

Enforcement Report - Week of January 9, 2019

Class II Drugs Event

Event ID:

81865

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

12/21/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

12/31/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

LUPIN SOMERSET

400 Campus Dr

Somerset NJ United States

Distribution Pattern:

Nationwide in the USA and Puerto Rico.

Associated Products

Product Description:

Nitrofurantoin Oral Suspension, USP, 25mg/5mL, 230 mL bottle, Rx only, Manufactured by: Novel Laboratories, Inc., Somerset, NJ 08873; Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, MD 21202, NDC 43386-450-11.

Product Quantity:

23,460 bottles

Reason for Recall:

Subpotent Drug: Expansion of June 2018 recall of lots S700065 and S700619 due to below specification results for assay.

Recall Number:

D-0346-2019

Code Information:

Lot #: S700038, S700044, S700059, S700065, Exp 28-Feb-19; S700410, S700427, Exp 30-Jun-19; S700617, S700619, Exp 31-Aug-19; S700813, S700815, S700869, Exp 31-Oct-19; S700871, S700873, Exp 30-Nov-19; S700875, S701073, Exp 31-Dec-19.

Not Yet Classified Drugs Event

Event ID:

81883

Product Type:

Drugs

Status:

Ongoing

Date Terminated:
Recall Initiation Date:

01/02/2019

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:
Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Hiers Enterprises, LLC dba Northwest Compounding Pharmacy

1350 Ne Stephens St Ste 42

Roseburg OR United States

Distribution Pattern:

Product was distributed exclusively in the state of Oregon to 3 Medical facilities, 1 Physician's office and 80 consumers/patients.

Associated Products

Product Description:

Cyclosporin liquid 0.2%, RX, plastic dropper bottle, dry eye, 10/24/18 Cyclosporin liquid 0.5%, RX, plastic dropper bottle, dry eye, 7/27/18
 Cyclosporin liquid 1%, RX, plastic dropper bottle, dry eye, 7/19/18 Cyclosporin liquid 0.05%, RX, plastic dropper bottle, dry eye, 10/12/18-11/2/18
 Cyclosporin liquid 2%, RX, plastic dropper bottle, dry eye, 8/17/2018-10/17/18

Product Quantity:

830 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19,
 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19,
 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19,
 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19,
 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

Epinephrine liquid 1:1000, RX, glass vial, various, 10/10/18-10/22/18

Product Quantity:

50 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19,
 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19,
 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19,
 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19,
 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

60 Glutathione liquid, 100mg/ml Glutathione liquid, 200mg/ml

Product Quantity:

60 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19,
 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19,
 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19,
 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19,
 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

HCG liquid, 1000u/ml, RX, glass vial, various, 10/16/18

Product Quantity:

30 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19,
 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19,
 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19,

10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

Hydroxyprogesterone liquid, 250mg/ml, RX, glass vial, pregnancy retention 10/25/18

Product Quantity:

20 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19, 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19, 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19, 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

Lidocaine gel 2%, RX, plastic dropper, analgesic 10/22/18 Lidocaine liquid 1%, RX, glass vial, analgesic, 10/22/18

Product Quantity:

125 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19, 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19, 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19, 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

Lidocaine/Epinephrine liquid 1%/1:1000, RX, glass vial, analgesic, 8/7/18

Product Quantity:

50 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19, 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19, 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19, 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

MIC B vitamin liquid 25/50/50/1/1/1mg/ml RX glass vial, health support, 10/29/18 MIC Ba vitamin liquid 25/50/50/1/1/100/250/20mg/1.5ml, RX, glass vial, health 10/19/18

Product Quantity:

310 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19, 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19,

10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19, 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

Methocarbamol liquid 100mg/ml, RX, glass vial, muscle relaxer, 10/8/18-10/31/18

Product Quantity:

300 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19, 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19, 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19, 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

Testosterone Cypionate liquid 200mg/ml, RX, glass vial, HRT, 10/1/18

Product Quantity:

200 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19, 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19, 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19, 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19

Product Description:

Vitamin B12 liquid 1000mcg/ml, RX, glass vial, health support, 10/16/18 Vitamin B12a liquid 1000mcg/ml, RX, glass vial, health support, 10/18/18

Product Quantity:

150 ml

Reason for Recall:

Lack of Assurance of Sterility

Recall Number:**Code Information:**

10042018@10 exp 3/2/19, 07272018@2 exp 1/23/19, 07192018@12 exp 1/15/19, 11022018@18 exp 3/2/19, 10122018@30 exp 3/2/19, 08172018@7 exp 2/13/19, 09202018@16 exp 3/2/19, 10172018@32 exp 3/2/19, 10102018@13 exp 1/8/19, 10222018@33 exp 1/20/19, 10292018@17 exp 1/27/19, 10092018@5 1/7/19, 10162018@22 exp 1/14/19, 10252018@24 exp 3/31/19, 10222018@15 exp 1/20/19, 10222018@40 exp 1/20/19, 08072018@30 exp 2/3/19, 10292018@15 exp 1/31/19, 10192018@8 exp 2/28/19, 10082018@34 exp 1/6/19, 10312018@27 exp 1/29/19, 10022018@54 exp 3/30/19, 10162018@28 exp 1/14/19 10182018@38 exp 1/16/19