

## COMPANY ANNOUNCEMENT

# Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Over-The-Counter Ophthalmic Products Sold By Natural Ophthalmics And TRP Company, Inc.

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

July 16, 2019

**FDA Publish Date:**

July 16, 2019

**Product Type:**

Drugs

**Reason for Announcement:**

Due to lack of sterility assurance

**Company Name:**

Altaire Pharmaceuticals, Inc.

**Brand Name:**

Natural Ophthalmics, TRP/Target Up & Up

**Product Description:**

Over-The-Counter Ophthalmic Products

## Company Announcement

Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling the Over-the-Counter (OTC) drug products and lots, within expiry, sold by Natural Ophthalmics and TRP Company, Inc. during the time period as indicated in the tables below. As a precautionary measure, Altaire is voluntarily initiating the recall due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. The

FDA has determined these issues indicate a lack of sterility assurance. Administration of a non-sterile product intended to be sterile may result in serious and potentially life threatening infections or death.

This recall is being carried out to the RETAIL LEVEL and IS ONLY FOR THE SPECIFIC LOTS LISTED BELOW. No other lots are being recalled. A Retail Level recall is limited to product lots currently in inventory of the distributors and retail outlets.

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 IN-HOUSE AND THIRD PARTY STERILITY TESTING, FOR THE PRODUCTS.

### NATURAL OPHTHALMICS

Product Description: Natural Ophthalmics Ortho-K Thick Comfort Gel

NDC#: 68770-143-15 Product Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17210      | 7/19            | 9/13/2017                      |
| 17378      | 12/19           | 2/12/2018                      |
| 18175      | 7/20            | 8/23/2018                      |

Product Description: Natural Ophthalmics Women's Tear Stimulation Dry Eye Drops

NDC#: 68770-103-15 Product Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17281      | 9/19            | 11/28/2017                     |
| 18120      | 5/20            | 6/25/2018                      |

Product Description: Natural Ophthalmics Ortho-K Thin Eye Drops

NDC#: 68770-144-15 Product Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17375      | 12/19           | 2/12/2018                      |
| 17376      | 12/19           | 2/13/2018                      |

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 18190      | 7/20            | 8/23/2018                      |
| 18191      | 8/20            | 8/23/2018                      |

Product Description: Natural Ophthalmics Tear Stimulation Forte Dry Eye Drops

NDC#: 68770-104-15 Product Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17374      | 12/19           | 2/12/2018                      |
| 18196      | 8/20            | 9/20/2018                      |

Product Description: Natural Ophthalmics Cataract Eye Drops with Cineraria

NDC#: 68770-130-15 Product Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17282      | 9/19            | 11/15/2017                     |
| 18121      | 5/20            | 6/25/2018                      |

Product Description: Natural Ophthalmics Allergy Desensitization Eye Drops

NDC#: 68770-120-15 Product Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 18114      | 5/20            | 5/18/2018                      |

### TRP

Product Description: TRP/ TARGET up & up intensive relief lubricating eye drop

Item#: 31012 Product Size: 10 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17290      | 9/19            | 11/2/2017                      |
| 18052      | 2/20            | 4/20/2018                      |

Product Description: TRP Blur Relief

NDC#: 17312-002-11 Product Size: 15 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 16256      | 09/19           | 11/16/2016                     |
| 17194      | 7/20            | 8/3/2017                       |

Product Description: TRP Styte Relief

NDC#: 17312-014-13 Product Size: 4 g

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| RHP        | 8/19            | 10/13/2017                     |
| RLD        | 12/19           | 1/26/2018                      |
| SDE        | 4/20            | 5/14/2018                      |
| SID        | 9/20            | 11/6/2018                      |

Product Description: TRP Pink Eye Relief

NDC#: 17312-013-15 Product Size: 10 mL

| Lot Number | Expiration Date | Manufacturer Initial Ship Date |
|------------|-----------------|--------------------------------|
| 17185      | 6/20            | 7/31/2017                      |
| 17228      | 7/20            | 10/23/2017                     |
| 17349      | 11/20           | 12/19/2017                     |
| 18073      | 3/21            | 5/23/2018                      |
| 18218      | 8/21            | 10/9/2018                      |
| 18303      | 12/21           | 1/21/2019                      |

The above products are labeled exclusively for Natural Ophthalmics and TRP Company, Inc. Altaire ships the products labeled for Natural Ophthalmics and TRP Company, Inc. only to Natural Ophthalmics and TRP Company, Inc., respectively. The products are distributed at the retail level.

Altaire has notified Natural Ophthalmics and TRP Company, Inc. by e-mail on July 16, 2019 announcing the recalls of the products/lots identified herein, with specific directions for return of all units of the impacted lots.

Any questions regarding this VOLUNTARY RECALL to the RETAIL LEVEL can be directed to Altaire Pharmaceuticals Inc., by calling 1-800-258-2471, or e-mailing [otcdruggist@aol.com](mailto:otcdruggist@aol.com) (<mailto:otcdruggist@aol.com>) Monday thru Friday from 8:30 a.m. to 5:00 p.m. ET.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/forms-reporting-fda>) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

Altaire takes its mission of customer safety and providing quality products very seriously. The company is committed to, and diligently working to, ensure the sufficiency of Quality Assurance controls over critical systems in its manufacturing facility.

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## Company Contact Information

### Consumers:

Altaire Pharmaceuticals Inc.



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