estradiol 15 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles. Sterile Office Use Only, For Subcutaneous Use Only, Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013, NDC: 69761-015-01
Product Quantity:
6,227 pellets
Reason for Recall:
CGMP deviations- Lack of Quality Assurance
Recall Number:
D-0893-2017
Code Information:
Lot# C028; Exp. 02/28/18 Lot# C005; Exp. 07/11/17 Lot# B142; Exp. 11/21/17 Lot# B114; Exp. 10/10/17 Lot# B099; Exp. 09/16/17 Lot# B069; Exp. 07/12/17 Lot# B048; Exp. 06/6/17

Product Description:
Estradiol 12.5 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only, Rx Only, Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013, NDC: 69761-012-01
Product Quantity:
4,883 pellets.
Reason for Recall:
CGMP deviations- Lack of Quality Assurance

Recall Number:
D-0894-2017
Code Information:
Lot# C044; Exp. 03/14/18 Lot# C013; Exp. 07/23/17 Lot# B150; Exp. 12/6/17 Lot# B119; Exp. 10/18/17 Lot# B097; Exp. 09/14/17 Lot# B061; Exp. 07/5/17

Product Description:
Estradiol 10 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only , For Subcutaneous Use Only Rx Only Manufactured by: Qualgen 14844 Bristol Park Blvd Edmond, OK 73013 NDC: 69761-010-01
Product Quantity:
5,260 pellets.
Reason for Recall:
CGMP deviations- Lack of Quality Assurance
Recall Number:
D-0895-2017
Code Information:
Lot# C021; Exp. 08/20/17 Lot# B160, Exp. 12/29/17 Lot# B140; Exp. 11/15/17 Lot# B107; Exp. 09/29/17 Lot# B079; Exp. 08/15/17 Lot# B046; Exp. 06/01/17

Product Description:
Estradiol 6 mg pellet 99.5% Estradiol USP, .5% Stearic Acid NF in 1 count, 12 count, and 30 count bottles, Sterile Office Use Only, For Subcutaneous Use Only Rx Only, Manufactured by; Qualgen 14844 Bristol Park Blvd. Edmond, OK 73013 NDC: 69761-006-01.
Product Quantity:
4,815 pellets.
Reason for Recall:
CGMP deviations- Lack of Quality Assurance
Recall Number:
D-0896-2017
Code Information:
Lot# C046; Exp. 03/15/18 Lot# C025; Exp. 08/23/17 Lot# B159; Exp. 12/28/17 Lot# B121; Exp. 10/10/17 Lot# B118; Exp. 10/17/17 Lot# B086; Exp. 08/29/17 Lot# B068; Exp. 07/11/17 Lot# B053; Exp. 06/14/17 Lot# B034; Exp. 04/26/17

Class II Drugs Event
Event ID:
77353
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
05/22/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/02/2017

Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States
Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Zenatane (isotretinoin) Capsules, USP, 10 mg, 30-count (3 x 10 Prescription Packs) per carton, Rx Only, Manufactured By: Cipla Limited, Kurkumbh Village, Pune 413802 India, Manufactured For: Dr. Reddy's Laboratories, Bachupally 500 090 India, NDC 55111-135-81
Product Quantity:
13,221 cartons
Reason for Recall:
Failed Dissolution Specifications: out of specification results observed for low dissolution.
Recall Number:
D-0883-2017
Code Information:
Lot #: KB50471, Exp 06/17; KB50710, KB50710A, Exp 08/17; KB60198, Exp 02/18

Product Description:
Zenatane (isotretinoin) Capsules, USP, 20 mg, 30-count (3 x 10 Prescription Packs) per carton, Rx Only, Manufactured By: Cipla Limited, Kurkumbh Village, Pune 413802 India, Manufactured For: Dr. Reddy's Laboratories, Bachupally 500 090 India, NDC 55111-136-81
Product Quantity:
89,118 cartons
Reason for Recall:
Failed Dissolution Specifications: out of specification results observed for low dissolution.
Recall Number:
D-0884-2017
Code Information:
Lot #: KB50361, KB50362, Exp 05/17; KB50540, Exp 07/17; KB50638, KB50639, Exp 08/17; KB50725, KB50726, KB50755, KB50756, Exp 09/17; 01KB60255, 79KB60252, 79KB60253, 79KB60254, Exp 03/18; 01KB60347, 01KB60348, 01KB60349, 01KB60350, 79KB60351, Exp 05/18; 01KB60421, 01KB60422, 01KB60423, 79KB60419, 79KB60420, Exp 06/18

Product Description:
Zenatane (isotretinoin) Capsules, USP, 30 mg, 30-count (3 x 10 Prescription Packs) per carton, Rx Only, Manufactured By: Cipla Limited, Kurkumbh Village, Pune 413802 India, Manufactured For: Dr. Reddy's Laboratories, Bachupally 500 090 India, NDC 55111-113-81
Product Quantity:
223,650 cartons
Reason for Recall:
Failed Dissolution Specifications: out of specification results observed for low dissolution.
Recall Number:
D-0885-2017

Code Information:
Lot #: KB50414, KB50456, Exp 05/17; KB50457, KB50458, KB50459, KB50460, Exp 06/17; KB 50580, KB50581, KB50582, KB50583, KB50599, KB50600, Exp 07/17; KB50646, KB50647, KB 50721, KB50722, KB50723, KB50724, Exp 09/17; KB50833, KB50834, KB50835, KB50836, KB 50837, Exp 10/17; KB50902, KB50903, KB50904, Exp 11/17; KB60037, KB60038, KB60039, K B60040, KB60041, Exp 12/17; KB60109, KB60110, KB60111, KB60112, KB60113, Exp 01/18; 01KB60249, 01KB60266, 01KB60268, 01KB60269, 01KB60284, Exp 03/18; 01KB60369, 01KB 60372, 79KB60368, 79KB60371, Exp 05/18; 79KB60507, 79KB60508, 79KB60509, 79KB60510 , 79KB60511, 79KB60512, 79KB60513, 79KB60514, 79KB60515, 79KB60516, Exp 07/18; 79K B60570, 79KB60571, 79KB60585, 79KB60586, Exp 08/18;

Product Description:
Zenatane (isotretinoin) Capsules, USP, 40 mg, 30-count (3 x 10 Prescription Packs) per carton, Rx Only, Manufactured By: Cipla Limited, Kurkumbh Village, Pune 413802 India, Manufactured For: Dr. Reddy's Laboratories, Bachupally 500 090 India, NDC 55111-137-81
Product Quantity:
452,290 cartons
Reason for Recall:
Failed Dissolution Specifications: out of specification results observed for low dissolution.
Recall Number:
D-0886-2017
Code Information:
Lot #: KB50363, KB50364, KB50365, KB50366, KB50367, KB50368, KB50369, KB50370, KB5 0371, Exp 05/17; 01KB50598, KB50541, KB50542, KB50543, KB50544, KB50545, KB50546, K B50547, KB50548, KB50549, KB50550, KB50551, Exp 07/17; 01KB50643, 01KB50644, KB506 40, KB50641, KB50642, KB50645, Exp 08/17; KB50715, KB50716, KB50717, KB50718, KB507 19, KB50720, KB50757, KB50758, KB50759, KB50760, KB50761, Exp 09/17; KB50872, KB508 74, KB50875, KB50876, KB50916, KB50938, KB50943, Exp 11/17; 01KB60062, 01KB60063, 0 1KB60064, 01KB60065, 01KB60066, 01KB60101, KB60025, KB60026, KB60027, KB60028, K B60029, KB60030, KB60031, KB60032, KB60059, KB60060, KB60061, Exp 12/17; 01KB60100 , 01KB60161, Exp 01/18; 01KB60256, 01KB60257, 01KB60258, 01KB60259, 01KB60260, Exp 03/18; 01KB60292, 01KB60293, 01KB60294, 01KB60314, 01KB60321, 01KB60333, 01KB6033 4, 79KB60295, 79KB60296, 79KB60332, 79KB60335, 79KB60346, Exp 04/18; 01KB60393, 01 KB60394, 79KB60390, 79KB60391, 79KB60392, Exp 05/18; 01KB60505, 01KB60506, 01KB60 538, 79KB60502, 79KB60503, 79KB60504, 79KB60535, 79KB60536, 79KB60537, 79KB60539, 79KB60542, Exp 07/18; 01KB60589, 79KB60566, 79KB60567, 79KB60568, 79KB60569, 79KB 60587, 79KB60588, Exp 08/18

Class II Drugs Event
Event ID:
77397
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
06/01/2017

Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/06/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
L. Perrigo Company
515 Eastern Ave
Allegan MI United States
Distribution Pattern:
Nationwide in the US and Canada

Associated Products

Product Description:
Option 2, Levonorgestrel Tablet, 1.5 mg, Emergency Contraceptive, 1 Tablet per box, Distributed By Perrigo, Allegan, MI 49010. NDC 0113-2003-12
Product Quantity:
181,776 (units/eaches)
Reason for Recall:
Defective Container: Carton is missing the tablet blister strip and tablet.
Recall Number:
D-0887-2017
Code Information:
Lot #: 6LV1114, 6LV1115, 6LV1116, 6MV0976, 6MV0977, Exp.04/18; 7AV1173, 7AV1175, 7AV 1176, Exp.07/18.

Class II Drugs Event
Event ID:
77398
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/13/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/02/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Spectrum Laboratory Products, Inc.
755 and 769 Jersey Ave
New Brunswick NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Estradiol (17-B-Estradiol; Estra-1,3,5(10)-triene-3, 17B-diol; Oestradiol) Plant Base, Micronized, U.S.P active pharmaceutical ingredient, packaged in 1g, 5g, 25g, 6 x 25g, and 100g containers, Rx only, Spectrum Chemical Mfg. Corp, Gardena, CA 90248, New Brunswick, NJ 08901, Product code E1435.
Product Quantity:
48 containers
Reason for Recall:
CGMP Deviations: these repackaged and redistributed products are being recalled due to a recall notice from the active pharmaceutical ingredient manufacturer for deviations from current Good Manufacturing Practices that were found during a recent FDA inspection.
Recall Number:
D-0881-2017
Code Information:
Lot #: 2FH0257, Exp 09/30/2017; 2GA0254, Exp 03/24/2018

Product Description:
Levonorgestrel, U.S.P. active pharmaceutical ingredient, packaged in 1 kg container, Rx only, Spectrum Chemical Mfg. Corp, Gardena, CA 90248, New Brunswick, NJ 08901, Product code L1229.
Product Quantity:
1 container
Reason for Recall:
CGMP Deviations: these repackaged and redistributed products are being recalled due to a recall notice from the active pharmaceutical ingredient manufacturer for deviations from current Good Manufacturing Practices that were found during a recent FDA inspection.
Recall Number:
D-0882-2017
Code Information:
Lot #: 2FD0376, Exp 02/21/21

Class II Drugs Event
Event ID:
77428
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
06/01/2017
Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
06/07/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
MedPark Pharmacy, LLC
2002 Medical Pkwy Ste 170
Annapolis MD United States
Distribution Pattern:
Distributed to patient in Maryland

Associated Products

Product Description:
methylcobalamin 1mg/1mL, vial for injection, Rx only, MedPark Pharmacy 2002 Medical Pkwy. # 170 Annapolis, MD 21401
Product Quantity:
1 (5mL) vial
Reason for Recall:
Lack of Assurance of Sterility
Recall Number:
D-0888-2017
Code Information:
Lot #: 20170323-01, Exp.09/18/2017

Class III Drugs Event

Event ID:
77122
Product Type:
Drugs
Status:
Ongoing
Date Terminated:
Recall Initiation Date:
04/27/2017
Voluntary / Mandated:
Voluntary: Firm Initiated
Center Classification Date:
06/07/2017
Initial Firm Notification of Consignee or Public:
Letter
Recalling Firm:
Hetero USA Inc
1035 Centennial Ave
Piscataway NJ United States
Distribution Pattern:
Nationwide

Associated Products

Product Description:
Acyclovir Tablets, USP, 800 mg, 100-count bottle, Rx Only, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, by Hetero Labs Limited, Unit V, Polepally, Jadcherla, Mahaboob Nagar - 509 301, India, NDC 31722-778-01
Product Quantity:
13,692 bottles
Reason for Recall:
Presence of Foreign Substance: human hair melded into tablet.
Recall Number:
D-0897-2017
Code Information:
Lot # ACY16075 Exp. 09/2018