DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable John D. Dingell
House of Representatives
Washington, D.C. 20515-2215

APR 26 2013

Dear Mr. Dingell:

Thank you for your letter of October 16, 2012, concerning the fungal meningitis outbreak associated with methylprednisolone acetate, a steroid injectable product distributed by the New England Compounding Center (NECC).

We have restated your questions below in bold, followed by our responses.

1. **Please provide a complete list of the products produced at NECC, including the proprietary name, the nonproprietary name or common name, the quantity of doses produced, dosage forms, strengths, route of administration, and proposed indication for each of the products. How many of these products were prepared based on a prescription for a specific patient?**

   The list of products subject to NECC's voluntary recall is available on NECC's website, *www.neccrx.com*. Due to the ongoing criminal investigation, we are not able to provide additional information at this time.

2. **How many facilities, in how many states, have received NECC products?**

   A list that includes this information as received by FDA is available on FDA's website at *http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf.*

3. **Please provide an estimate of how many patients are at risk from infection or meningitis from the use of NECC products. How does FDA intend to notify patients that may have been treated with NECC products?**

   As part of the public health investigation, FDA has learned that approximately 14,000 patients have been exposed to methylprednisolone acetate from the suspect lots of product. CDC and the departments of health in the affected states have been working together to notify those patients who were treated with the suspect product after May 21, 2012. A notice from the Centers for Disease Control and Prevention (CDC), "Notice to Clinicians: Continued Vigilance Urged for Fungal Infections among Patients Who Received Contaminated Steroid Injections," is available on CDC's website at *http://emergency.cdc.gov/HAN/han00342.asp.* Through active notification by clinics with assistance from states and CDC in early October, nearly all of these exposed persons were contacted at least once and informed of their risk for fungal infection as a result of receiving

injections with contaminated medication. FDA has also advised health care professionals to follow up with patients who have been treated with NECC injectable products shipped after May 21, 2012.

4. **Do any of NECC's products remain on the market? If so, which products remain on the market? Of those that remain on the market, how many doses remain on the market?**

   As of October 6, 2012, all products compounded and distributed by NECC were recalled by the firm. NECC posted notice of the recall on their website, *www.neccrx.com*. As of January 30, 2013, as part of the public health investigation into the outbreak, FDA had completed 1,155 audit checks with customers who received NECC products. FDA found no unexpired product remaining for use at any of the customers and all customers had knowledge of the recall either through NECC, CDC, state health departments, the media, or other sources.

Thank you, again, for contacting us concerning this important matter. If you have further questions, please let us know.

Sincerely,

Michele Mital

Michele Mital
Acting Associate Commissioner
for Legislation