ITEM: 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%: Recall for Particulate Matter

SPECIFIC INCIDENT(S): Allergan is conducting a voluntary recall for 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% due to small black particulate matter that may cause eye pain, eye swelling, ocular discomfort or eye irritation.

GENERAL INFORMATION:

- Reports document complaints of a small black particle (which is part of the cap) at the time of use potentially introduced into the product by the action of unscrewing the cap from the aluminum tube.
- Allergan has received adverse events reports that 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 blurred vision (1).
- Affected products and lots are included below:

<table>
<thead>
<tr>
<th>NDC</th>
<th>DESCRIPTION</th>
<th>LOT NUMBER, EXPIRATION DATE</th>
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<tbody>
<tr>
<td>0023-0312-04</td>
<td>REFRESH® Lacri-Lube® 3.5 g</td>
<td>84746, Apr-17; 84987, May-17; 85087, May-17; 85359, Jun-17; 85721, Jul-17; 86045, Aug-17; 86406, Sep-17; 86594, Oct-17; 87021, Nov-17</td>
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<tr>
<td>0023-0312-07</td>
<td>REFRESH® Lacri-Lube® 7g</td>
<td>86470, Sep-17; 86829, Oct-17; 87105, Nov-17</td>
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<tr>
<td>0023-0240-04</td>
<td>REFRESH P.M.® 3.5 g</td>
<td>85165, May-17; 85228, May-17; 85244, Jun-17; 85374, Jun-17; 85561, Jul-17; 85694, Jul-17; 85834, Aug-17; 85977, Aug-17; 85985, Aug-17; 86073, Aug-17; 85599, Sep-17; 86290, Sep-17; 86325, Sep-17; 86411, Sep-17; 86427, Sep-17; 86506, Sep-17; 86515, Sep-17; 86517, Sep-17; 86746, Oct-17; 86792, Oct-17; 86789, Oct-17; 86809, Oct-17; 86822, Oct-17; 86822A, Oct-17; 86932, Nov-17; 87100, Nov-17; 87068, Nov-17; 87156, Dec-17; 87261, Dec-17; 87493, Jan-18; 87494, Feb-18; 87731, Feb-18</td>
</tr>
<tr>
<td>0023-0240-04</td>
<td>REFRESH P.M.® 3.5 g (Professional Sample Pack)</td>
<td>85165, May-17; 86789, Oct-17</td>
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</table>
This alert is an extension of the product sequestration actions in Product Recall Office Log # 9972 (available at: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html).

Providers should continue to report any adverse reactions with the use of REFRESH® Lacri-Lube®, REFRESH P.M.®, FML® (fluorometholone ophthalmic ointment) 0.1%, Blephamide® (sulfacetamide sodium and prednisolone acetate ophthalmic ointment, USP) 10%/0.2% product(s) by entering the information into CPRS’ Allergies/Adverse Reactions field and/or via local reporting mechanisms. Adverse events should also be reported, as appropriate, to the VA ADERS program and FDA MedWatch (1-800-FDA-1088, fax 1-800- FDA-0178, online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or by mail).

### ACTIONS:

**PROVIDER NOTIFICATION:**

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS** (and Chief Nurse Executives): Forward this document to all appropriate providers who prescribe this agent (e.g., primary care providers, eye care specialists, and pharmacy staff, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

**PATIENT NOTIFICATION:**

- **Chief of Pharmacy:** Within 10 business days of issue (due 09/16/2015):
  - Determine whether the affected product(s) was dispensed to any patient(s) for home administration.
  - If an affected lot(s) was dispensed to a patient(s) for home administration, then:
    - Identify the patient(s).
    - Contact the patient(s) who may have received the affected product(s) for home administration by letter (or other means).
    - A sample letter can be found at: https://vaww.cmopnational.va.gov/cmop/PBM/Other%20Documents%20and%20Resources/ASA%20Recall%20Patient%20Letter%20Template. doc.
    - This template can be altered according to site-specific needs.
    - Provide patient(s) in possession of the recalled product with
instructions on the following:

• How to return the product being recalled to the pharmacy.
• How to obtain a new supply of product.
• Patients should not continue to take the product until they obtain replacement product.
• When the correct product is received, patients should begin using the new product and return the recalled supply as instructed.

  o Communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the VHA Alerts and Recalls Website: http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html.

SOURCE: FDA


ATTACHMENT(S): None.

CONTACTS: Pharmacy Benefits Management Services (PBM) at (708)786-7862.