

Enforcement Report - Week of March 17, 2021

Class III Drugs Event

Event ID:
87382

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/02/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/11/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ferring Pharmaceuticals Inc
100 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Distributed nationwide in the USA.

Associated Products

Product Description:

Menopur 75 IU, (menotropins for injection), packaged as a) 5 single dose vials of Menotropins for injection, 5 single dose vials of 0.9% Sodium Chloride Injection, USP 2 mL, NDC 55566-7501-2; b) Professional Sample Kit: 3 single dose vials of Menotropins for injection, 3 single dose vials of 0.9% Sodium Chloride Injection, USP 2 mL, NDC 55566-7501-3; Rx Only, Manufactured for Ferring Pharmaceuticals Inc. Parsippany, NJ 07054. Diluent manufactured for Ferring Pharmaceuticals Inc.

Product Quantity:

1,155,601 cartons/5 vials per carton 12546 physician samples

Reason for Recall:

Failed pH specifications: Out of Specification pH results for 0.9% Sodium Chloride, USP

Recall Number:

D-0299-2021

Code Information:

Lots# a) P12585AC, Exp. Date 31-Mar-2020 P12677AA, Exp. Date 31-Mar-2020 P12678AA, Exp. Date 31-Jul-2020 P12679AA, Exp. Date 31-Jul-2020 P12680EA, Exp. Date 31-Jul-2020 P15461AA, Exp. Date 31-Jul-2020 P15462AA, Exp. Date 31-Aug-2020 P15463AA, Exp. Date 31-Aug-2020 P15870AA, Exp. Date 31-Aug-2020 P15872AA, Exp. Date 31-Aug-2020 P16099AA, Exp. Date 31-Aug-2020 P16100AA, Exp. Date 30-Sep-2020 P16101AC, Exp. Date 30-Sep-2020 P16248AA, Exp. Date 30-Sep-2020 P16770AA, Exp. Date 30-Nov-2020 P16771AA, Exp. Date 30-Nov-2020 R10623AA, Exp. Date 31-Jan-2021 R10624AA, Exp. Date 31-Jan-2021 R10980AA, Exp. Date 31-Jan-2021 R11085AA, Exp. Date 31-Jan-2021 R11086AA, Exp. Date 31-Jan-2021 R11088AA, Exp. Date 28-Feb-2021 R11343AA, Exp. Date 28-Feb-2021 R11416AA, Exp. Date 28-Feb-2021 R11417AA, Exp. Date 28-Feb-2021 R11418AA, Exp. Date 28-Feb-2021 R11419AA, Exp. Date 28-Feb-2021 R12100AA, Exp. Date 28-Feb-2021 R12101AA, Exp. Date 28-Feb-2021 R12102AA, Exp. Date 31-Mar-2021 R12263CA, Exp. Date 31-Mar-2021 R12264AA, Exp. Date 31-Mar-2021 R12598AA, Exp. Date 31-Mar-2021 R12599AA, Exp. Date 31-Mar-2021 R12858AA, Exp. Date 30-Apr-2021 R12859AA, Exp. Date 30-Apr-2021 R12860AA, Exp. Date 31-Jul-2021 R12861AA, Exp. Date 31-Jul-2021 R14321AA, Exp. Date 30-Nov-2021 R14753AA, Exp. Date 31-Jul-2021 R14865AA, Exp. Date 31-Jul-2021 R14866AA, Exp. Date 31-Jul-2021 R15132AA, Exp. Date 31-Aug-2021 R15133AA, Exp. Date 31-Aug-2021 R15330AA, Exp. Date 31-Aug-2021 R15331AA, Exp. Date 31-Aug-2021 R15332AA, Exp. Date 31-Aug-2021 R15333AA, Exp. Date 31-Aug-2021 R15969AA, Exp. Date 30-Sep-2021 R15970AA, Exp. Date 30-Sep-2021 R16231AA, Exp. Date 30-Sep-2021 R16379AA, Exp. Date 31-Oct-2021 R16403AA, Exp. Date 31-Oct-2021 R16405AA, Exp. Date 31-Oct-2021 R16660AA, Exp. Date 31-Oct-2021 R16696AA, Exp. Date 30-Nov-2021 R16770AA, Exp. Date 31-Oct-2021 R17019AA, Exp. Date 31-Oct-2021 R17020AA, Exp. Date 30-Nov-2021 R17148AA, Exp. Date 30-Nov-2021 S11615AA, Exp. Date 28-Feb-2022 S11616AA, Exp. Date 28-Feb-2022 S11617AA, Exp. Date 28-Feb-2022 S11618AA, Exp. Date 28-Feb-2022 S11619AA, Exp. Date 28-Feb-2022 S11620AA, Exp. Date 28-Feb-2022 S11621AA, Exp. Date 28-Feb-2022 S11623AA, Exp. Date 28-Feb-2022 S12026AA, Exp. Date 31-Mar-2022 S12413AA, Exp. Date 31-Mar-2022 S12436AA, Exp. Date 31-Mar-2022 S12437AA, Exp. Date 30-Apr-2022 S12438AA, Exp. Date 31-May-2022 S12439AA, Exp. Date 31-May-2022 b) Physician Samples P16101AA, Exp. Date 30-Sep-2020 R15332AC, Exp. Date 31-Aug-2021 S11625AA, Exp. Date 28-Feb-2022