COMPANY ANNOUNCEMENT

NDAL MFG INC Issues Voluntary Nationwide Recall of ManukaGuard Allercleanse Nasal Spray Due to Contamination with Yeast

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:

February 10, 2021

FDA Publish Date:

February 10, 2021

Reason for Announcement:

Due to Yeast Contamination

Company Name:

NDAL MFG INC

Brand Name:

ManukaGuard

Product Description:

Allercleanse Nasal Spray

Company Announcement

NDAL MFG INC is voluntarily recalling one lot of Manukaguard Allercleanse, nasal spray to the consumer level. The Allercleanse nasal sprays have been found to be contaminated with yeast.

Risk Statement: The use of Allercleanse (manuka honey) nasal spray contaminated with yeasts, in the population most likely to use it (children, adults, and elderly), may result in adverse events that necessitate medical or surgical intervention. However, use of this

contaminated product in immunosuppressed individuals may result in life threatening invasive fungal infections. NDAL MFG INC has not received any reports of adverse events related to this recall.

The product is used as a NASAL SPRAY to clean nasal passages and sinuses of irritants and other environmental contaminants and is packaged in cardboard box with one nasal spray per box UPC 858631002128. The affected Allercleanse lot is lot # 2010045 and BB 10/2023 expiration date. Product was distributed Nationwide in the USA to 1 e-commerce website amazon.com, distributors and retail stores.

NDAL MFG INC has notified its distributors and customers by e-mail followed by telephone and further email and has arranged for return/replacement etc. of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop using/return to place of purchase/discard/contact their doctor, etc., if they have not already done so.

Consumers with questions regarding this recall can contact NDAL MFG INC by phone 1-800-916-1220 or e-mail address SUPPORT@MANUKAGUARD.COM (mailto:SUPPORT@MANUKAGUARD.COM), M-F 7:30 am to 4 pm PST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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/medwatch-forms-fda-safety-reporting) 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.

Company Contact Information

Consumers:

NDAL MFG INC

-800-916-1220

SUPPORT@MANUKAGUARD.COM (mailto:SUPPORT@MANUKAGUARD.COM)

Media:

GAVIN GEAR

1-800-916-1220

Product Photos

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