Enforcement Report - Week of January 15, 2020

Class II Drugs Event

Event ID:
84516

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/05/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
Natiowide

Associated Products

Product Description:
Glenmark Ranitidine Tablets USP 150 mg Rx Only 60 Tablets Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bandez, Goa 403513, India NDC 68462-248-60 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ NDC 684862-248-60

Product Quantity:
208,668 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0639-2020

Code Information:
7701164A 7701471A 7701670B 7701827A 7702242A 7702705A 7702947A 7703408A 7704494A 7704495A 19190289 19190342 19190372 7702737A

Product Description:
Glenmark Ranitidine Tablets USP 150 mg Rx Only 100 Tablets Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bandez, Goa 403513, India NDC 68462-248-01 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ NDC 684862-248-60

Product Quantity:
217,956 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0640-2020

Code Information:
7701033A 7701826A 7702344A 7702345A 7702489A 7702706A 7702707A 7702708A 7702858A 7702859A 7702860A 7702928A 7702929A 7703196A 7703634A 7704492A 7704493A 7705159A 19190289 19190342 19190372

Product Description:
Glenmark Ranitidine Tablets USP 300 mg Rx Only 30 Tablets Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bandez, Goa 403513, India NDC 68462-249-30 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ NDC 684862-248-60

Product Quantity:
98,988 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0641-2020

Code Information:
7701429A 7701522A 7702255A 7704745A 19190456 19190472 19190490

Product Description:
Glenmark Ranitidine Tablets USP 300 mg Rx Only 100 Tablets Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bandez, Goa 403513, India NDC 68462-249-01 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ NDC 684862-248-60

Product Quantity:
1,309,536 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0642-2020

Code Information:
7701030A 7701031A 7701062A 7701063A 7701110A 7701111A 7701112A 7701185A 7701186A 7701187A 7701188A 7701189A 7701269A 7701270A 7701278A 7701279A 7701386A 7701400A 7701401A 7701406A 7701421A 7701434A 7701435A 7701436A 7701452A 7701453A 7701521A 7701522B 7701553A 7701554A 7701555A 7701556A 7701582A 7701817A 7701828A 7701829A 7702001A 7702002A 7702003A 7702012A 7702026A 7702027A 7702064A 7702140A 7702253A 7702254A 7702285A 7702286A 7702287A 7702288A 7702294A 7702413A 7702462A 7702491A 7702492A 7702504A 7702505A 7702515A 7702698A 7702699A 7702700A 7702714A 7702719A 7702720A 7702747A 7702748A 7702749A 7702750A 7702751A 7702872A 7702873A 7702874A 7702917A 7702918A 7702919A 7702921A 7702922A 7702923A 7702945A 7703205A 7703410A 7703411A 7703412A 7703413A 7703414A 7703415A 7703451A 7703452A 7703453A 7703578A 7703579A 7703580A 7703581A 7703591A 7703592A 7703593A 7704372A 7704373A 7704374A 7704426A 7704427A 7704432A 7704463A 7704464A 7704465A 7704466A 7704508A 7704509A 7704510A 7704511A 7704512A 7704513A 7704563A 7704564A 7704746A 7704747A 7704748A 7704813A 7704841A 7704989A 7704990A 7705106A 7705320A 7705321A 7705322A 7705323A 7705324A 7705325A 7705326A 7705694A 7705703A 7705704A 7705702A 19190456 19190472 19190490 7701809A 7704862A 7704863A 7704864A 7704865A 7704866A 7704933A 7704934A

Product Description:
Glenmark Ranitidine Tablets USP 300 mg Rx Only 250 Tablets Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bandez, Goa 403513, India NDC 68462-249-20 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ NDC 684862-248-60

Product Quantity:
500,960 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0643-2020

Code Information:
7701069A 7701070A 7701084A 7701085A 7701087A 7701094A 7701095A 7701140A 7701141A 7701142A 7701157A 7701162A 7701182A 7701217A 7701218A 7701219A 7701236A 7701237A 7701220A 7701456A 7701470A 7701520A 7701671A 7701696A 7701697A 7701698A 7701797A 7701928A 7701929A 7701942A 7701943A 7702065A 7702066A 7702067A 7702095A 7702096A 7702097A 7702098A 7702188A 7702189A 7702190A 7702196A 7702197A 7702198A 7702199A 7702348A 7702338A 7702347A 7702349A 7702350A 7702391A 7702392A 7702546A 7702547A 7702548A 7702616A 7702617A 7702618A 7702619A 7702620A 7702763A 7702764A 7702851A 7702852A 7702853A 7702854A 7702855A 7702868A 7702869A 7702870A 7702871A 7702920A 7703054A 7703055A 7703056A 7703057A 7703058A 7703206A 7703208A 7703454A 7703455A 7703456A 7703486A 7703487A 7703488A 7703489A 7703490A 7703945A 7703946A 7703947A 7704111A 7704112A 7704113A 7704234A 7704235A 7704236A 7704237A 7704285A 7704286A 7704287A 7704288A 7704370A 7704371A 7704428A 7704429A 7704430A 7704431A 7704814A 7704838A 7704839A 7704840A 7704935A 7704936A 7704992A 7704996A 7704997A 7704998A 7704999A 7705037A 7705298A 7705299A 7705300A 7705301A 7705302A 7705303A 7705546A 7705584A 7705544A 7705545A 7705572A 7705585A 19190456 19190472 19190490 19191934 19191942 19191959 19192504

Product Description:
Glenmark Ranitidine Tablets USP 150 mg Rx Only 500 Tablets Manufactured by: Glenmark Pharmaceuticals Ltd. Colvale-Bandez, Goa 403513, India NDC 68462-248-05 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ NDC 684862-248-60

Product Quantity:
1,712,632 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0644-2020

Code Information:
7701034A 7701057A 7701058A 7701059A 7701060A 7701061A 7701071A 7701072A 7701073A 7701074A 7701105A 7701106A 7701107A 7701108A 7701109A 7701113A 7701114A 7701115A 7701116A 7701121A 7701122A 7701123A 7701124A 7701125A 7701126A 7701151A 7701152A 7701165A 7701154A 7701155A 7701163A 7701176A 7701190A 7701221A 7701222A 7701223A 7701224A 7701225A 7701235A 7701253A 7701254A 7701255A 7701256A 7701257A 7701258A 7701259A 7701266A 7701267A 7701268A 7701273A 7701275A 7701276A 7701277A 7701294A 7701295A 7701296A 7701297A 7701300A 7701301A 7701302A 7701303A 7701304A 7701306A 7701307A 7701308A 7701309A 7701310A 7701311A 7701312A 7701313A 7701314A 7701315A 7701316A 7701328A 7701329A 7701330A 7701331A 7701332A 7701333A 7701344A 7701153A 7701175A 7701234A 7701274A 7701305A 7701345A 7701352A 7701353A 7701354A 7701355A 7701356A 7701382A 7701383A 7701384A 7701385A 7701402A 7701403A 7701404A 7701405A 7701419A 7701420A 7701422A 7701423A 7701424A 7701425A 7701426A 7701427A 7701430A 7701432A 7701433A 7701448A 7701449A 7701450A 7701451A 7701454A 7701455A 7701471B 7701557A 7701558A 7701559A 7701583A 7701584A 7701585A 7701586A 7701587A 7701588A 7701614A 7701615A 7701616A 7701621A 7701637A 7701638A 7701639A 7701652A 7701653A 7701654A 7701655A 7701656A 7701657A 7701658A 7701664A 7701665A 7701666A 7701667A 7701668A 7701669A 7701670A 7701680A 7701613A 7701699A 7701700A 7701701A 7701714A 7701715A 7701716A 7701717A 7701718A 7701719A 7701720A 7701721A 7701781A 7701782A 7701783A 7701784A 7701796A 7701926A 7701927A 7701937A 7701938A 7701939A 7701940A 7701941A 7702004A 7702005A 7702006A 7702007A 7702008A 7702009A 7702010A 7702011A 7702013A 7702014A 7702068A 7702222A 7702223A 7702224A 7702230A 7702231A 7702232A 7702233A 7702242B 7702243A 7702244A 7702245A 7702246A 7702247A 7702248A 7702249A 7702250A 7702251A 7702252A 7702291A 7702292A 7702293A 7702302A 7702303A 7702304A 7702305A 7702306A 7702307A 7702308A 7702309A 7702331A 7702332A 7702333A 7702334A 7702339A 7702340A 7702346A 7702353A 7702354A 7702355A 7702356A 7702376A 7702377A 7702378A 7702379A 7702390A 7702310A 7702411A 7702412A 7702490A 7702493A 7702494A 7702498A 7702499A 7702500A 7702501A 7702502A 7702503A 7702516A 7702517A 7702518A 7702519A 7702549A 7702550A 7702551A 7702552A 7702601A 7702602A 7702603A 7702604A 7702605A 7702606A 7702607A 7702608A 7702621A 7702622A 7702623A 7702655A 7702656A 7702657A 7702658A 7702741A 7702742A 7702743A 7702765A 7702766A 7702777A 7702778A 7702779A 7702780A 7702781A 7702782A 7702783A 7702784A 7702794A 7702795A 7702796A 7702797A 7702811A 7702812A 7702813A 7702814A 7702815A 7702816A 7702817A 7702818A 7702819A 7702820A 7702821A 7702822A 7702848A 7702849A 7702850A 7702856A 7702857A 7702861A 7702896A 7702897A 7702898A 7702899A 7702910A 7702911A 7702912A 7702913A 7702914A 7702915A 7702916A 7702924A 7702925A 7702926A 7702927A 7703060A 7703061A 7703062A 7703063A 7703064A 7703065A 7703066A 7703067A 7703068A 7703144A 7703145A 7703146A 7703147A 7703174A 7703175A 7703176A 7703177A 7703178A 7703179A 7703180A 7703181A 7703182A 7703183A 7703191A 7703192A 7703193A 7703194A 7703195A 7703236A 7703237A 7703238A 7703239A 7703240A 7703248A 7703249A 7703250A 7703251A 7703252A 7703253A 7703254A 7703255A 7703283A 7703284A 7703290A 7703291A 7703292A 7703293A 7703294A 7703295A 7703296A 7703318A 7703330A 7703331A 7703332A 7703333A 7703334A 7703347A 7703348A 7703349A 7703350A 7703351A 7703394A 7703395A 7703409A 7703491A 7703492A 7703493A 7703494A 7703495A 7703496A 7703497A 7703498A 7703499A 7703500A 7703501A 7703502A 7703503A 7703504A 7703635A 7703636A 7703637A 7703638A 7703775A 7703776A 7703777A 7703778A 7703779A 7703780A 7703781A 7703782A 7703783A 7703925A 7703926A 7703934A 7703935A 7703936A 7703937A 7703938A 7703939A 7703970A 7703971A 7703972A 7704003A 7704004A 7704098A 7704099A 7704100A 7704101A 7704102A 7704103A 7704104A 7704181A 7704182A 7704183A 7704184A 7704185A 7704186A 7704187A 7704188A 7704189A 7704190A 7704191A 7704192A 7704193A 7704297A 7704298A 7704299A 7704300A 7704301A 7704302A 7704327A 7704328A 7704329A 7704330A 7704331A 7704332A 7704333A 7704334A 7704408A 7704409A 7704410A 7704411A 7704412A 7704413A 7704419A 7704420A 7704421A 7704422A 7704423A 7704424A 7704425A 7704496A 7704497A 7704502A 7704503A 7704504A 7704505A 7704506A 7704507A 7704559A 7704560A 7704561A 7704562A 7704574A 7704575A 7704606A 7704607A 7704608A 7704649A 7704650A 7704651A 7704652A 7704653A 7704654A 7704655A 7704656A 7704657A 7704658A 7704659A 7704673A 7704674A 7704675A 7704676A 7704677A 7704678A 7704679A 7704735A 7704736A 7704737A 7704738A 7704739A 7704810A 7704811A 7704812A 7704834A 7704835A 7704836A 7704837A 7704856A 7704857A 7704948A 7704949A 7704950A 7704951A 7704971A 7704972A 7704973A 7704974A 7704975A 7704976A 7704977A 7704980A 7704981A 7704982A 7704983A 7704984A 7704985A 7705014A 7705049A 7705125A 7705126A 7705127A 7705128A 7705129A 7705130A 7705131A 7705132A 7705133A 7705134A 7705135A 7705136A 7705137A 7705138A 7705150A 7705151A 7705152A 7705153A 7705382A 7705383A 7705386A 7705388A 7705391A 7705566A 7705568A 7705569A 7705589A 7705591A 7705595A 7705596A 7705597A 7705598A 7705599A 7705600A 7705601A 7705614A 7705615A 7705618A 7705619A 7705620A 7705621A 7705622A 7705623A 7705624A 7705387A 7705389A 7705390A 7705592A 7705593A 7705594A 7705602A 7705616A 7705617A 19190289 19190342 19190372 19190385 19191898 19192447 19192461 19192468 19192481 7702624A 7702625A 7702738A 7702739A 7702740A 7704858A 7704859A 7704860A 7704861A 7704892A 7704893A 7704894A 7704895A 7704896A 7704912A 7704926A 7704927A 7704928A 7704929A 7704930A 7704931A 7704932A

Class II Drugs Event

Event ID:
84550

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/09/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/08/2020

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Asclemed USA Inc. dba Enovachem Pharmaceuticals
379 Van Ness Ave Ste 1403
Torrance CA United States

Distribution Pattern:
Product was distributed to 6 physician's offices within the state of California.

Associated Products

Product Description:
Estriol, USP, (Micronized), 0.06 g, Distributed by Enovachem Pharmaceuticals, Torrance CA; NCD #76420-049-36

Product Quantity:
8.52 gm

Reason for Recall:
Failed Impurities/Degradation Specifications: Additional testing found Out of Specification impurity test results.

Recall Number:
D-0650-2020

Code Information:
Lot Code/Exp. Date: 11061901, 04011903, 04221904, 04241904, 06031902, 07301905, 09061903, EXP 12/31/2020

Product Description:
Estriol, USP, (Micronized), 0.12 g, Distributed by Enovachem Pharmaceuticals, Torrance CA; NCD #76420-049-37

Product Quantity:
42.12 gm

Reason for Recall:
Failed Impurities/Degradation Specifications: Additional testing found Out of Specification impurity test results.

Recall Number:
D-0651-2020

Code Information:
Lot Code/Exp. Date: 11061901, 11061803, 11281804, 11291804, 04171902, 05201901, 08121902, EXP 12/31/2020; 08161901, 10111903, EXP 5/31/2021; 11211904, 10161901, EXP 8/31/2021

Product Description:
Estriol, USP, (Micronized), 0.24 g, Distributed by Enovachem Pharmaceuticals, Torrance CA; NCD #76420-049-38

Product Quantity:
56.4 gm

Reason for Recall:
Failed Impurities/Degradation Specifications: Additional testing found Out of Specification impurity test results.

Recall Number:
D-0652-2020

Code Information:
Lot Code/Exp. Date: 11191804, 12281802, 01211902, 01281901, 02071903, 02221902, 03111903, 03251902, 04011905, 04091903, 04221907, 05211902, 06071902, 06241903, 07111903, 07301902, 08271902, 09061904, 09161902, EXP 12/31/2020; 09161901, 10091905, 10221902, 10311901, EXP 5/31/2021; 11211902, 10311902, EXP 8/31/2021

Class II Drugs Event

Event ID:
84571

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/26/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/03/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Blisovi Fe 1.5/30 (norethindrone acetate and ethinyl estradiol tablets USP and ferrous fumarate tablets 75mg), Rx Only, Distributed by: Lupin Pharmaceuticals Inc Baltimore, MD 21202, Manufactured for: Lupin Limited Pithampur 454775 INDIA 240875, NDC 68180-866-11

Product Quantity:
41,863 cartons/3 wallets per carton

Reason for Recall:
Failed Tablet/Capsule Specifications: Complaints related to crumbling of tablets when popped out of the blister pack.

Recall Number:
D-0638-2020

Code Information:
Lot: H801227, Exp. Date January 2020

Class II Drugs Event

Event ID:
84583

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/26/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/06/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AAA Pharmaceutical, Inc.
681 Main St
Lumberton NJ United States

Distribution Pattern:
Product was distributed to one consignee who may have distributed the product further to their retail stores.

Associated Products

Product Description:
Ranitidine 150 mg tablets, 24 count bottles, NDC 37808-196-01.

Product Quantity:
34,272 (24-count bottles)

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0645-2020

Code Information:
P134458, Sept 2020 P134943, Aug 2020 P135840, Aug, 2020 P136622, April 2021 P136871, April 2021 P137347, April 2021 P137424, April 2021

Product Description:
Ranitidine 150 mg tablets, 130 count bottles, NDC 37808-196-04.

Product Quantity:
31,536 (130-count bottles)

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0646-2020

Code Information:
P134457, Sept 2020 P135156, Aug 2020 P135156, Aug 2020 P135243, Aug 2020 P135877, Sept 2020 P136145, Aug 2020 P136146, Sept 2020 P136623, April 2021 P136728, April, 2021 P136994, April, 2021 P137348, April, 2021 P137423, April, 2021 P137499, April, 2021

Class II Drugs Event

Event ID:
84610

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/07/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Appco Pharma LLC
262 Old New Brunswick Rd Unit N
Piscataway NJ United States

Distribution Pattern:
Product was distributed to 6 major distributors/wholesalers some with multiple locations who may have further distribute the product.

Associated Products

Product Description:
Ranitidine Capsules 300 mg, 30 count bottles. Rx only, Manufactured by: Appco Pharma LLC, Piscataway, NJ 08854, Distributed by: ANI Pharmaceuticals, Inc., Baudette, MN 56623, NDC 62559-691-30.

Product Quantity:
1,632 bottes

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0648-2020

Code Information:
Batch # 1905227UE, exp. date Apr-2021 1905228UE, exp. date Apr-2021

Product Description:
Ranitidine Capsules 150 mg, (a) 60 count bottles (NDC 62559-690-60) , (b) 500 count bottles (NDC 62559-690-05), Rx only, Manufactured by: Appco Pharma LLC, Piscataway, NJ 08854, Distributed by: ANI Pharmaceuticals, Inc., Baudette, MN 56623.

Product Quantity:
624 bottes

Reason for Recall:
CGMP Deviations: Impurity N-nitrosodimethylamine (NDMA) found in API

Recall Number:
D-0649-2020

Code Information:
Batch # 1905225VN, exp. date Apr-2021 1905226VD, exp. date Apr-2021 1906295UN, exp. date May-2021 1906296UN, exp. date May-2021 1906297UN, exp. date May-2021 1906298UD, exp. date May-2021

Class III Drugs Event

Event ID:
84620

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/20/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/16/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Idelle Labs
One Helen Of Troy Plaza
El Paso TX United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
SURE 48 hr Confidence Unscented invisible solid Anti-Perspirant & Deodorant, Net Wt. 2.6 oz (73g) NDC# 41595-5509-2 UPC 8 83484 71717 2 Made in Canada and Distributed by Idelle Labs, Ltd., El Paso, TX 79912

Product Quantity:
Unknown

Reason for Recall:
Labeling Product Contains Undeclared API: Active Ingredient on label is not the active ingredient in the product.

Recall Number:
D-0783-2020

Code Information:
Lots: 19273K1, 19274K1, 19274K2, 19725K1, 19725K2, 19726K1

Product Description:
SURE 48hr Confidence Nourishing Coconut invisible solid Antiperspirant & Deodorant Net Wt 2.6 oz (73g) NDC# 41595-5547-1 UPC 8 83484 31020 5 Made in Canada and Distributed by Idelle Labs, Ltd., El Paso, TX 79912

Product Quantity:
Unknown

Reason for Recall:
Labeling Product Contains Undeclared API: Active Ingredient on label is not the active ingredient in the product.

Recall Number:
D-0784-2020

Code Information:
Lot: 19277K1

Product Description:
SURE 48hr Confidence Regular Original Solid Anti-Perspirant & Deodorant Net Wt 2.7 oz (76g) NDC# 41595-5514-1 UPC 8 83484 717936 6 Made in Canada and Distributed by Idelle Labs, Ltd., El Paso, TX 79912

Product Quantity:
Unknown

Reason for Recall:
Labeling Product Contains Undeclared API: Active Ingredient on label is not the active ingredient in the product.

Recall Number:
D-0785-2020

Code Information:
Lots: 19279K1, 19279K2, 19280K1

Product Description:
SURE 48hr Confidence Unscented Original Solid Anti-Perspirant & Deodorant Net Wt 2.7 oz (76g) NDC# 41595-5513-2 UPC 8 83484 71794 3 Made in Canada and Distributed by Idelle Labs, Ltd., El Paso, TX 79912

Product Quantity:
Unknown

Reason for Recall:
Labeling Product Contains Undeclared API: Active Ingredient on label is not the active ingredient in the product.

Recall Number:
D-0786-2020

Code Information:
Lots: 19277K2, 19278K1