COMPANY ANNOUNCEMENT

Green Pharmaceuticals Inc Issues Voluntary Nationwide Recall of SnoreStop NasoSpray Due to Microbial Contamination

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:

June 09, 2022

FDA Publish Date:

June 09, 2022

Product Type:

Drugs

Reason for Announcement:

Due to microbial contamination identified as Providencia rettgeri.

Company Name:

Green Pharmaceuticals Inc

Brand Name:

SnoreStop

Product Description:

Nasal spray

Company Announcement

FOR IMMEDIATE RELEASE – June 09, 2022 **–** Camarillo, California, Green Pharmaceuticals Inc is voluntarily recalling lot 2373/21222 of SnoreStop NasoSpray, packaged in 0.3 FL OZ (9ml) bottles to the consumer level. FDA testing found product to contain microbial contamination identified as *Providencia rettgeri*.

This microorganism is rarely associated with human illness; however, in immunocompromised patients, the use of the recalled product could potentially result in severe or life-threatening adverse events such as bacteremia/sepsis, pneumonia, invasive fungal rhinosinusitis, or disseminated fungal infection. In non-immunocompromised patients, the use of the recalled product may result in infectious complications that are expected to be less severe and more readily responsive to treatment. To date, Green Pharmaceuticals Inc has not received any reports of adverse events related to this recalled lot.

The product is used as a nasal spray to temporarily help stop or reduce symptoms of non-apneic snoring and is packaged in one single unit plastic bottle with a nasal pump as a delivery system. The affected SnoreStop NasoSpray lot include the following: 2372/21222 (2373 is printed on a sticker placed on the bottom of the bottle and 21222 is on a sticker placed on the outer packaging). The product can be identified by a clear transparent plastic box with the name SnoreStop NasoSpray. The product was distributed nationwide in health food stores and online.

Green Pharmaceuticals Inc is notifying its retailers and customers by email and is arranging for return and replacement of all recalled products. Consumers and retailers that have product which is being recalled should stop using and return to place of purchase.

Consumers with questions regarding this recall can contact Green Pharmaceuticals Inc by phone at 805-388- 0600 or e-mail address (mail@snorestop.com (mailto:mail@snorestop.com)), Monday through Friday, 8 AM to 5 PM Pacific Standard Time. 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:** www.fda.gov/medwatch/report.htm (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm (/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:

Green Pharmaceuticals Inc

805-388-0600

mail@snorestop.com (mailto:mail@snorestop.com)

Product Photos

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