

ALTAIRE PHARMACEUTICALS, INC.
AQUEBOGUE, NY

URGENT: DRUG RECALL NOTICE

July 16, 2019

Via E-mail: rhaggerty@prestigebrands.com, apetterelli@prestigebrands.com

Attn.: Mr. Robert Haggerty
Mr. Andrew Petterelli
Prestige Brands
600 White Plains Road Suite 250
Tarrytown NY 10591

Dear Mr. Haggerty and Mr. Petterelli:

Please allow this communication to inform you of a recall to the RETAIL LEVEL involving the Over-the-Counter (OTC) drug products as identified below:

Clear Eyes Redness Relief
Clear Eyes Redness Relief (Handy)
Clear Eyes Redness Reliever (Little Drug)
Clear Eyes Redness Reliever (Select Corp)

This recall is being carried out to the RETAIL LEVEL and IS ONLY FOR THE SPECIFIC LOTS LISTED BELOW. A Retail Level Recall is limited to product lots currently in inventory. No other lots are being recalled. Please reference the tables below for identification of impacted drug product lots and distribution dates:

PRESTIGE

Product Description: Clear Eyes Redness Relief

UPC#: 6-78112-25415-6 Product Size: 15 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
16195	7/19	8/9/2016
16211	8/19	8/30/2016
16216	8/19	9/8/2016

Product Description: Clear Eyes Redness Relief

UPC#: 6-78112-25419-4 Product Size: 30 mL

Lot Number	Expiration Date	Manufacturer Initial Ship Date
16205	7/19	8/16/2016

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16211	8/19	8/30/2016
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Product Description: Clear Eyes Redness Relief (Handy Pocket Pal)

UPC#: 6-78112-25418-7

Product Size: 0.2 FL. Oz.

Lot Number	Expiration Date	Manufacturer Initial Ship Date
16192	7/19	9/23/2016
16203	7/19	10/14/2016
16242	9/19	11/1/2016
16280	10/19	11/7/2016
16285	10/19	12/1/2016
16300	11/19	12/15/2016
16336	12/19	1/26/2017
17002	1/20	2/3/2017
17012	1/20	2/27/2017
17051	2/20	3/30/2017
17130	04/20	06/12/2017
17147	05/20	08/29/2017

Product Description: Clear Eyes Redness Relief (Little Drug)

UPC#: 7-92554-70103-7

Product Size: 0.2 FL. Oz.

Lot Number	Expiration Date	Manufacturer Initial Ship Date
16321	11/19	1/6/2017
16336	12/19	1/26/2017
17012	1/20	2/27/2017
17034	2/20	3/9/2017
17051	2/20	3/31/2017

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17147	5/20	8/29/2017
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Product Description: Clear Eyes Redness Relief (Select Corp)

UPC#: 6-55708-01039-6

Product Size: 0.2 FL. Oz.

Lot Number	Expiration Date	Manufacturer Initial Ship Date
16192	7/19	9/26/2016
16203	7/19	10/14/2016
16321	11/19	01/10/2017
17002	1/20	2/6/2017
17034	2/20	3/9/2017

As a precautionary measure, Altaire is initiating a RETAIL LEVEL recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility.

The products are manufactured and labeled exclusively for Prestige Brands. Altaire ships the products labeled for Prestige Brands only to Prestige Brands. The products are distributed at the retail level. Altaire has also requested that Prestige Brands perform a subrecall.

Altaire further advises as follows:

TO DATE ALTAIRE HAS NOT RECEIVED ANY REPORTS OF ADVERSE EVENTS FOR THE PRODUCTS.

TO DATE ALTAIRE HAS NOT OBTAINED ANY OUT OF SPECIFICATIONS RESULTS, INCLUDING STERILITY TESTING, FOR THE PRODUCTS.

This recall is being carried out to the RETAIL LEVEL and is only for the specific products/lots listed above that are currently in your inventory.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

ACTION (to be taken by Prestige Brands):

1. Stop dispensing and distributing these lots. Immediately QUARANTINE product.
2. Please perform a physical inventory (a.k.a. physical count) and record this data on the RECALL RESPONSE FORM included with this notice for each Recalled Product.
3. Complete and return the attached RECALL RESPONSE FORM for each Recalled Product **even if you do not have the recalled product in inventory.**

ALTAIRE PHARMACEUTICALS, INC.
AQUEBOGUE, NY

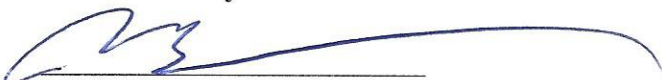
4. Altaire ships this product only to Prestige Brands. If Prestige Brands further distributed this product, please forward this notice to and conduct a subrecall with your distribution channel. This is a RETAIL LEVEL RECALL.
5. Return the recalled product and the Verification Form within 30 days to:
Altaire Pharmaceuticals, Inc.
311 West Lane
Aquebogue, NY 11931
6. Credit for returned units will be issued ONLY following confirmation of receipt, inspection, and confirmation of count of returned units, by Altaire.

OTHER INFORMATION:

1. Michael S Sawaya has been assigned Retail Coordinator. He can be reached for product questions and questions about the recall process at 631-722-5988 ext 32 or msawaya@altairephramainc.com
2. For shipping assistance please contact Joseph Sawaya at 631-722-5988 ext 16 or otcdruggist@aol.com
- 3 Adverse Reactions or quality problems experienced with the use of the products/lots identified herein may be reported to the FDA MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
 - **Online:** www.fda.gov/medwatch/report.htm
 - **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
 - **Fax:** 1-800-FDA-0178

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience cause by this action.

Authorized By:



Michael S Sawaya
General Counsel