

# Enforcement Report - Week of March 6, 2019

## Class III Drugs Event

**Event ID:**

82249

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

02/26/2019

**Voluntary / Mandated:**

Voluntary: Firm Initiated

**Center Classification Date:**

02/28/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Lupin Pharmaceuticals Inc.  
111 S Calvert St Fl 21ST  
Baltimore MD United States

**Distribution Pattern:**

Nationwide in the USA and Puerto Rico.

## Associated Products

**Product Description:**

Moxifloxacin Ophthalmic Solution USP, 0.5%, 3 mL bottle, Rx only, Manufactured by: Lupin Limited, Pithampur (M.P.) 454 775, INDIA, NDC 68180-422-01.

**Product Quantity:**

674,628 bottles

**Reason for Recall:**

Failed Impurities/Degradation Specifications: Expansion of July 2018 and February 2019 recall due to high out-of-specification for impurities.

**Recall Number:**

D-0517-2019

**Code Information:**

Lots: H701618, H701619, H701620, Exp March 2019; H702220, H702221, H702222, H702223, H702224, H702225, H702351, Exp April 2019; H702971, H702972, H702973, H702974, H703151, H703152, H703153, Exp June 2019; H703155, H703682, H703683, Exp July 2019; H704243, H704245, H704247, Exp September 2019; H704707, H704709, H705038, H705039, Exp October 2019; H705561, Exp November 2019; H800394, H800395, H800617, H800618, Exp January 2020; H801585, H801586, H801721, H801722, Exp March 2020; H802138, H802139, H802140, Exp April 2020; H802421, H802707, H802718, Exp May 2020; H803187, H803188, H803232, Exp June 2020; H803749, H803750, Exp July 2020; H804326, H804327, H804328, H804330, H804549, H804552, H804630, H804632, Exp September 2020; H805163, H805361, H805362, H805676, Exp November 2020; H805690, H805692, H805694, Exp December 2020