Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: August 25, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Allergan plc - RECALL [Drug]

AFFECTED PRODUCT: **REFRESH® Lacri-Lube® 3.5g and 7g for dry eye, REFRESH P.M.® 3.5g for dry eye, FML® (fluorometholone ophthalmic ointment) 0.1% (sterile ophthalmic ointment topical anti-inflammatory agent for ophthalmic use, 3.5g), and Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2% sterile topical ophthalmic ointment combining an antibacterial and a corticosteroid, 3.5g.**

SUMMARY: **Unclassified Recall; The recall has been initiated due to a small number of customer complaints which reported a small black particle at the time of use. This black particle, which is part of the cap, can be created by the action of unscrewing the cap from the aluminum tube, and potentially introduced into the product.**

NDC	Description	Lot Number	Expiration Date
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	84746	Apr-17
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	84987	May-17
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	85087	May-17
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	85359	Jun-17
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	85721	Jul-17
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	86045	Aug-17
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	86406	Sep-17
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	86594	Oct-17

0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	87021	Nov-17
0023-0312-07	REFRESH® Lacri-Lube® 7g	86470	Sep-17
0023-0312-07	REFRESH® Lacri-Lube® 7g	86829	Oct-17
0023-0312-07	REFRESH® Lacri-Lube® 7g	87105	Nov-17
0023-0240-04	REFRESH P.M.® 3.5 g	85165	May-17
0023-0240-04	REFRESH P.M.® 3.5 g	85228	May-17
0023-0240-04	REFRESH P.M.® 3.5 g	85244	Jun-17
0023-0240-04	REFRESH P.M.® 3.5 g	85351	Jun-17
0023-0240-04	REFRESH P.M.® 3.5 g	85374	Jun-17
0023-0240-04	REFRESH P.M.® 3.5 g	85397	Jun-17
0023-0240-04	REFRESH P.M.® 3.5 g	85561	Jul-17
0023-0240-04	REFRESH P.M.® 3.5 g	85676	Jul-17
0023-0240-04	REFRESH P.M.® 3.5 g	85694	Jul-17
0023-0240-04	REFRESH P.M.® 3.5 g	85834	Aug-17
0023-0240-04	REFRESH P.M.® 3.5 g	85977	Aug-17
0023-0240-04	REFRESH P.M.® 3.5 g	85985	Aug-17
0023-0240-04	REFRESH P.M.® 3.5 g	86073	Aug-17
0023-0240-04	REFRESH P.M.® 3.5 g	85599	Sep-17
0023-0240-04	REFRESH P.M.® 3.5 g	86290	Sep-17
0023-0240-04	REFRESH P.M.® 3.5 g	86325	Sep-17
0023-0240-04	REFRESH P.M.® 3.5 g	86411	Sep-17
0023-0240-	REFRESH P.M.® 3.5 g	86427	Sep-17

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0023-0240-04	REFRESH P.M.® 3.5 g	86506	Sep-17
0023-0240-04	REFRESH P.M.® 3.5 g	86515	Sep-17
0023-0240-04	REFRESH P.M.® 3.5 g	86517	Sep-17
0023-0240-04	REFRESH P.M.® 3.5 g	86746	Oct-17
0023-0240-04	REFRESH P.M.® 3.5 g	86792	Oct-17
0023-0240-04	REFRESH P.M.® 3.5 g	86789	Oct-17
0023-0240-04	REFRESH P.M.® 3.5 g	86809	Oct-17
0023-0240-04	REFRESH P.M.® 3.5 g	86822	Oct-17
0023-0240-04	REFRESH P.M.® 3.5 g	86822A	Oct-17
0023-0240-04	REFRESH P.M.® 3.5 g	86932	Nov-17
0023-0240-04	REFRESH P.M.® 3.5 g	87100	Nov-17
0023-0240-04	REFRESH P.M.® 3.5 g	87068	Nov-17
0023-0240-04	REFRESH P.M.® 3.5 g	87156	Dec-17
0023-0240-04	REFRESH P.M.® 3.5 g	87261	Dec-17
0023-0240-04	REFRESH P.M.® 3.5 g	87493	Jan-18
0023-0240-04	REFRESH P.M.® 3.5 g	87494	Feb-18
0023-0240-04	REFRESH P.M.® 3.5 g	87731	Feb-18
0023-0240-04	REFRESH P.M.® 3.5 g (Professional Sample Pack)	85165	May-17
0023-0240-04	REFRESH P.M.® 3.5 g (Professional Sample Pack)	86789	Oct-17
0023-0316-04	FML® (fluorometholone ophthalmic ointment) 0.1%, 3.5 g	86258	Sep-17
0023-0316-04	FML® (fluorometholone ophthalmic ointment) 0.1%, 3.5 g	87189	Dec-17
0023-	FML® (fluorometholone ophthalmic ointment) 0.1%, 3.5 g	87514	Feb-18

0316-04			
0023-0313-04	Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2%, 3.5 g	86430	Sep-17
0023-0313-04	Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2%, 3.5 g	87806	Feb-18
0023-0313-04	Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2%, 3.5 g	88147	Mar-18

The lot number and expiration date may be found on the bottom flap of the carton with the safety seal and on the crimp seal of the product tube.

The recalled products were distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. If there are questions or if assistance is required in response to this recall, please use the contact information below.**

Product Returns Contact GENCO at: 877-674-2087 7 am to 5 pm CST	**Credit/Reimbursements** Contact Allergan at: 1-800-811-4148 7am to 5pm PST	**Allergan Medical Inquiries:** 1-800-433-8871 option 2 8am - 5pm **PST** **Adverse Events/Products Complaints:** 1-800-624-4261 Option 3 (8am - 5pm **CST**)

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Allergan Issues Voluntary Nationwide Recall In The U.S. Of Specific Lots Of REFRESH® Lacri-Lube®, REFRESH P.M. ®, FML® (fluorometholone ophthalmic ointment) 0.1%, and Blephamide® (Sulfacetamide Sodium And Prednisolone Acetate Ophthalmic Ointment, USP) 10%/0.2% For Particulate Matter

Contact:
Media:
Mark Marmur
(973)906-1526

FOR IMMEDIATE RELEASE - Dublin, Ireland – August 24, 2015 – Allergan plc, today announced that it is conducting a voluntary recall down to consumer level of specific lots of its REFRESH® Lacri-Lube® 3.5g and 7g for dry eye, REFRESH P.M.® 3.5g for dry eye, FML® (fluorometholone ophthalmic ointment) 0.1% (sterile ophthalmic ointment topical anti-inflammatory agent for ophthalmic use, 3.5g), and Blephamide® (sulfacetamide

sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2% sterile topical ophthalmic ointment combining an antibacterial and a corticosteroid, 3.5g.

Allergan chose to initiate this recall based on a small number of customer complaints which reported a small black particle at the time of use. This black particle, which is part of the cap, can be created by the action of unscrewing the cap from the aluminum tube, and potentially introduced into the product. Reported adverse events include Foreign Body in Eye (12), Eye Irritation (2), Ocular Discomfort (2), Product Contamination (2), Superficial Injury of Eye (2), Eye Pain (1), Eye Swelling (1) and Vision Blurred (1).

Specific lots are being voluntarily recalled in the interest of patient safety. If the particle gets into the eye, potential adverse events may include eye pain, eye swelling, ocular discomfort or eye irritation. Please contact your physician or healthcare provider if you have any of these symptoms when using these products. The lot number and expiration date may be found on the bottom flap of the carton with the safety seal and on the crimp seal of the product tube.

Specific information on product and lots that are being voluntarily recalled are below

NDC	Description	Lot Number	Expiration Date
0023-0312-04	REFRESH® Lacri-Lube® 3.5 g	84746	Apr-17
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0023-0313-04	Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2%, 3.5 g	87806	Feb-18
0023-0313-04	Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2%, 3.5 g	88147	Mar-18

Allergan has informed the U.S. Food and Drug Administration of this voluntary recall. The recall only applies to specific lots of the REFRESH® Lacri-Lube®, REFRESH P.M. ®, FML® (fluorometholone ophthalmic ointment) 0.1%, Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2%. This recall does not affect any other REFRESH or Allergan product.

Allergan is contacting retailers and wholesalers who have been shipped affected product lots to initiate the recall and is informing them of the steps needed to return affected product.

The company is asking consumers who currently have product from any of the affected lots of REFRESH® Lacri-Lube®, REFRESH P.M. ®, FML® (fluorometholone ophthalmic ointment) 0.1% , Blephamide® (sulfacetamide sodium or prednisolone acetate ophthalmic ointment, USP) 10%/0.2%, to stop using the product and return it to Allergan.

If there are questions or if assistance is required in response to this recall, please use the contact information below.

CONTACT INFORMATION		
Product Returns Contact GENCO at: 877-674-2087 7 am to 5 pm CST	**Credit/Reimbursements** Contact Allergan at: 1-800-811-4148 7am to 5pm PST	**Allergan** **Medical Inquiries**: 1-800-433-8871 option 2 8am - 5pm **PST** **Adverse Events/Products Complaints**: 1-800-624-4261 Option 3 (8am - 5pm **CST**)
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088		

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of this product.

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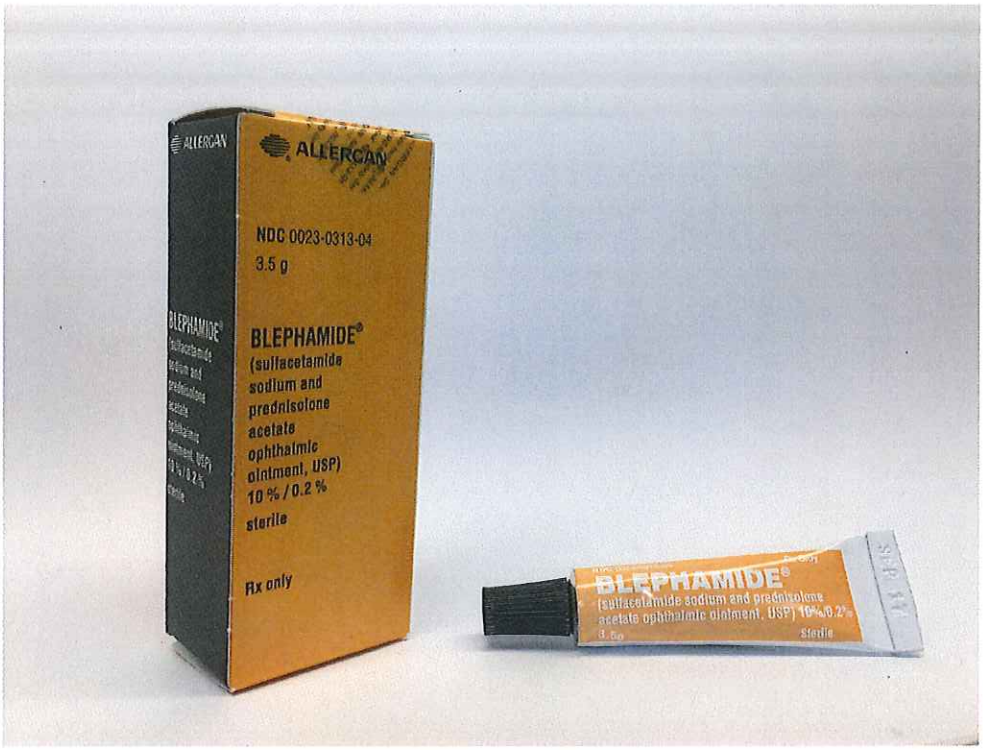
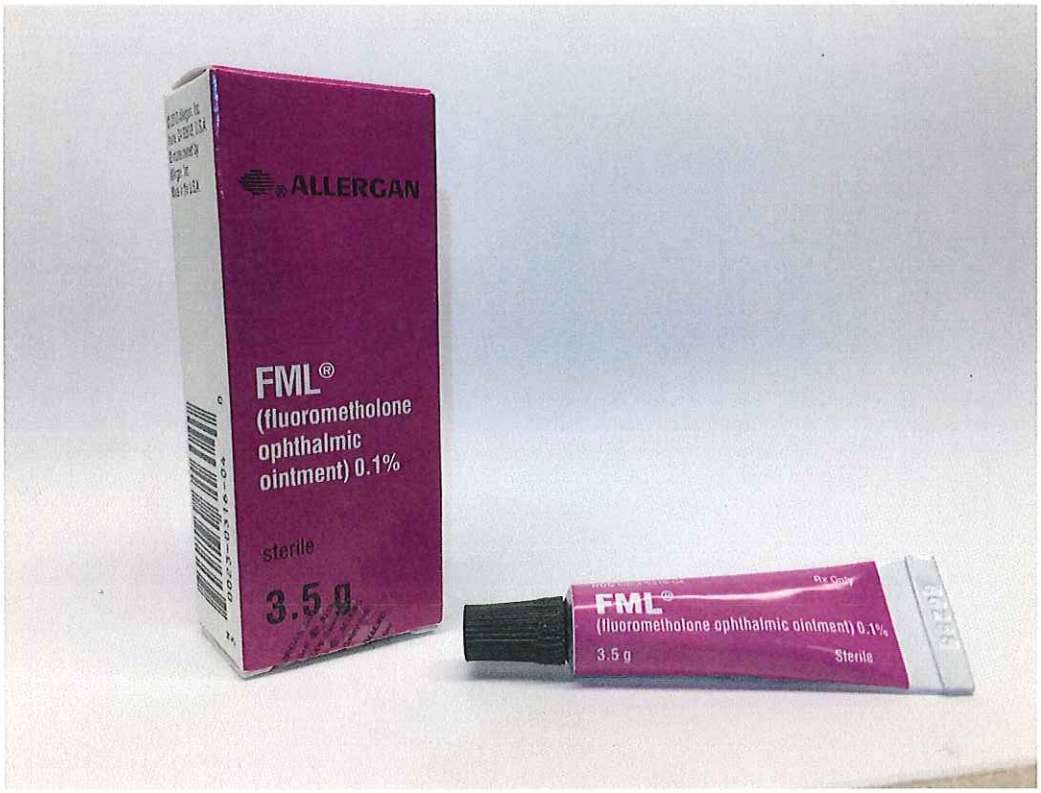
Allergan Issues Voluntary Nationwide Recall In The U.S. Of Specific Lots Of REFRESH® Lacri-Lube®, REFRESH P.M. ®, FML® (fluorometholone ophthalmic ointment) 0.1%, and Blephamide® (Sulfacetamide Sodium And Prednisolone Acetate Ophthalmic Ointment, USP) 10%/0.2% For Particulate Matter
Photo


ALLERGAN
NDC 0023-0313-04
3.5 g
BLEPHAMIDE®
(sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP)
10 % / 0.2 %
sterile
Rx only
BLEPHAMIDE®
(sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2%
Sterile


ALLERGAN
FML®
(fluorometholone ophthalmic ointment) 0.1%
sterile
3.5 g
Rx Only
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Sterile