Enforcement Report - Week of July 1, 2020

Class II Drugs Event

Event ID:
85706

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/11/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/19/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
BIOTA Biosciences LLC
1601 5th Ave Ste 1100
Seattle WA United States

Distribution Pattern:
Nationwide within the United States and New Zealand

Associated Products

Product Description:
Sterile Cannabidiol (CBD) 4mg/mL, 10mL vial

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility and Marketed without an approved NDA/ANDA: Product contains unapproved Cannabidiol and Curcumin

Recall Number:
D-1326-2020

Code Information:
Lot #: 2H071219P, 2H0712019P, 2H07122019P, Exp. Date 7/12/2021

Product Description:
Sterile Curcumin, 4mg/mL, 10mL vial

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility and Marketed without an approved NDA/ANDA: Product contains unapproved Cannabidiol and Curcumin

Recall Number:
D-1327-2020

Code Information:
Lot #: 2H071219CCD, 2H0712019CCD, 2H07122019CCD, Exp. Date 7/12/2021

Product Description:
Sterile Cannabidiol (CBD) 50mg/mL, 10mL vial

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility and Marketed without an approved NDA/ANDA: Product contains unapproved Cannabidiol and Curcumin

Recall Number:
D-1328-2020

Code Information:
Lot #: 101019P, 1010019P,10102019P, Exp. Date 10/10/2021

Product Description:
Sterile Cannabidiol (CBD) + Curcumin 50mg/mL, 10 mL vial

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility and Marketed without an approved NDA/ANDA: Product contains unapproved Cannabidiol and Curcumin

Recall Number:
D-1329-2020

Code Information:
Lot #: 101019PC, 1010019PC, 10102019PC, Exp. Date 10/10/2021

Product Description:
Sterile Curcumin 50mg/mL, 10 mL vial

Product Quantity:

Reason for Recall:
Lack of Assurance of Sterility and Marketed without an approved NDA/ANDA: Product contains unapproved Cannabidiol and Curcumin

Recall Number:
D-1330-2020

Code Information:
Lot #: 071219CCD, 0712019CCD, 07122019CCD, Exp. Date 7/12/2021

Class II Drugs Event

Event ID:
85781

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/29/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/25/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Amneal Pharmaceuticals of New York, LLC
50 Horseblock Rd
Brookhaven NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, USP, 500 mg, Rx Only, 100 count bottles, Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 53746-0178-01

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1343-2020

Code Information:
HA07419A 1/31/2021 HB00119A 1/31/2021 HB00219A 1/31/2021 HB00319A 1/31/2021; HB00419A 2/28/2021 HB00519A 2/28/2021 HB00619A 2/28/2021 HB00719A 2/28/2021 HB00819A 2/28/2021 HB00919A 2/28/2021 HB01019A 2/28/2021 HB05119A 2/28/2021 HB05219A 2/28/2021 HB05319A 2/28/2021 HB05419A 2/28/2021 HB05519A 2/28/2021 HB09519A 2/28/2021 HB09619A 2/28/2021 HB09719A 2/28/2021 HB09819A 2/28/2021 HB09919A 2/28/2021; HC08219A 3/31/2021 HC08319A 3/31/2021 HC08419A 3/31/2021 HC08519A 3/31/2021 HC09019A 3/31/2021 HC09119A 3/31/2021 HC09219A 3/31/2021 HC09319A 3/31/2021 HC09419A 3/31/2021; HD03419B 4/30/2021 HD03519B 4/30/2021 HD03619B 4/30/2021 HD03719B 4/30/2021 HD03819B 4/30/2021 HD03919B 4/30/2021 HD04019B 4/30/2021 HD04119B 4/30/2021 HD04219A 4/30/2021 HD05819A 4/30/2021 HD05919A 4/30/2021 HD06019A 4/30/2021 HD06119A 4/30/2021 HD06219A 4/30/2021 HD06319A 4/30/2021 HD06419A

4/30/2021 HD09019A 4/30/2021 HD09119A 4/30/2021 HD09219A 4/30/2021 HE01219B 4/30/2021 HE01319B 4/30/2021 HE01419B 4/30/2021 HE01519B 4/30/2021; HE01619A 5/31/2021 HE01719A 5/31/2021 HE01819A 5/31/2021 HE04419A 5/31/2021 HE04519A 5/31/2021 HE04619A 5/31/2021 HE04719A 5/31/2021 HE04819A 5/31/2021 HE04919A 5/31/2021 HE05019A 5/31/2021 HE05119A 5/31/2021 HE05219A 5/31/2021 HE05319A 5/31/2021 HE07219A 5/31/2021 HE07319A 5/31/2021 HE07419A 5/31/2021 HE07519A 5/31/2021 HE07619A 5/31/2021 HF02219A 5/31/2021 HF02319A 5/31/2021; HF02419A 6/30/2021 HF02519A 6/30/2021 HF02619A 6/30/2021 HF02719A 6/30/2021 HF02819A 6/30/2021 HF02919A 6/30/2021 HF03019A 6/30/2021 HF03119A 6/30/2021 HF03219A 6/30/2021 HF03319A 6/30/2021 HF05419A 6/30/2021; HF03918A 6/30/2020 HF04018A 6/30/2020 HF04118A 6/30/2020 HF04218A 6/30/2020 HF04318A 6/30/2020 HF04418A 6/30/2020 HF06518A 6/30/2020 HF06818B 6/30/2020 HF06918B 6/30/2020 HF07018B 6/30/2020 HF07118B 6/30/2020 HF07218A 6/30/2020 HF07318A 6/30/2020 HF07418A 6/30/2020 HF08318A 6/30/2020 HF08418A 6/30/2020 HF08518A 6/30/2020; HF11219A 6/30/2021 HF11319A 6/30/2021 HF11419A 6/30/2021 HF11519A 6/30/2021 HF11619A 6/30/2021 HF11719A 6/30/2021 HF11819A 6/30/2021 HF11919A 6/30/2021 HF12019A 6/30/2021 HG00719A 6/30/2021 HG00819A 6/30/2021 HG00919A 6/30/2021 HG01019A 6/30/2021 HG01119A 6/30/2021 HG01219A 6/30/2021 HG01319A 6/30/2021 HG01419A 6/30/2021; HG01519A 7/31/2021 HG01619A 7/31/2021 HG02919A 7/31/2021 HG03019A 7/31/2021 HG03119A 7/31/2021 HG03219A 7/31/2021 HG03319A 7/31/2021 HG03419A 7/31/2021 HG03519A 7/31/2021 HG03619A 7/31/2021 HG03719A 7/31/2021 HG03819A 7/31/2021; HH08218A 8/31/2020 HH08318A 8/31/2020 HH08418A 8/31/2020 HH08518A 8/31/2020 HH08618A 8/31/2020 HH08718A 8/31/2020 HH08818A 8/31/2020 HH08918A 8/31/2020 HH09018A 8/31/2020 HH09118A 8/31/2020 HH09218A 8/31/2020 HH09318A 8/31/2020 HH09418A 8/31/2020 HH09518A 8/31/2020 HH09618A 8/31/2020 HH11218A 8/31/2020 HH11318A 8/31/2020 HH11418A 8/31/2020 HH11518A 8/31/2020; HH11618A 9/30/2020 HH11718A 9/30/2020 HJ04818A 9/30/2020 HJ04918A 9/30/2020 HJ08518A 9/30/2020; HJ08618A 10/31/2020 HJ08718A 10/31/2020 HJ08818A 10/31/2020 HJ08918A 10/31/2020 HJ09018A 10/31/2020 HJ09118A 10/31/2020 HK03718A 10/31/2020 HK03818A 10/31/2020 HK03918A 10/31/2020 HK04018A 10/31/2020 HK04118A 10/31/2020 HK04218A 10/31/2020 HK04318A 10/31/2020 HK04418A 10/31/2020 HK04518A 10/31/2020 HK04618A 10/31/2020 HK09318A 10/31/2020 HK09418A 10/31/2020 HK09518A 10/31/2020 HK09618A 10/31/2020 HK09718A 10/31/2020; HM00218A 12/31/2020 HM00318A 12/31/2020 HM00418A 12/31/2020 HM00518A 12/31/2020 HM00618B 12/31/2020 HM00718B 12/31/2020 HM00818B 12/31/2020 HM00918B 12/31/2020 HM01018B 12/31/2020; HM02918A 1/31/2021 HM03018A 1/31/2021 HM03218A 1/31/2021 HM03318A 1/31/2021 HM03418A 1/31/2021 HM03518A 1/31/2021 HM03618A 1/31/2021 HM03718A 1/31/2021 HM03818A 1/31/2021

Product Description:
amneal Metformin Hydrochloride Extended-release Tablets, USP 500 mg Rx Only 90 Tablets bottles, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Ahmedabad, 388213, INDIA Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08907 NDC 65162-178-09

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1344-2020

Code Information:
AM190123A 1/31/2021 AM190193A 1/31/2021 AM190194A 1/31/2021 AM190195A 1/31/2021 AM190196A 1/31/2021 AM190197A 1/31/2021 AM190198A 1/31/2021 AM190199A 1/31/2021 AM190200A 2/28/2021 AM190201A 2/28/2021 AM190202A 2/28/2021 AM190269A 2/28/2021 AM190270A 2/28/2021 AM190271A 2/28/2021 AM190272A 2/28/2021 AM190289A 2/28/2021 AM190290A 2/28/2021 AM190291A 2/28/2021 AM190292A 2/28/2021 AM190293A 2/28/2021 AM190294A 2/28/2021 AM190549A 4/30/2021 AM190550A 4/30/2021 AM190551A 4/30/2021 AM190552A 4/30/2021 AM190553A 4/30/2021 AM190554A 4/30/2021 AM190555A 5/31/2021 AM190556A 5/31/2021 AM190586A 5/31/2021 AM190587A 5/31/2021 AM190588A 5/31/2021 AM190589A 5/31/2021 AM190590A 5/31/2021 AM190605A 5/31/2021 AM190673A 6/30/2021 AM190707A 6/30/2021 AM190708A 6/30/2021 AM190709A 6/30/2021 AM190710A 6/30/2021 AM190714C 6/30/2021 AM190751C 6/30/2021 AM190752C 6/30/2021 AM190753A 8/31/2021 AM190754A 8/31/2021 AM190755A 8/31/2021 AM190756A 8/31/2021 AM190757A 8/31/2021 AM190929A 8/31/2021 AM190930A 8/31/2021 AM190931A 8/31/2021 AM190932A 8/31/2021 AM190933A 8/31/2021 AM190995A 8/31/2021 AM191000A 8/31/2021 AM191001A 8/31/2021 AM191002A 8/31/2021 AM191003A 8/31/2021 AM191034A 9/30/2021 AM191035A 9/30/2021 AM191036A 9/30/2021 AM191037A 9/30/2021 AM191038A 9/30/2021 AM191039A 9/30/2021 AM191086A 9/30/2021

Product Description:
amneal Metformin Hydrochloride Extended-release Tablets, USP, 500 mg Rx Only, 500 Tablets bottles, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Ahmedabad 388213, INDIA Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 65162-178-50

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1345-2020

Code Information:
AM180641A 6/30/2020 AM180642A 6/30/2020 AM180643A 6/30/2020 AM180644A 6/30/2020 AM180645A 6/30/2020 AM180646A 6/30/2020 AM180647A 6/30/2020 AM180880A 7/31/2020 AM180881A 7/31/2020 AM180882A 7/31/2020 AM180883A 7/31/2020 AM180884A 7/31/2020 AM180885A 7/31/2020 AM180886A 7/31/2020 AM180887A 7/31/2020 AM180888A 7/31/2020 AM180889A 7/31/2020 AM180936A 7/31/2020 AM180937A 7/31/2020 AM180938A 7/31/2020 AM180939A 7/31/2020 AM180940A 7/31/2020 AM180960A 7/31/2020 AM180961A 7/31/2020 AM180962A 7/31/2020 AM180963A 7/31/2020 AM180964A 7/31/2020 AM180965A 7/31/2020 AM180992A 7/31/2020 AM180993A 7/31/2020 AM180994A 8/31/2020 AM180995A 8/31/2020 AM180996A 8/31/2020 AM180997A 8/31/2020 AM181037A 8/31/2020 AM181038A 8/31/2020

AM181039A 8/31/2020 AM181040A 8/31/2020 AM181041A 8/31/2020 AM181079A 8/31/2020 AM181080A 8/31/2020 AM181081A 8/31/2020 AM181082A 8/31/2020 AM181083A 8/31/2020 AM181084A 8/31/2020 AM181085A 8/31/2020 AM181086A 8/31/2020 AM181087A 8/31/2020 AM181088A 8/31/2020 AM181089A 8/31/2020 AM181093A 8/31/2020 AM181094A 8/31/2020 AM181095A 8/31/2020 AM181096A 8/31/2020 AM181097A 8/31/2020 AM181098A 8/31/2020 AM181099A 8/31/2020 AM181100A 8/31/2020 AM181101A 8/31/2020 AM181102A 8/31/2020 AM181116A 8/31/2020 AM181117A 9/30/2020 AM181129A 8/31/2020 AM181130A 8/31/2020 AM181131A 8/31/2020 AM181132A 8/31/2020 AM181133A 9/30/2020 AM181134A 9/30/2020 AM181135A 9/30/2020 AM181136A 9/30/2020 AM181137A 9/30/2020 AM181138A 9/30/2020 AM181183A 9/30/2020 AM181184A 9/30/2020 AM181185A 9/30/2020 AM181186A 9/30/2020 AM181187A 9/30/2020 AM181188A 9/30/2020 AM181189A 9/30/2020 AM181190A 9/30/2020 AM181235A 9/30/2020 AM181236A 9/30/2020 AM181237A 9/30/2020 AM181238A 9/30/2020 AM181239A 9/30/2020 AM181240A 9/30/2020 AM181242A 9/30/2020 AM181243A 9/30/2020 AM181314A 10/31/2020 AM181315A 11/30/2020 AM190121B 12/31/2020 AM190122B 12/31/2020 AM190713AA 6/30/2021 AM191248A 10/31/2021 AM191249A 10/31/2021 AM200192 1/31/2022 AM200322A 2/28/2022

Product Description:
amneal Metformin Hydrochloride Extended-release Tablets, USP, 500 mg Rx only, 90 Tablets bottles, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Ahmedabad, 388213, INDIA, Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 65162-178-09

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1346-2020

Code Information:
AM190123A 1/31/2021 AM190193A 1/31/2021 AM190194A 1/31/2021 AM190195A 1/31/2021 AM190196A 1/31/2021 AM190197A 1/31/2021 AM190198A 1/31/2021 AM190199A 1/31/2021 AM190200A 2/28/2021 AM190201A 2/28/2021 AM190202A 2/28/2021 AM190269A 2/28/2021 AM190270A 2/28/2021 AM190271A 2/28/2021 AM190272A 2/28/2021 AM190289A 2/28/2021 AM190290A 2/28/2021 AM190291A 2/28/2021 AM190292A 2/28/2021 AM190293A 2/28/2021 AM190294A 2/28/2021 AM190549A 4/30/2021 AM190550A 4/30/2021 AM190551A 4/30/2021 AM190552A 4/30/2021 AM190553A 4/30/2021 AM190554A 4/30/2021 AM190555A 5/31/2021 AM190556A 5/31/2021 AM190586A 5/31/2021 AM190587A 5/31/2021 AM190588A 5/31/2021 AM190589A 5/31/2021 AM190590A 5/31/2021 AM190605A 5/31/2021 AM190673A 6/30/2021 AM190707A 6/30/2021 AM190708A 6/30/2021 AM190709A 6/30/2021 AM190710A 6/30/2021 AM190714C 6/30/2021 AM190751C 6/30/2021 AM190752C 6/30/2021 AM190753A 8/31/2021 AM190754A 8/31/2021 AM190755A 8/31/2021 AM190756A 8/31/2021 AM190757A 8/31/2021 AM190929A 8/31/2021 AM190930A 8/31/2021 AM190931A 8/31/2021 AM190932A 8/31/2021 AM190933A 8/31/2021 AM190995A 8/31/2021 AM191000A 8/31/2021 AM191001A 8/31/2021 AM191002A 8/31/2021 AM191003A 8/31/2021 AM191034A 9/30/2021 AM191035A 9/30/2021 AM191036A 9/30/2021 AM191037A 9/30/2021 AM191038A 9/30/2021 AM191039A 9/30/2021 AM191086A 9/30/2021

Product Description:
amneal Metformin Hydrochloride Extended-release Tablets, USP, 500 mg Rx only, 100 Tablets bottles, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Ahmedabad 382213 India Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 65162-178-10

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1347-2020

Code Information:
AM181118AA 10/31/2020 AM181191AA 9/30/2020 AM181192AA 9/30/2020 AM181235AA 9/30/2020 AM181236AA 9/30/2020 AM181237AA 9/30/2020 AM181240AA 9/30/2020 AM181241AA 9/30/2020 AM181242AA 9/30/2020 AM181243AA 9/30/2020 AM181244AA 10/31/2020 AM181268AA 10/31/2020 AM181269AA 10/31/2020 AM181270AA 10/30/2020 AM181271AA 10/31/2020 AM181272AA 10/31/2020 AM181273AA 10/31/2020 AM181274AA 10/31/2020 AM181275AA 10/31/2020 AM181276AA 10/31/2020 AM181277AA 10/31/2020 AM181307AA 10/31/2020 AM181308AA 10/31/2020 AM181309AA 10/31/2020 AM181310AA 10/31/2020 AM181311AA 10/31/2020 AM181313AA 10/31/2020 AM181314AA 10/31/2020 AM181315AA 11/30/2020 AM181316AA 11/30/2020 AM181317AA 12/31/2020 AM181419AA 11/30/2020 AM181420AA 11/30/2020 AM181421AA 11/30/2020 AM181422AA 11/30/2020 AM181423AA 11/30/2020 AM181424AA 11/30/2020 AM181425AA 11/30/2020 AM181430BA 12/31/2020 AM181455AA 12/31/2020 AM181456AA 12/31/2020 AM181457AA 12/31/2020 AM181458AA 12/31/2020 AM181459AA 12/31/2020 AM181460AA 12/31/2020 AM181461AA 12/31/2020 AM181462AA 12/31/2020 AM181463AA 12/31/2020 AM181464AA 12/31/2020 AM181465AA 12/31/2020 AM190054AA 12/31/2020 AM190055AA 12/31/2020 AM190057AA 12/31/2020 AM190058AA 12/31/2020 AM190102AA 12/31/2020 AM190103AA 12/31/2020 AM190104AA 12/31/2020 AM190105AA 12/31/2020 AM190106AA 12/31/2020 AM190107AA 12/31/2020 AM190108AA 12/31/2020 AM190120AA 12/31/2020 AM190633AA 5/31/2021 AM190634AA 5/31/2021 AM190635AA 5/31/2021 AM190636AA 5/31/2021 AM190637AA 5/31/2021 AM190638AA 5/31/2021 AM190640AA 5/31/2021 AM190641AA 5/31/2021 AM190642AA 5/31/2021 AM190664AA 5/31/2021 AM190665AA 5/31/2021 AM190666AA 5/31/2021 AM190667AA 5/31/2021 AM190668AA 5/31/2021 AM190669AA 6/30/2021 AM190670AA 6/30/2021 AM190671AA 6/30/2021 AM190672AA 6/30/2021 AM190714AA 6/30/2021 AM190934A 8/31/2021 AM190991A 8/31/2021 AM190992A 8/31/2021 AM190993A 8/31/2021 AM190994A 8/31/2021 AM191040A 9/30/2021 AM191041A 9/30/2021 AM191083A 9/30/2021 AM191084A 9/30/2021 AM191085A 9/30/2021 AM191091A 9/30/2021 AM191092A 9/30/2021 AM191105A 9/30/2021 AM191106A 10/31/2021 AM191107A 10/31/2021 AM191109A 10/31/2021 AM191186A 10/31/2021 AM191187A 10/31/2021 AM191188A 10/31/2021 AM191189A 10/31/2021 AM191190A 10/31/2021 AM191191A 10/31/2021 AM191192A 10/31/2021 AM191193A 10/31/2021 AM191194A 10/31/2021

AM191195A 10/31/2021 AM191244A 10/31/2021 AM191245A 10/31/2021 AM191246A 10/31/2021 AM191247A 10/31/2021 AM191294A 11/30/2021 AM191295A 11/30/2021 AM191296A 11/30/2021 AM191365A 11/30/2021 AM191366A 11/30/2021 AM191367A 11/30/2021 AM191392A 11/30/2021 AM191393A 11/30/2021 AM191394A 11/30/2021 AM191395A 12/31/2021 AM200001A 12/31/2021 AM200002A 12/31/2021 AM200003A 12/31/2021 AM200004A 12/31/2021 AM200005A 12/31/2021 AM200006A 12/31/2021 AM200045A 12/31/2021 AM200046A 12/31/2021 AM200047A 12/31/2021 AM200048A 12/31/2021 AM200049A 12/31/2021 AM200050A 12/31/2021 AM200051A 12/31/2021 AM200052A 12/31/2021 AM200053A 12/31/2021 AM200081A 12/31/2021 AM200082A 12/31/2021 AM200083 12/31/2021 AM200087A 12/31/2021 AM200088A 12/31/2021 AM200089 12/31/2021 AM200090 12/31/2021 AM200091 12/31/2021 AM200100 1/31/2022 AM200101 1/31/2022 AM200102 1/31/2022 AM200138 1/31/2022 AM200139 1/31/2022 AM200140 1/31/2022 AM200141 1/31/2022 AM200142 1/31/2022 AM200143 1/31/2022 AM200144 1/31/2022 AM200193 1/31/2022 AM200194 1/31/2022 AM200195 1/31/2022 AM200196 1/31/2022 AM200197 1/31/2022 AM200198 1/31/2022 AM200199 1/31/2022 AM200200 1/31/2022 AM200202 1/31/2022 AM200203 1/31/2022 AM200204 1/31/2022 AM200205 1/31/2022 AM200206 1/31/2022 AM200207 1/31/2022 AM200208 1/31/2022 AM200209 1/31/2022 AM200210 1/31/2022 AM200211 1/31/2022 AM200284 2/28/2022 AM200285 2/28/2022 AM200287 2/28/2022 AM200288 2/28/2022 AM200289 2/28/2022 AM200290 2/28/2022 AM200291 2/28/2022 AM200292 2/28/2022

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, USP, 750 mg Rx only 100 Tablets bottles, Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 53746-0179-01

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1348-2020

Code Information:
HF02318A 6/30/2020 HF02418A 6/30/2020 HF02518A 6/30/2020 HF07718A 6/30/2020 HH02118A 7/31/2020 HM04418A 12/31/2020 HM04518A 12/31/2020 HM04618A 12/31/2020 HM04718A 12/31/2020 HM05518A 12/31/2020 HM05618A 12/31/2020 HM05718A 12/31/2020 HM05818A 12/31/2020 HM05918A 12/31/2020 HM06018A 12/31/2020

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, USP, 750 mg, Rx only, 100 Tablets bottles, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Ahmedabad, 388213, INDIA Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 65162-179-10

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1349-2020

Code Information:
AM181337A 10/31/2020 AM181338A 10/31/2020 AM181339A 11/30/2020 AM181340A 11/30/2020 AM181341A 11/30/2020 AM181342A 11/30/2020 AM181343A 11/30/2020 AM181344A 11/30/2020 AM181356A 11/30/2020 AM181357A 11/30/2020 AM181358A 11/30/2020 AM181359A 11/30/2020 AM181360A 11/30/2020 AM181361A 11/30/2020 AM181362A 11/30/2020 AM181363A 11/30/2020 AM181415A 11/30/2020 AM190040B 12/31/2020 AM190041A 12/31/2020 AM190042A 12/31/2020 AM190043A 12/31/2020 AM190044A 12/31/2020 AM190045A 12/31/2020 AM190046A 12/31/2020 AM190473B 4/30/2021 AM190474A 4/30/2021 AM190475A 4/30/2021 AM190476A 4/30/2021 AM190477A 4/30/2021 AM190478A 4/30/2021 AM190479A 4/30/2021 AM190480A 4/30/2021 AM190481A 4/30/2021 AM190482A 4/30/2021 AM190834A 7/31/2021 AM190835A 7/31/2021 AM190836A 7/31/2021 AM190837A 7/31/2021 AM190838A 7/31/2021 AM191004A 8/31/2021 AM191005A 8/31/2021 AM191006A 8/31/2021 AM191007A 8/31/2021 AM191008A 9/30/2021 AM191271A 10/31/2021 AM191272A 10/31/2021 AM191273A 10/31/2021 AM191274A 10/31/2021 AM191338A 11/30/2021 AM191339A 11/30/2021 AM191340A 11/30/2021 AM191341 12/31/2021 AM191342 12/31/2021 AM200109 12/31/2021 AM200110 12/31/2021 AM200111 12/31/2021

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, USP, Bulk, Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 53746-0178-BULK

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1350-2020

Code Information:
HA01320A 1/31/2021 HA01420A 1/31/2021 HA06820A 1/31/2021 HB03620A 1/31/2021 HB03720A 1/31/2021 HB03820A 1/31/2021 HB03920A 1/31/2021 HB04020A 1/31/2021 HB04120A 1/31/2021 HB04220A 1/31/2021 HB04320A 2/28/2021 HB04420A 1/31/2021 HB04520A 2/28/2021

HB05020A 2/28/2021 HB05120A 2/28/2021 HB05220A 2/28/2021 HB05320A 2/28/2021 HB05420A 2/28/2021 HB05520A 2/28/2021 HB05620A 2/28/2021 HB07020A 2/28/2021 HB07120A 2/28/2021 HB07220A 2/28/2021 HB07320A 2/28/2021 HB07520A 2/28/2021 HB07620A 2/28/2021 HB07720A 2/28/2021 HB07820A 2/28/2021 HB07920A 2/28/2021 HB08020A 2/28/2021 HB08220A 2/28/2021 HF05519A 6/30/2020 HF05619A 6/30/2020 HF05719A 6/30/2020 HF05819A 6/30/2020 HF05919A 6/30/2020 HF06019A 6/30/2020 HF06119A 6/30/2020 HF06219A 6/30/2020 HF06319A 6/30/2020 HF07719A 6/30/2020 HF07819A 6/30/2020 HF07919A 6/30/2020 HF08019A 6/30/2020 HF08119A 6/30/2020 HF08219A 6/30/2020 HF08319A 6/30/2020 HF08419A 6/30/2020 HF08519A 6/30/2020 HF08619A 6/30/2020 HF10119A 6/30/2020 HF10219A 6/30/2020 HF10319A 6/30/2020 HF10419A 6/30/2020 HF10519A 6/30/2020 HF10619A 6/30/2020 HF10719A 6/30/2020 HF10819A 6/30/2020 HF10919A 6/30/2020 HF11019A 6/30/2020 HF11119A 6/30/2020 HG07219A 7/31/2020 HG07319A 7/31/2020 HG07419A 7/31/2020 HG07519A 7/31/2020 HG07619A 7/31/2020 HG07719A 7/31/2020 HG07819A 7/31/2020 HG07919A 7/31/2020 HG08019A 7/31/2020 HG08119A 7/31/2020 HH00619A 7/31/2020 HH00719A 7/31/2020 HH00819A 7/31/2020 HH00919A 7/31/2020 HH01019A 7/31/2020 HH01119A 8/31/2020 HH01219A 8/31/2020 HH01319A 8/31/2020 HH01419A 8/31/2020 HH01519A 8/31/2020 HH07319A 8/31/2020 HH07419A 8/31/2020 HH07519A 8/31/2020 HH07619A 8/31/2020 HH07719A 8/31/2020 HH07819A 8/31/2020 HH07919A 8/31/2020 HH08019A 8/31/2020 HH08119A 8/31/2020 HH08219A 8/31/2020 HH11119A 10/31/2020 HH11219A 10/31/2020 HH11319A 10/31/2020 HH11419A 10/31/2020 HH11519A 10/31/2020 HH11619A 10/31/2020 HH11719A 10/31/2020 HH11819A 10/31/2020 HH11919A 10/31/2020 HH12019A 10/31/2020 HH12119A 10/31/2020 HH12219A 10/31/2020 HH12319A 10/31/2020 HH12419A 10/31/2020 HH12519A 10/31/2020 HH12619A 10/31/2020 HH12719A 10/31/2020 HH12819A 10/31/2020 HH12919A 10/31/2020 HH13019A 10/31/2020 HL00119A 10/31/2020 HL00219A 11/30/2020 HL00319A 11/30/2020 HL00419A 11/30/2020 HL00519A 11/30/2020 HL00619A 11/30/2020 HL00719A 11/30/2020 HL00819A 11/30/2020 HL00919A 11/30/2020 HL01019A 11/30/2020

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, 500 mg USP, 500 tablets bottles, Rx only, Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 53746-0178-05

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1351-2020

Code Information:
HF06618A 6/30/2020 HF06718A 6/30/2020

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, USP, 500 mg, 1000 tablets bottles, Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 53746-0178-10

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1352-2020

Code Information:
HF08618A 6/30/2020 HF08718A 6/30/2020 HF15418A 7/31/2020 HF15518A 7/31/2020 HH11818A 9/30/2020 HJ00818A 9/30/2020 HJ00918A 9/30/2020 HJ01018A 9/30/2020

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, USP, 500 mg, 1000 tablets bottles, Manufactured by: Amneal Pharmaceuticals Pvt. Ltd. Ahmedabad, 388213, INDIA Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 65162-0178-11

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1353-2020

Code Information:
HF08618A 6/30/2020 HF08718A 6/30/2020 HF15418A 7/31/2020 HF15518A 7/31/2020 HH11818A 9/30/2020 HJ00818A 9/30/2020 HJ00918A 9/30/2020 HJ01018A 9/30/2020

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, USP, Bulk, Rx Only, Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 53746-0179-BULK

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1354-2020

Code Information:
HA01520A 1/31/2021 HA01620A 1/31/2021 HG01719A 7/31/2020 HG01819A 7/31/2020 HH09319A 8/31/2020 HH09419A 9/30/2020 HK07619A 10/31/2020 HK07719A 10/31/2020

Product Description:
amneal Metformin Hydrochloride Extended-Release Tablets, USP, 750 mg, 100 tablets bottles, Distributed by: Amneal Pharmaceuticals LLC Bridgewater, NJ 08807 NDC 65162-0179-01

Product Quantity:

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1355-2020

Code Information:
AM181337A

Class II Drugs Event

Event ID:
85797

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/02/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/19/2020

Initial Firm Notification of Consignee or Public:
Press Release

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

Distribution Pattern:
Product was distributed throughout the United States, including Puerto Rico.

Associated Products

Product Description:
Metformin Hydrochloride Extended - Release Tablets, USP, 500 mg, a) 100 (NDC 62037-571-01) and b) 1,000 (NDC 62037-571-10) count bottles, Rx Only, Manufactured by: Watson Pharma Private Limited, Verna, Salcette Goa, Distributed by: Actavis Pharma, Inc., Parsippany, NJ

Product Quantity:
a) 92,793 bottles and b) 4,824 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1331-2020

Code Information:
a) 1329548A, exp. date 06/2020 1338302M, exp. date 10/2020 1348968M, exp. date 10/2020 1348969M, exp. date 10/2020 1348970M, exp. date 11/2020 1376339M,, exp. date 09/2021 b) 1323460M, exp. date 06/2020 1330919M, exp. date 6/2020 1338300A, exp. date 10/2020 1341135M, exp. date 12/2020 1391828M, exp. date 11/2021

Product Description:
Metformin Hydrochloride Extended-Release Tablets, USP 750 mg, a) 100 (NDC 62037-577-01) and b) 1000 (NDC 62037-577-10), Rx Only, Manufactured by: Watson Pharma Private Limited, Verna, Salcette Goa, Distributed by: Actavis Pharma, Inc., Parsippany, NJ

Product Quantity:
a) 15,329 bottles and b) 137 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1332-2020

Code Information:
a) 1333338M, exp. date 08/2020, 1333339A, exp. date 08/2020; b) 1354471A, exp. date 02/2021

Class II Drugs Event

Event ID:
85806

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/03/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
A.P. Deauville, LLC
594 Jersey Ave Unit C
New Brunswick NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Soft Whisper by Powerstick Dandruff Shampoo (Pyrithione Zinc), 14.4 FL OZ. (426 mL), A.P. Deauville LLC New Brunswick, NJ 08901, NDC 42913-020-00, UPC 815195014097

Product Quantity:
82,800 bottles

Reason for Recall:
cGMP Deviations: Soft Whisper Dandruff Shampoo was produced with water that failed USP specifications.

Recall Number:
D-1337-2020

Code Information:
Lot #: 070421E211; 070921E221; 071021E231; 071021E241, Exp 7/2021

Class II Drugs Event

Event ID:
85818

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/05/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/25/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Marksans Pharma Limited

& L - 83 Plots L - 82 Verna, Goa
Vasco Da Gama India

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Time-Cap Labs, Inc. Metformin Hydrochloride Extended-Release Tablets, USP 500 mg Rx Only 100 Tablets bottles, Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue Farmingdale, NY 11735, USA Manufactured by: Marksans Pharma Ltd. Plot No, L-82, L-83, Verna Intl. Estate, Verna, Goa-403 722, India NDC 49483-623-01

Product Quantity:
11279 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1356-2020

Code Information:
XP9004, exp 12/2020

Class II Drugs Event

Event ID:
85828

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/05/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/20/2020

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
PD-Rx Pharmaceuticals, Inc.
727 N Ann Arbor Ave
Oklahoma City OK United States

Distribution Pattern:
United States.

Associated Products

Product Description:
metFORMIN HCL ER 500 mg, a) 30 tablets (NDC 72789-009-30); b) 60 tablets (NDC 72789-009-60); c) 90 tablets (NDC 72789-009-90); d) 180 tablets (NDC 72789-009-93); e) 100 tablets (NDC 49483-0623-01) bottles, Rx only PD-Rx Pharmaceuticals Incorporated, Oklahoma City, OK 73127

Product Quantity:
1969 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1333-2020

Code Information:
Lots: a) A20B02, I19D03, J19A98, K19E32, L19C86 Exp. 12/31/2020; b) I19D55, I19F50, K19A18, K19D87, L19B34, L19D23, L19E74 Exp. 12/31/2020; c) I19E91, I19F33, J19B88, J19E70, K19D26, L19A65 Exp. 12/31/2020; d) I19C21 Exp. 08/21/2020, I19C57, J19C21, J19C67, K19B53, L19C77, L19E44 Exp. 12/31/2020; e) XP9004 Exp. 12/31/2020

Class II Drugs Event

Event ID:
85833

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Crown Laboratories
349 Lafe Cox Dr
Johnson City TN United States

Distribution Pattern:
Distributed Nationwide in the USA.

Associated Products

Product Description:
Nystatin Cream, USP 100,000 units per gram, 30 grams, Rx Only, Manufactured and Distributed by: Crown Laboratories, Inc. Johnson City, TN 37604, NDC 0316-0221-30

Product Quantity:
62,274 tubes

Reason for Recall:
Subpotent Drug: Out of specification for assay at the 9-month interval for Nystatin Cream, USP.

Recall Number:
D-1338-2020

Code Information:
Lot: Y0378A, EXP 07/2021

Product Description:
Nystatin Cream, USP 100,000 units per gram, 15 grams, Rx Only, Manufactured and Distributed by: Crown Laboratories, Inc. Johnson City, TN 37604, NDC 0316-0221-15

Product Quantity:
35,931 tubes

Reason for Recall:
Subpotent Drug: Out of specification for assay at the 9-month interval for Nystatin Cream, USP.

Recall Number:
D-1339-2020

Code Information:
Lot: Y0378, EXP 07/2021

Class II Drugs Event

Event ID:
85835

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alembic Pharmaceuticals Limited
Near Baska
Tajpura India

Distribution Pattern:
Nationwide in the U.S.

Associated Products

Product Description:
Aripiprazole Tablets, USP, 2 mg, 30 Tablets per bottle, Rx only, Manufactured by: Alembic Pharmaceuticals Limited (Formulation Division) Panelav 389350, Gujarat, India Manufactured for: Alembic Pharmaceuticals, Inc. 750 Route 202, Bridgewater, NJ 08807 USA, NDC 62332-097-30.

Product Quantity:
19,153 bottles

Reason for Recall:
Labeling: Label mix up: Bottles labeled as aripiprazole 2 mg, 30 count had aripiprazole 5 mg tablets, 100 count.

Recall Number:
D-1341-2020

Code Information:
Lot: 1905003298 Exp. 01/31/2021

Class II Drugs Event

Event ID:
85840

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/11/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/20/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Lupin Pharmaceuticals Inc.
Harborplace Tower 111 S Calvert St Fl 21st
Baltimore MD United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
Metformin Hydrochloride Extended-release Tablets USP, 500 mg, 60 count bottle, Rx only, Manufactured for Lupin Pharmaceuticals, Inc., Baltimore, MD Manufactured by: Lupin Limited Goa INDIA (NDC 68180-336-07)

Product Quantity:
6,540 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level

Recall Number:
D-1334-2020

Code Information:
Batch # G901203, exp. date 12/2020

Class II Drugs Event

Event ID:
85852

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/12/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/30/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Clozapine Tablets USP tablet, 100mg, 500-count bottle, Rx only, Distributed by: Aurobindo Pharma USA, Inc. 279 Princeton-Hightstown Road East Windsor, NJ 08520, Made in India, NDC 65862-846-05

Product Quantity:
1440 bottles

Reason for Recall:
Presence of foreign tablet: Consumer complaint of Clozapine Tablets 50mg being present in 500 count bottles of Clozapine Tablets USP 100mg.

Recall Number:
D-1370-2020

Code Information:
Lot #: CZSC20003-A, Exp 1/2022

Class III Drugs Event

Event ID:
85547

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/23/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/23/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
QuVa Pharma, Inc.
1075 W Park One Dr Ste 100
Sugar Land TX United States

Distribution Pattern:
Distributed Nationwide in the US.

Associated Products

Product Description:
R.E.C.K. (Ropivacaine, Epinephrine, Clonidine, Ketorolac) in Sodium Chloride solution 50 mL in 60 mL Syringe, Compounded by QuVa 519 Bloombury, NJ 08804, NDC 70092143350

Product Quantity:
17,050 syringes

Reason for Recall:
Presence of Particulate Matter: Fresenius Kabi recalling vials of Ketorolac

Recall Number:
D-1335-2020

Code Information:
Lots: 30008721, Exp. 4/26/2020; 30008198, 30008554, Exp. 4/29/2020; 30008861, Exp. 4/30/2020; 30008859, Exp. 5/5/2020; 30008949, Exp. 5/10/2020; 30009073, Exp. 5/14/2020; 30009074, Exp. 30009138, Exp. 5/17/2020; 30009139, 30009227, Exp. 5/19/2020; 30009228, Exp. 5/20/2020; 30009387, 30009388, Exp. 5/27/2020; 30009410, 30009411, Exp. 5/28/2020; 30009413, Exp. 5/31/2020; 30009412, 30009489, Exp. 6/1/2020; 30009539, 30009563, Exp. 6/3/2020

Class III Drugs Event

Event ID:
85725

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/27/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Duavee (conjugated estrogens/bazedoxifene) tablets 0.45/20 mg, packaged in 2 blister cards containing 15 tablets each (30 tablets), Rx Only, Distributed by Wyeth Pharmaceuticals LLC A subsidiary of Pfizer In Philadelphia, PA 19101 Made in Ireland, NDC 00008-1123-12

Product Quantity:
544400 packages

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-1342-2020

Code Information:
Lot #: AF7814, 2021 AUG 31; AH6565, 2021 SEP 30, AP5189, 2020 SEP30; CG8921, 2022 FEB 28; CL6603, DH5847, 2022 MAR 31; T17703, T99214 2020 JUN 30, W46878, X07330, 2020 SEP 30; X99074, 2021 JUN 30

Class III Drugs Event

Event ID:
85829

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/15/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/29/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Rising Pharmaceuticals, Inc.
250 Pehle Ave Ste 601
Saddle Brook NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Timolol Maleate USP, 0.5%, 5 mL, Sterile Opthalmic Solution, Rx Only, For Topical Application in the Eye, Distributed by: Rising Pharmaceuticals, Inc. Saddle Brook, NJ 07663, Manufactured by: FDC Limited B-8, MIDC Industrial Area, Waluj, Aurangbad - 431 136 Marahastra, India, NDC 64980-514-05

Product Quantity:

Reason for Recall:
Labeling: Label mix-up: A case of Timolol Maleate Sterile Ophthalmic solution USP 0.25%, 5ml, had the outer carton for Timolol Maleate Sterile Ophthalmic solution USP 0.5%, 5ml but the bottle inside was Timolol Maleate Sterile Ophthalmic solution USP 0.25%, 5ml.

Recall Number:
D-1367-2020

Code Information:
Lot # 089A016, Exp 12/31/2020

Product Description:
Timolol Maleate Sterile Opthalmic Solution,USP 0.25%, 5 mL, Rx Only, For Topical Application, Distributed by: Rising Pharmaceuticals, Inc. Saddle Brook, NJ 07863, Manufactured by: FDC Limited B-8, MDC Industrial Area, Waluj, Aurangabad - 431-136 Maharashtra, India, NDC 64980-513-05

Product Quantity:
15,072 bottles

Reason for Recall:
Labeling: Label mix-up: A case of Timolol Maleate Sterile Ophthalmic solution USP 0.25%, 5ml, had the outer carton for Timolol Maleate Sterile Ophthalmic solution USP 0.5%, 5ml but the bottle inside was Timolol Maleate Sterile Ophthalmic solution USP 0.25%, 5ml.

Recall Number:
D-1368-2020

Code Information:
Lot # 089A016, Exp 12/2020

Not Yet Classified Drugs Event

Event ID:
85842

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Nabumetone Tablets, USP, 500 mg, 100 Tablets per carton (10 tablets x 10 blister cards), Rx only, Distributed by: American Health Packaging,

Columbus, Ohio 43217, NDC carton: 60687-374-01, NDC unit dose: 60687-374-11

Product Quantity:
265 cartons

Reason for Recall:
Labeling Not Elsewhere Classified: The statement Pharmacist: Dispense with the accompanying Medication Guide was not included on the carton label.

Recall Number:

Code Information:
Lot #: 189551, Exp 04/30/2021