MCKESSON

URGENT DRUG RECALL

July 23, 2019

Dear Valued McKesson Customer:

Altaire Pharmaceuticals has notified McKesson Medical-Surgical (MMS) of an Urgent Drug Recall regarding specific lots of their Eye Wash. This notice has been issued due to management concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility. Affected product first shipped April 18, 2017.

This Urgent Drug Recall is being done with the knowledge of the U.S. Food and Drug Administration.

For clinical inquiries, please contact Altaire Pharmaceuticals at **(631) 722-5988**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table below for a list of affected item(s) and lot number(s) distributed by McKesson Medical-Surgical

MMS #	NDC #	MFG Catalog #	Description	Affected Lot(s)	Exp. Date
1113446 733243	59390-0175-18	175-18	EYE WASH, IRR 1OZ (144/CS)	17200 17322 18026 18100 18236 19052	7/31/2019 10/31/2020 1/31/2021 4/30/2021 9/30/2021 2/28/2022
1113227 714325	59390-0175-35	175-35	EYE WASH, IRRIGATING 4OZ (36 CS)	17087 17088 17109 17110 17306 17307 17318 17323 18014 18045 18059 18063 18117 18134 18228 18261 19119	3/31/2020 3/31/2020 4/30/2020 4/30/2020 10/31/2020 10/31/2020 10/31/2020 10/31/2020 1/31/2021 2/28/2021 3/31/2021 3/31/2021 5/31/2021 5/31/2021 9/30/2021 10/31/2021 4/30/2022

McKesson Customer Instructions:

1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in the item table.

2.) A copy of the Urgent Drug Recall from Altaire Pharmaceuticals has been included for reference.

3.) If you have no products matching the affected item(s) and lot number(s), no further action is needed.

4.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at mmsrecalls@mckesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
   - **Please note**: Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.

5.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this notification and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at mmsrecalls@mckesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical, Inc.

McKesson Medical-Surgical
Drug Recall Reply Form: RC-2019-170
Altaire Pharmaceuticals Eye Wash

July 23, 2019

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at **(866) 871-0270** should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____ Ship to Acct Number: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account Name: _____

Address: _____

City, State Zip: _____

☐ I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Qty	Unit of Measure	MMS #	NDC #	MFG Catalog #	Description
		1113227	59390-0175-35	175-35	EYE WASH, IRRIGATING 4OZ (36 CS)
		714325	59390-0175-35	175-35	EYE WASH, IRRIGATING 4OZ
		1113446	59390-0175-18	175-18	EYE WASH, IRR 1OZ (144/CS)
		733243	59390-0175-18	175-18	EYE WASH, IRR 1OZ BT

*Return Affected lot numbers only

*** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected lot numbers are listed on the McKesson customer letter.**

If you are on a McKesson truck route, a delivery professional will pick up the affected products, otherwise you will receive UPS return label(s) via email or fax.

☐ I am on a McKesson truck route, please schedule a delivery professional pick up.

☐ Please send my UPS/Return label by ☐ **Fax** or ☐ **Email**. Number of UPS Parcels to be returned: _____

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

ALTAIRE PHARMACEUTICALS, INC.
AQUEBOGUE, NY

URGENT: DRUG RECALL NOTICE

July 15, 2019

Via E-mail: Christine.dixon@mckesson.com

McKesson Medical-Surgical
4345 Southpoint Blvd
Jacksonville, FL 32216
Attention: Christine Dixon, Category Manager

Dear Ms. Dixon:

Please allow this communication to inform you of a recall involving the over-the-counter (OTC) drug products as identified below:

Eye Wash 1oz NDC # 59390-175-18 Formula # A0013

Eye Wash 4oz NDC # 59390-175-35 Formula # A0013

Please reference the tables below for identification of impacted drug product lots and distribution dates:

Product Description: Altaire Eye Wash
NDC#: 59390-175-18 Product Size: 1 Fl. Oz.

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17200	7/19	7/28/2017
17322	10/20	11/27/2017
18026	1/21	3/5/2018
18100	4/21	6/18/2018
18236	9/21	11/1/2018
19052	2/22	3/22/2019

ALTAIRE PHARMACEUTICALS, INC.
AQUEBOGUE, NY

Product Description: Altaire Eye Wash
NDC#: 59390-175-35 Product Size: 4 Fl. Oz.

Lot Number	Expiration Date	Manufacturer Initial Ship Date
17087	3/20	4/18/2017
17088	3/20	4/28/2017
17109	4/20	5/15/2017
17110	4/20	6/12/2017
17306	10/20	11/1/2017
17307	10/20	11/3/2017
17318	10/20	12/21/2017
17323	10/20	1/30/2018
18014	1/21	4/10/2018
18045	2/21	4/16/2018
18059	3/21	2/2/2018
18063	3/21	4/18/2018
18117	5/21	6/14/2018
18134	5/21	8/24/2018
18228	9/21	11/2/2018
18261	10/21	1/8/2019
19119	4/22	6/3/2019

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.

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 SPECIFICATION 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 McKesson Medical-Surgical.):

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~~**.

4. ~~Altaire ships this product directly to McKesson Medical-Surgical. If McKesson Medical-Surgical further distributed this product, please forward this notice to and conduct a sub-recall with your customers.~~ 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 Extension 32 or msawaya@altairephramainc.com

2. For shipping assistance please contact Joseph Sawaya at 631-722-5988 Extension 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

July 15, 2019