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CDC Health Advisory

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Contamination Identified in Additional Medical Products from New England Compounding Center

Summary: As part of the ongoing investigation of the multistate outbreak of fungal meningitis and other infections, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) continue to test medical products from the New England Compounding Center (NECC) in Framingham, Mass. NECC is the firm that distributed and recalled injectable steroid medications implicated in the current outbreak of fungal meningitis and other infections. CDC and FDA are reporting today that product testing has identified bacterial contamination with several *Bacillus* species and closely related bacterial organisms in unopened vials of betamethasone and cardioplegia solution that were distributed and later recalled by NECC on October 6, 2012. These bacteria are commonly found in the environment and have been rarely reported as a cause of human disease; it is not known how product contamination with these species might affect patients. Although clinical infection is possible, CDC has not received reports of laboratory-confirmed cases of infection due to *Bacillus* or closely related organisms linked to these products. CDC's recommendations to healthcare providers for diagnosing and treating symptomatic patients who have received NECC products have not changed as a result of these findings. Additional microbial organisms may be identified in recalled NECC products as additional laboratory testing is completed.

Background

On September 26, 2012, NECC voluntarily recalled three lots of methylprednisolone acetate (PF) 80mg/ml[1] associated with the multistate outbreak of fungal meningitis and other infections. As previously confirmed by CDC and FDA, the fungus *Exserohilum rostratum* was identified from two different lots of NECC-supplied, preservative-free methylprednisolone acetate (Lot #06292012@26 and Lot #08102012@51); testing on the third implicated lot of preservative-free methylprednisolone acetate (Lot #05212012@68) is ongoing. Two types of fungus not known to be human pathogens were also identified from product from the two tested lots, namely *Rhodotorula laryngis* and *Rhizopus stolonifer*. Among these fungal organisms, only *Exserohilum rostratum* has been associated with human infections in this outbreak.

On October 6, NECC expanded its recall to include all products in circulation that were distributed from its facility in Framingham, Mass. FDA released a MedWatch Safety Alert on October 15 stating that the sterility of any injectable drugs, including ophthalmic drugs that are injectable or used in conjunction with eye surgery, and cardioplegic solutions produced by NECC is of significant concern. As part of the ongoing investigation, FDA and CDC have been testing various NECC products for evidence of contamination. Laboratory testing at CDC and FDA has found multiple species of *Bacillus* and closely related bacterial organisms in unopened vials of betamethasone and cardioplegia solution, as shown in the table below.

Medication	Lot number	Microbial contamination
Betamethasone	08202012@141	*Paenibacillus pabuli/amolyticus, Bacillus idriensis, Bacillus flexus, Bacillus simplex, Lysinibacillus sp.*
Betamethasone	07032012@22	*Bacillus niabensis, Bacillus circulans*
Betamethasone	07302012@52	*Bacillus lentus, Bacillus circulans*
Cardioplegia solution	09242012@55	*Bacillus halmapalus, Brevibacillus choshinensis*

Other cultures for these products, including fungal cultures, are pending.

Recommendations to Healthcare Providers

CDC and FDA have previously advised that healthcare professionals should cease use of any product produced by NECC. On October 15, FDA issued a MedWatch Safety Alert advising clinicians to follow-up with patients who received any injectable NECC product, including betamethasone or cardioplegia solution purchased from or distributed by NECC after May 21, 2012. Clinicians were also requested to report any suspected adverse events following use of these products to FDA's MedWatch program.

CDC continues to investigate reports of potential infections in patients receiving other NECC products. As of November 1, CDC has received no reports of confirmed infections resulting from injection of any NECC product except those from the three recalled lots of preservative-free methylprednisolone acetate.[1]

CDC's recommendations to healthcare providers for diagnosing and treating symptomatic patients who have received NECC products have not changed as a result of these findings. CDC continues to recommend routine laboratory and microbiologic tests, including bacterial and fungal cultures, deemed necessary by treating clinicians.

These bacteria have been rarely reported as a cause of human disease. Nevertheless, clinicians should consider these product findings when reviewing laboratory results from patients who have been exposed to a NECC product, since *Bacillus* and related bacteria are often considered in clinical results to be possible skin contaminants. Physicians should continue to report infections potentially related to NECC products to FDA's MedWatch and to state health departments.

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[1] NECC lots of methylprednisolone acetate (PF) 80mg/ml:

Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012
Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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