



August 24, 2018

## **URGENT DRUG RECALL**

Tiffany Brown  
Smith Drug  
[tbrown@smithdrug.com](mailto:tbrown@smithdrug.com)

Dear Customer,

This is to inform you of Product Quest Manufacturing LLC (PQ) recall expansion involving:

All lots within expiry of nasal products

As you may be aware, PQ recently notified FDA of the company's decision to conduct a voluntary recall of certain lots of OTC drug products due to out-of-specification results relating to either microbial contamination or product stability. In response, FDA requested that PQ consider expanding the scope of its recall. After examining the potential risks associated with PQ products currently on the market, PQ notified FDA that the company will expand the scope of the voluntary recall to include all lots of nasal products and a baby oral gel product manufactured at its Florida facility. There is no known microbial contamination associated with the nasal products and baby oral gels that are the subject of this expanded recall. PQ is simply acting out of an abundance of caution. Repetitive use of a nasal spray or other nasal product containing a gram-negative pathogen can potentially lead to colonization and subsequent infection which can be life threatening in certain patient populations, such as those with cystic fibrosis or immune-compromised individuals.

We are contacting you because, based on our shipping records, you received nasal products that are within marketed expiry (See Table 1).

We recommend that you immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

In order to establish a chain of custody for the returned product, please provide the quantity of the product to be returned, the method by which the product will be returned, and the date of shipment. Please return the product to the following address:



PQ LLC

540 Carswell Avenue

Holly Hills, FL 32117

This recall should be carried out to the retail level. Your assistance is appreciated and necessary to prevent consumer harm.

Please complete and return the enclosed response form as soon as possible. If you have any questions, call Kathryn Weingart at 704-939-4342.

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

Sincerely,

*Kathryn Weingart*

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Kathryn Weingart  
Vice President Quality & Regulatory Affairs

Encl:  
Recall Response Form  
Table 1, Nasal Product Within Expiration



## RECALL RESPONSE FORM

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the [date of] letter.
- I have checked my stock and have quarantined inventory consisting of [ ] units or cases.
- Indicate disposition of recalled product:
  - returned (specify quantity, date and method)/held for return;
  - destroyed (specify quantity, date and method);
  - relabeled (specify quantity and date);
  - quarantined pending correction (**specify quantity**);
  - transfused - Blood or blood products (**specify quantity and date**);
  - implanted (specify quantity and date)

Attached is a list of customers who received/ may have received this product. Please notify my customers.

Any adverse events associated with recalled/failed product? Yes  No

If yes, please explain: \_\_\_\_\_

I have checked my stock and have performed the appropriate method of disposition to the inventory consisting of \_\_\_\_\_ [units, cases, etc.].

Please check the appropriate box(es) to describe the nature of your business:

- |   |  |
|---|--|
| <input type="checkbox"/> Wholesaler/distributor         | <input type="checkbox"/> Food service/restaurant   |
| <input type="checkbox"/> Grocery corporate headquarters | <input type="checkbox"/> Manufacturer              |
| <input type="checkbox"/> Repacker                       | <input type="checkbox"/> Hospital/Medical facility |
| <input type="checkbox"/> Pharmacy-retail                | <input type="checkbox"/> Medical laboratory        |
| <input type="checkbox"/> Hospital pharmacies            |  |
| <input type="checkbox"/> Retailer                       |  |
| <input type="checkbox"/> Other: _____                   |  |

Name/Title	
Telephone	
Email address	



Firm Name	
Address	
City/State	

PLEASE FAX COMPLETED RESPONSE FORM TO Tel. # 386-239-8393, ATTN:  
PQ SITE MANAGER OR MAIL TO:

PQ LLC  
330 Carswell Ave.  
Daytona Beach, FL  
32117

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Table 1. Nasal Product within Expiration

Lot Code	Sum of Units Shipped	Expiration Date	Product Description
SCH-HMIST-00	108		HUMIST SALINE NASAL MIST 1.5oz ( 45ml )
162956H	36	8/25/2019	HUMIST SALINE NASAL MIST 1.5oz ( 45ml )
SCH-RHI30-00	72		RHINAL DROPS 1OZ (30 ml) 302747525311
160653B	72	3/8/2019	RHINAL DROPS 1OZ(30 ML)