Indiana State Department of Health
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Mitchell E. Daniels, Jr.
*Governor*

Gregory N. Larkin, M.D., F.A.A.F.P.
*State Health Commissioner*

**DATE:** October 21, 2011

**TO:** All Local Health Departments
Attn: Chief Food Inspection Officer

**FROM:** A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

**SUBJECT:** Insight Pharmaceuticals, LLC Recall

**SUGGESTED ACTION:** **Unclassified Recall; One lot (34,092 bottles) of Nostrilla Nasal Decongestant nasal spray to the consumer level, because it may contain the bacteria *Burkholderia cepacia;* Recommend notification of affected stores via phone, fax or e-mail.**

**From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The recall was initiated following internal investigations which determined the potential presence of a microbial contaminant that exceeds the product specifications and may consequently result in a subpar product. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.**

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## Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

## Insight Pharmaceuticals Issues A Voluntary Nationwide Recall Of "Nostrilla Nasal Decongestant" Due To Bacterial Contamination

**Contact:**
Consumer:
1-877-546-9059

Media:
Robyn Ungar
610-228-2131

**FOR IMMEDIATE RELEASE** - October 19, 2011 - Insight Pharmaceuticals, LLC of Langhorne, Pa., is recalling one lot (34,092 bottles) of Nostrilla Nasal Decongestant nasal spray to the consumer level, because it may contain the bacteria *Burkholderia cepacia*.

*Burkholderia cepacia* may cause serious infection in individuals with a compromised immune system or chronic lung condition (i.e. cystic fibrosis). However, the possibility of infection is remote in healthy individuals.

Nostrilla Nasal Decongestant, lot #11G075, UPC Code 6373673005, was distributed nationwide through normal retail outlets and pharmacies. The product comes in a 1/2 ounce, plastic bottle marked with lot #11G075 on the label and with an expiration date of 05/2014 stamped on the side. No illnesses have been reported to date in connection with this problem.

The recall was initiated following internal investigations which determined the potential presence of a microbial contaminant that exceeds the product specifications and may consequently result in a subpar product. This contaminant has been found sporadically throughout only the respective manufacturing lot, #11G075.

Consumers who have purchased "Nostrilla Decongestant, lot #11G075" are urged to return the product and contact the company at 1-877-546-9059 Monday through Friday from 9 am-5 pm EST time zone. 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.

- **Online**:www.fda.gov/medwatch/report.htm[11]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[22]. Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

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

"It is our commitment to our customers to provide them with products they can rely on as safe and effective for their FDA-approved uses," says Gary R. Downing, CEO of Insight Pharmaceuticals, LLC. "Through our standard testing procedures and protocols, we discovered the potential presence of a bacterial contaminant in one lot of Nostrilla, and reported it to the FDA. Consumer safety is our #1 priority, and we'll take all necessary action to ensure Nostrilla, as well as all of our products, comply with FDA regulations and requirements.

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