**Company Announcement**

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.

# Centurion Labs Issues Voluntary Nationwide Recall of Ninjacof (Lot # 200N1601) and Ninjacof A (Lot# 201NA1601) Products Due to Potential *Burkholderia Cepacia* Contamination

**For Immediate Release**

August 22, 2017

**Contact**

**Consumers**

**recall@centurionlabs.com (mailto:recall@centurionlabs.com)**
(601) 852-3681

**Announcement**

**View Product Photos**

Centurion Labs is voluntarily recalling, as a precautionary measure, 1 lot of Ninjacof (Lot# 200N1601) and 1 lot of Ninjacof A (Lot# 201NA1601) manufactured by Vilvet (Dania Beach, FL) and distributed by Centurion Labs to the retail level due to potential contamination with *Burkholderia cepacia.* Centurion was notified by the FDA regarding the potential contamination as they discovered this product may have been manufactured in a Pharmatech, FDA registered facility, in Davie, FL. that was found to have a product that contained B. cepacia.

Use of a product that may contain *B. cepacia*, could result in infections in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis. Some of these infections may be serious or even life threatening in the at-risk patient population.

Ninjacof and Ninjacof A are used to temporarily relieve symptoms due to the common cold, allergic rhinitis or other respiratory allergies and the products are sold in 473 mL bottles with the expiration date of 11/2018. The affected products are Ninjacof with Lot# 200N1601 (NDC 23359-032-16) and Ninjacof A with Lot# 201NA1601 (NDC 23359-033-16) and both were distributed within the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, Missouri, Mississippi, New Jersey, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, and Texas.

Centurion Labs is notifying its distributors and customers by recall letter. To date Centurion Labs has not found any *B. cepacia* or received any complaints for the products or lots listed. However, it is recommended that patients, pharmacies, and healthcare facilities that have the recalled product on hand stop their use immediately.

Consumers with questions regarding this recall can contact the company at Centurion Customer Support: **recall@centurionlabs.com (mailto:recall@centurionlabs.com)** or 601-852-3681 (M-F 8am – 5pm Central Standard Time).

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 (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://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.

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