



DATE: October 9, 2012
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: New England Compounding Pharmacy, Inc. Recall

SUGGESTED ACTION: Unclassified Recall; all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts due to the potential risk of contamination; Information is being sent in case of consumer inquiry.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. NECC is notifying its customers of this recall by fax. Clinics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice.

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.

**New England Compounding Center Issues
Voluntary Nationwide Recall of All Products**

FOR IMMEDIATE RELEASE – October 6, 2012 – New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (NECC) today announced a recall of all products

currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts. This action is being taken out of an abundance of caution due to the potential risk of contamination, and in cooperation with an investigation being conducted by the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention and the Massachusetts Board of Registration in Pharmacy. The FDA had previously issued guidance for medical professionals that all products distributed by NECC should be retained and secured. While there is no indication at this time of any contamination in other NECC products, this recall is being taken as a precautionary measure. Products from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo that can be accessed [here](#)¹ ². A complete list of all products subject to this recall can be accessed [here](#)³.

NECC is notifying its customers of this recall by fax. Clinics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice.

Adverse reactions or quality problems experienced with the use of any 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.htm⁴
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm⁵. 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.

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