

Enforcement Report - Week of March 16, 2016

Biologics	Cosmetics	Devices	Drugs	Food	Tobacco
Veterinary					

Class I Drugs Event

Event ID:

72294

Product Type:

Drugs

Status:

Ongoing

Recalling Firm:

Tf Supplements

6666 Gulf Fwy

Houston TX United States

Recall Initiation Date:

09/25/2015

Center Classification Date:

03/09/2016

Date Terminated:
Voluntary / Mandated:

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Press Release

Distribution Pattern:

Nationwide

Associated Products

Product Description:

RHINO 7 3000, 6 count Bottle,
Distributed by Rhino 7, Made in USA

Product Quantity:

350 Bottles

Code Information:

All lots

Reason for Recall:

Marketed without an Approved
NDA/ANDA: Products contain
undeclared desmethyl carbondenafil
and dapoxetine.

Recall Number:

D-0771-2016

Product Description:

Rhino 7 Platinum 3000, 1 count Blister
Pack, Distributed by Rhino 7, Made in
USA, UPC 700729253748

Reason for Recall:

Marketed without an Approved
NDA/ANDA: Products contain
undeclared desmethyl carbondenafil

Product Quantity:

128 Blister Packs

Code Information:

All lots

and dapoxetine.

Recall Number:

D-0772-2016

Class II Drugs Event**Event ID:**

73304

Product Type:

Drugs

Status:

Ongoing

Recalling Firm:

Hartley Medical Center Pharmacy,

Incorporated

113 W Victoria St

Long Beach CA United States

Recall Initiation Date:

02/04/2016

Center Classification Date:

03/04/2016

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Telephone

Distribution Pattern:

Nationwide. No foreign distribution.

Associated Products**Product Description:**Morphine Sulfate 6 mg/ml/Bupivacaine
HCL 32 mg/ml, vol. 22 ml syringe, Rx
only, Hartley Med Ctr Pharmacy, Long
Beach, CA**Product Quantity:**

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0736-2016

Product Description:Baclofen 5000 mcg/ml, vol. 20 ml
syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA**Reason for Recall:**

Lack of Assurance of Sterility

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Recall Number:

D-0737-2016

Product Description:

Hydromorphone HCL 10
mg/ml/Baclofen 460
mcg/ml/Bupivacaine HCL, vol. 40 ml
syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0738-2016

Product Description:

Morphine Sulfate 0.5 mg/ml/Baclofen
1000 mcg/ml/, vol. 20 ml syringe, Rx
only, Hartley Med Ctr Pharmacy, Long
Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0739-2016

Product Description:

Hydromorphone 12 mg/ml/Baclofen
450 mcg/ml, vol. 20 ml, syringe, Rx
only, Hartley Med Ctr Pharmacy, Long
Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0740-2016

Product Description:

Morphine Sulfate 9 mg/ml/Sufentanil
Cit 180 mcg/ml/Bupivacaine HCL 33
mg/ml, vol. 20 ml vial, Rx only, Hartley
Med Ctr Pharmacy, Long Beach, CA

Product Quantity:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

1 vial

D-0741-2016

Code Information:

BUD: 5/3/2016

Product Description:

Sufentanil Cit 1000 mcg/ml/Baclofen
300 mcg/ml, vol. 20 ml syringe, Rx
only, Hartley Med Ctr Pharmacy, Long
Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0742-2016

Product Description:

Morphine Sulfate 0.6 mg/ml, vol. 200
ml syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

2 syringes

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0743-2016

Product Description:

Morphine Sulfate 20
mg/ml/Bupivacaine HCL 11.3 mg/ml,
vol. 40 ml syringe, Rx only, Hartley
Med Ctr Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0744-2016

Product Description:

Morphine Sulfate 50
mg/ml/Bupivacaine HCL 24 mg/ml, vol.
20 ml syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0745-2016

BUD: 5/3/2016

Product Description:

Hydromorphone HCL 10
mg/ml/Bupivacaine HCL 30 mg/ml, vol.
20 ml syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0746-2016

Product Description:

Morphine Sulfate 10 mg/ml, vol. 20 ml
syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0747-2016

Product Description:

Baclofen 2000 mcg/ml, vol. 20 ml
syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0748-2016

Product Description:

Hydromorphone HCL 20
mg/ml/Bupivacaine HCL 40 mg/ml, vol.
20 ml syringe Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0749-2016

Product Description:**Reason for Recall:**

Hydromorphone HCL 25 mg/ml, vol. 40 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Lack of Assurance of Sterility

Product Quantity:

1 syringe

Recall Number:

D-0750-2016

Code Information:

BUD: 5/3/2016

Product Description:

Hydromorphone HCL 10 mg/ml/Fentanyl Citrate 0.15 mg/ml, vol. 40 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Reason for Recall:

Lack of Assurance of Sterility

Product Quantity:

1 syringe

Recall Number:

D-0751-2016

Code Information:

BUD: 5/3/2016

Product Description:

Hydromorphone HCL 10 mg/ml, vol. 40 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Reason for Recall:

Lack of Assurance of Sterility

Product Quantity:

1 syringe

Recall Number:

D-0752-2016

Code Information:

BUD: 5/3/2016

Product Description:

Hydromorphone HCL 2 mg/ml, vol. 20 ml syringe, Rx only, Hartley Med Ctr Pharmacy Long Beach, CA

Reason for Recall:

Lack of Assurance of Sterility

Product Quantity:

1 syringe

Recall Number:

D-0753-2016

Code Information:

BUD: 5/3/2016

Product Description:

Morphine Sulfate 1.5 mg/ml, vol. 20 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Reason for Recall:

Lack of Assurance of Sterility

Product Quantity:

2 syringes

Recall Number:

D-0754-2016

Code Information:

BUD: 5/3/2016

Product Description:

Fentanyl Citrate 1.275 mg/ml/Baclofen
150 mcg/ml/Bupivacaine HCL 20
mg/ml/ Clonidine HCL 450 mcg/ml, vol.
40 ml syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0755-2016

Product Description:

Hydromorphone HCL 1 mg/ml, vol. 22
ml syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

2 syringes

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0756-2016

Product Description:

Hydromorphone HCL 25
mg/ml/Bupivacaine HCL 4 mg/ml, vol.
40 ml syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0757-2016

Product Description:

Hydromorphone HCL 10
mg/ml/Bupivacaine HCL 4 mg/ml, vol.
20 ml syringe, Rx only, Hartley Med Ctr
Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:**Reason for Recall:**

Lack of Assurance of Sterility

Recall Number:

D-0758-2016

BUD: 5/3/2016

Product Description:

Morphine Sulfate 11 mg/ml, vol. 20 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0759-2016

Product Description:

Hydromorphone HCL 7 mg/ml/Bupivacaine HCL 11.2 mg/ml, vol. 40 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0760-2016

Product Description:

Sufentanil Cit 200 mcg/ml/Clonidine HCL 1600 mcg/ml, vol. 42 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0761-2016

Product Description:

Morphine Sulfate 20 mg/ml, vol. 42 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Product Quantity:

1 syringe

Code Information:

BUD: 5/3/2016

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:

D-0762-2016

Product Description:**Reason for Recall:**

Morphine Sulfate 0.5 mg/ml, vol. 20 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Lack of Assurance of Sterility

Product Quantity:

1 syringe

Recall Number:

D-0763-2016

Code Information:

BUD: 5/3/2016

Product Description:

Hydromorphone HCL 0.5 mg/ml, vol. 20 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Reason for Recall:

Lack of Assurance of Sterility

Product Quantity:

1 syringe

Recall Number:

D-0764-2016

Code Information:

BUD: 5/3/2016

Product Description:

Sufentanil Cit 50 mcg/ml/Clonidine HCL 1 mcg/ml/Bupivacaine HCL 5 mg/ml, vol. 20 ml syringe, Rx only, Hartley Med Ctr Pharmacy, Long Beach, CA

Reason for Recall:

Lack of Assurance of Sterility

Product Quantity:

1 syringe

Recall Number:

D-0765-2016

Code Information:

BUD: 5/3/2016

Class III Drugs Event

Event ID:

73152

Voluntary / Mandated:

Voluntary: Firm Initiated

Product Type:

Drugs

Initial Firm Notification of Consignee or Public:

Letter

Status:

Ongoing

Distribution Pattern:

Nationwide

Recalling Firm:

Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Recall Initiation Date:

01/27/2016

Center Classification Date:

03/09/2016

Date Terminated:**Associated Products****Product Description:**

Atorvastatin Calcium 10 mg, 10 tablets per blister, 100-count package, Rx Only
 Manufactured by Apotex Inc. Toronto, Ontario, Canada, Packaged by GSMS Inc., Camarillo, CA 93010, NDC # 60429-323-77

Reason for Recall:

Failed Impurities/Degradation Specifications

Product Quantity:

222 100-count packages (22,000 tablets)

Recall Number:

D-0767-2016

Code Information:

Lot #GS005602; Exp. 10/15 Lot
 #GS008855; Exp. 09/17 Lot
 #GS009074; Exp. 08/17 Lot
 #GS009393; Exp. 08/17 Lot
 #GS009760; Exp. 10/17 Lot
 #GS010599; Exp. 11/17

Product Description:

Atorvastatin Calcium 20 mg, 10 tablets per blister, 100-count package, Rx Only
 Manufactured by Apotex Inc. Toronto, Ontario, Canada, Packaged by GSMS Inc., Camarillo, CA 93010, NDC # 60429-324-77

Reason for Recall:

Failed Impurities/Degradation Specifications

Product Quantity:

74 100-count packages (7,400 tablets)

Recall Number:

D-0768-2016

Code Information:

Lot #GS008856; Exp. 09/17 Lot
 #GS010268; Exp. 09/17 Lot
 #GS010600; Exp. 11/17

Product Description:

Atorvastatin Calcium 40 mg, 10 tablets per blister, 100-count package, Rx Only

Reason for Recall:

Failed Impurities/Degradation Specifications

Manufactured by Apotex Inc. Toronto,
Ontario, Canada, Packaged by GSMS
Inc., Camarillo, CA 93010, NDC #
60429-325-77

Product Quantity:

172 100-count packages (17,200
tablets)

Code Information:

Lot #GS009075; Exp. 09/17 Lot
#GS009763; Exp. 09/17 Lot
#GS010178; Exp. 10/17

Recall Number:

D-0769-2016

Product Description:

Atorvastatin Calcium 80 mg, 10 tablets
per blister, 100-count package, Rx Only
Manufactured by Apotex Inc. Toronto,
Ontario, Canada, Packaged by GSMS
Inc., Camarillo, CA 93010, NDC #
60429-326-77

Product Quantity:

168 100-count packages (16,800
tablets)

Code Information:

Lot #GS005603; Exp. 10/15 Lot
#GS006691; Exp. 08/17 Lot
#GS009073; Exp. 08/17 Lot
#GS009395; Exp. 08/17 Lot
#GS009764; Exp. 10/17

Reason for Recall:

Failed Impurities/Degradation
Specifications

Recall Number:

D-0770-2016

Class III Drugs Event**Event ID:**

73264

Product Type:

Drugs

Status:

Ongoing

Recalling Firm:

Ecolab Inc
370 Wabasha St N
Saint Paul MN United States

Recall Initiation Date:**Voluntary / Mandated:**

Voluntary: Firm Initiated

Initial Firm Notification of Consignee or Public:

Letter

Distribution Pattern:

Nationwide, Puerto Rico and Canada

02/12/2016

Center Classification Date:

03/08/2016

Date Terminated:**Associated Products****Product Description:**

Scrub-Stat 4 (chlorhexidine gluconate)
Foam Forming Solution, 4%, packaged
in a) 800 mL Plastic (HDPE) Bottles
(NDC 47593-265-36), b) 1250 mL
Plastic (HDPE) Bottles (NDC 47593-
468-59), OTC, Ecolab, St Paul, MN
55102

Product Quantity:

706 bottles

Code Information:

Lot #: a) L041051, Exp 04 /17;
L060151, L061951, Exp 06 /17; b)
L060151, L061951, Exp 06 /17

Reason for Recall:

Subpotent drug

Recall Number:

D-0766-2016