



Product Quest Manufacturing LLC Recalls All Nasal Products and Baby Oral Gels Manufactured at Florida Facility Due to Possible Microbial Contamination

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AUDIENCE: Pharmacy, Patient

ISSUE: Product Quest Manufacturing (“Product Quest”) announced its voluntary recall of Lot# 173089J of CVS Health 12 Hour Sinus Relief Nasal Mist due to a finding of microbial contamination identified as *Pseudomonas aeruginosa*. Out of an abundance of caution, Product Quest has decided to expand the recall to include all lots of nasal products and baby oral gels currently within expiration that were manufactured at the company’s 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. This recall should be carried out to the retail level.

BACKGROUND: Risk Statement: 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. Similarly, repetitive use of an oral gel product containing a pathogen can potentially lead to colonization and subsequent infection which can be life threatening in certain patient populations, including babies or very young children. To the best of Product Quest’s knowledge, the company has not received any reports of adverse events related to this recall to date.

The additional nasal and baby oral gel products included as part of this expanded recall are listed below in [Attachment A](#). The products can be identified by checking the item code, product description, lot #, and expiration date, as listed below in [Attachment A](#).

RECOMMENDATION: Product Quest is notifying its customers by oral and written communication and is arranging for return/replacement etc. of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop using the product and return it to the place of purchase.

Consumers with questions regarding this recall can contact **Product Quest Manufacturing LLC at 704-939-4342, Monday through Friday from 8 am to 4 pm, EST.** Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

Adverse reactions or quality problems experienced with the use of these products 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: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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.

[Attachment A](#)

Read the safety alert: [FDA Link](#)