Enforcement Report - Week of May 2, 2018

Class I Drugs Event

Event ID:
79555

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/15/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/24/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Bayer HealthCare Pharmaceuticals, Inc.
100 Bayer Blvd
Whippany NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
All Alka-Seltzer Plus¿ packages with a full front panel instant Redeemable Coupon (IRC) affixed to the individual carton. The recalled products can be identified by checking the Bayer logo located on the lower left corner of the front of the carton. If the logo has an orange or green background, the product is included in the recall.

Product Quantity:
188,631 units

Reason for Recall:
Labeling: Label Mix-Up: Bayer is recalling all Alka-Seltzer Plus packages, with a green or orange Bayer logo located on the lower left corner of the front of the carton, because the ingredients on the front sticker may not match the actual product in the carton.

Recall Number:
D-0697-2018

Code Information:
The recalled products can be identified by checking the Bayer logo located on the lower left corner of the front of the carton. If the logo has an orang e or green background, the product is included in the recall

Class II Drugs Event

Event ID:
79349

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/22/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Time-Cap Laboratories, Inc.
7 Michael Ave
Farmingdale NY United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Ibuprofen Tablets, USP, 200 mg, a) 50 tablets (NDC 49483-601-05), b) 100 tablets (NDC- 49483-601-01), c) 500 tablets (NDC 49483-601-50), d) 1000 tablets (NDC 49489-601-10), e) Bulk (49483-601-00) bottles, Brown, Manufactured for: Time Cap Labs, Inc., Farmingdale, NY 11735, Manufactured by: Marksans Pharma, Ltd., Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0685-2018

Code Information:
a) D167C, exp 2/18; b) D172C, exp 2/18, H057C, exp 6/18; c) D164C, exp 2/18, E135C, exp 3/18; d) D172C, exp 2/18, E135C, exp 3/18, F004C, exp 5/18; e) D175C, D176C, D177C, D178C, D179C, D180C, D162C, D163C, D164C, D165C, D166C, D168C, D169C, D170C, D171C, D173C, E104C, E105C, D191C, D192C, D193C, D194C, D195C, D196C, D197C, D198C, D199C, D200C, D201C, E106C, exp 2/18; L111C, F005C, F006C, F007C, F008C, H053C, H054C, H055C, H056C, exp 5/18; L112C, L113C, L114C, L115C, L116C, L117C, L118C, L119C, J008C, J009C, H057C, H058C, exp 6/18; L120C, L121C, L122C, L123C, L124C, exp 8/18

Product Description:
Ibuprofen Tablets, USP, 200 mg, a) 50 tablet (NDC 53943-291-15), b) 100 tablet (NDC 53943-291-12), c) 500 tablet (NDC 53943-291-14), Brown, Distributed by Drug Mart, Food Fair, Medina, Ohio 44256

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0686-2018

Code Information:
a) D167C, exp 2/18, E135C, exp 3/18; b) D172C, exp 2/18; c) D167C, exp 2/18, E135C, exp 3/18

Product Description:
Ibuprofen Tablets USP 400 mg, a) 100 tablet (NDC 49483-602-01) and b) 500 tablet (NDC 49483-602-50) bottles, Rx, Manufactured for: Time Cap labs, Inc., Farmingdale, NY 11735, USA, Manufactured by: Marksans Pharma, Ltd., Plot No. L-82, L-83 Verna indl. Estate Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0687-2018

Code Information:
a) M104C, exp 9/18, L016C, H092C, and H093C, exp 9/18 b) C128C, C129C, C130C, C132C, exp 3/18, HK6011, exp 7/18, L016C and H092C, exp 9/18,

Product Description:
Ibuprofen Tablets USP 400 mg, 500 tablet bottles (NDC 42582-111-18), Rx, Distributed by Bi-Coastal Pharma International, Shrewsbury, NJ, Manufactured by: Marksans Pharma, Ltd., Plot No. L-82, L-83 Verna indl. Estate Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0688-2018

Code Information:
C128C, C129C, exp 3/18

Product Description:
Ibuprofen Tablets USP 600 mg, a) 100 tablet (NDC 49483-603-01) and b) 500 tablet bottles (NDC 49483-603-50), Rx, Manufactured for: Time Caps Labs, Farmingdale, NY, Manufactured by: Marksans Pharma, Ltd., Plot No. L-82, L-83 Verna indl. Estate Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0689-2018

Code Information:
a) C135C, D044C, D045C, D038C, exp 3/18, F069C, exp 4/18, H095C, exp 9/18 b) C134C, C136C, D039C, D040C, D041C, D042C, D043C, exp 3/18, F043C F067C, F068C, D046C, D047C, exp 4/18, H094C, exp 7/18 H096C, L026C, and H095C, exp 9/18

Product Description:
Ibuprofen Tablets USP 600 mg, a) 100 tablets (NDC 42582-112-10) and b) 500 tablet bottles (NDC 42582-112-18), Rx, Distributed by: Bi-Coastal Pharma International, Shrewsbury, NJ, Manufactured by: Marksans Pharma, Ltd., Plot No. L-82, L-83 Verna indl. Estate Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0690-2018

Code Information:
a) D044C, D038C, D043C, exp 3/18, b) C136C, exp 3/18, D039C, D040C, D041C, D042C, 3/18

Product Description:
Ibuprofen Tablets USP 600 mg, a) 100 tablet (NDC 42582-112-01), b) 500 tablet bottles (NDC 42582-112-18), Rx, Distributed by Drug Mart, Food Fair, Medina, Ohio 44256

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0691-2018

Code Information:
a) C135C, exp 3/18 b) C134C, exp 3/18

Product Description:
Ibuprofen Tablets USP 800 mg, a) 100 tablet (NDC 49483-604-01) and b) 500 tablet (NDC 49483-604-50) bottles, Rx, Manufactured for: Time Cap labs, Inc., Farmingdale, NY 11735, USA, Manufactured by: Marksans Pharma, Ltd., Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0692-2018

Code Information:
a) C139C, C140C, exp 2/18, F044C, exp 8/18; b) D048C, D049C, D050C, D051C, C142C, C137C, C138C, C139C, C141C, exp 2/18; D052C, K207C, K208C, K209C, K210C, K211C, K212C, HM6122, HM6123, HM6124, HM6125, HM6126, K109C, K110C, K111C, HM6113, HM6114, HM6115, HM6116, HM6117, HM6118, F044C, H097C, H098C, H099C, H100C, H101C, K096C, K097C, K098C, K099C, K100C, K101C, K102C, exp 8/18; M105C, L017C, L018C, L019C, L020C, L021C, L022C, exp 9/18

Product Description:
Ibuprofen Tablets USP 800 mg, a) 100 tablet (NDC 42582-113-10) and b) 500 tablet (NDC 42582-113-18) bottles, Rx, Distributed by; Bi-Coastal Pharma International, Shrewsbury, NJ, Manufactured by: Marksans Pharma, Ltd., Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0693-2018

Code Information:
a) C140C, exp 2/18; b) D049C, D050C, D051C, C142C, C137C, C138C, C141C, exp 2/18; D073C, D074C, exp 3/18

Product Description:
Ibuprofen Caplets USP 200 mg, a) 50 caplets (NDC 49483-600-05), b) 100 caplets (NDC 49483-600-01), c) 500 caplets (NDC 49483-600-50), and d) BULK (NDC 49483-600-00) bottles, Rx, Manufactured for: Time Cap labs, Inc., Farmingdale, NY 11735, Manufactured by: Marksans Pharma, Ltd., Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0694-2018

Code Information:
a) F066C b) F066C c) F066C

Product Description:
Ibuprofen Caplets USP 200 mg, a) 50 caplets (NDC 53943-292-15), b) 100 caplets (NDC 53493-292-12), and c) 500 caplets (NDC 53493-292-14) bottles, Distributed by Drug Mart, Food Fair, Medina, Ohio 44256, Manufactured by: Marksans Pharma, Ltd., Verna, Goa-403 722, India

Product Quantity:

Reason for Recall:
CGMP Deviations: Various strengths of ibuprofen tablets/caplets are being recalled due to complaints of odor related to CGMP deficiencies.

Recall Number:
D-0695-2018

Code Information:
a) F066C b) F066C c) F066C

Class II Drugs Event

Event ID:
79803

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/11/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
04/26/2018

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Premier Pharmacy Labs Inc
8265 Commercial Way
Weeki Wachee FL United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Morphine Sulfate 2 mg/mL PF Injection. 1 mL in a 3ml Sterile Single-Dose Syringe. 8265 Commerical Way Weeki Wachee, FL 34613. NDC 69623-129-10

Product Quantity:
4555 syringes

Reason for Recall:
Lack of Assurance of Sterility:Microbial contamination was detected during routine testing of subsequent unreleased product lots due to interaction between the product syringe and tamper evident container closure, which may result in the potential introduction of microorganisms into the products.

Recall Number:
D-0699-2018

Code Information:
Lots: MOR030518IJDSA, MOR030518IJDSB, MOR030518IJDSC, MOR030518IJDSD, MOR030518IJDSE BUD: 06/03/2018;

Product Description:
Morphine Sulfate 4 mg/mL PF Injection. 1 mL in a 3ml Sterile Single-Dose Syringe. 8265 Commerical Way Weeki Wachee, FL 34613. NDC 69623-127-10

Product Quantity:
4192 syringes

Reason for Recall:
Lack of Assurance of Sterility:Microbial contamination was detected during routine testing of subsequent unreleased product lots due to interaction between the product syringe and tamper evident container closure, which may result in the potential introduction of microorganisms into the products.

Recall Number:
D-0700-2018

Code Information:
Lots: MOR022318NWDSA, MOR022318NWDSB, MOR022318NWDSC, MOR022318NWDSD, MOR022318NWDSE BUD: 05/24/2018

Product Description:
Hydromorphone HCl 1 mg/mL PF INJ. 1mL in a 3mL Sterile Single-Dose Syringe. 8265 Commercial Way Weeki Wachee, FL 34613 NDC 69623-249-10

Product Quantity:
3570 syringes

Reason for Recall:
Lack of Assurance of Sterility:Microbial contamination was detected during routine testing of subsequent unreleased product lots due to interaction between the product syringe and tamper evident container closure, which may result in the potential introduction of microorganisms into the products.

Recall Number:
D-0701-2018

Code Information:
Lots: HYD030118IJDSA, HYD030118IJDSB, HYD030118IJDSD, HYD030118IJDSE BUD: 05/30/2018

Product Description:
NEOstigmine Methylsulfate (1 mg/mL) 3mg per 3mL. 3mL Single Dose Syringe. Premier Pharmacy Labs. 8265 Commercial Way Weeki Wachee, FL 34613 NDC 69623-234-14.

Product Quantity:
600 syringes

Reason for Recall:
Lack of Assurance of Sterility:Microbial contamination was detected during routine testing of subsequent unreleased product lots due to interaction between the product syringe and tamper evident container closure, which may result in the potential introduction of microorganisms into the products.

Recall Number:
D-0702-2018

Code Information:
Lot: NEO022218SVDS BUD: 8/21/2018

Not Yet Classified Drugs Event

Event ID:
79860

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/13/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lyne Laboratories, Inc.
10 Burke Dr
Brockton MA United States

Distribution Pattern:
to be entered

Associated Products

Product Description:
Fluocinolone Acetonide Topical Oil, 0.01% (Body Oil) 118.28 mL (4 fl. oz.) Rx Only, Manufactured by: Lyne Laboratories, Inc. Brockton, MA 02307 Manufactured for: Rising Pharmaceuticals, Inc. Allendale, NJ 07401, NDC 64980-331-04, UPC 364980331043

Product Quantity:
12572 units

Reason for Recall:
Subpotent Drug

Recall Number:

Code Information:
Lot #: FR1603, FR1604A, Exp. 05/2018

Product Description:
Fluocinolone Acetonide Topical Oil, 0.01% (Ear Drops) 20 mL, Rx Only, Manufactured by: Lyne Laboratories, Inc. Brockton, MA 02307 Manufactured for: Rising Pharmaceuticals, Inc. Allendale, NJ 07401, NDC 64980-329-20, UPC 364980329200

Product Quantity:
17939 units

Reason for Recall:
Subpotent Drug

Recall Number:

Code Information:
Lot#: FR1604B, FR1604C, FR 1604D, Exp. 06/2018

Product Description:
Fluocinolone Acetonide Topical Oil, 0.01% (Scalp Oil) 118.28 mL (4 fl.oz.) Rx Only, Manufactured by: Lyne Laboratories, Inc. Brockton, MA 02307 Manufactured for: Rising Pharmaceuticals, Inc. Allendale, NJ 07401, NDC 64980-330-04, UPC 364980330046

Product Quantity:
23453 units

Reason for Recall:
Subpotent Drug

Recall Number:

Code Information:
Lot #: FR1601, FR1602, Exp. 05/2018

Not Yet Classified Drugs Event

Event ID:
79936

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/23/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mckesson Packaging Services
7101 Weddington Rd Nw
Concord NC United States

Distribution Pattern:
Nationwide with the US

Associated Products

Product Description:
Diltiazem HCl Extended-Release Capsules, USP 120 mg, 100-count bottles, Rx only, Mfg. By: Par Pharmaceutical One Ram Ridge Rd Chestnut Ridge, NY 10977. NDC: 63739-014-10

Product Quantity:
4266 cartons

Reason for Recall:
Failed Dissolution Specifications. High dissolution results were obtained during stability testing.

Recall Number:

Code Information:
Lot #: 0115086, Exp. 12/2018

Product Description:
Diltiazem CD (Diltiazem Hydrochloride Extended-Release Capsules, USP) 180 mg, 100-count bottles, Rx Only Mfg. By: Actavis 60 Columbia Rd., Bldg. B Morristown, NJ 07960. NDC 63739-284-10

Product Quantity:
7656 cartons

Reason for Recall:
Failed Dissolution Specifications. High dissolution results were obtained during stability testing.

Recall Number:

Code Information:
Lot #: 0114214, Exp. 09/2018

Product Description:
Diltiazem HCl Extended-Release Capsules, USP 240 mg, 100-count bottles, Rx Only, Mfg. By: Par Pharmaceutical One Ram Ridge Rd Chestnut Ridge, NY 10977. NDC: 63739-016-10

Product Quantity:
2966 cartons

Reason for Recall:
Failed Dissolution Specifications. High dissolution results were obtained during stability testing.

Recall Number:

Code Information:
Lot #: 0115087, Exp. 12/2018