

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
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July 31, 2015

Dr. Stephen Ostroff  
Acting Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

Dear Dr. Ostroff:

Pursuant to Rules X and XI of the U.S. House of Representatives, the committee is investigating management concerns with the NIH Clinical Center Pharmaceutical Development Section (PDS), and the adequacy of FDA's oversight of the facility.

On June 4, 2015, the NIH Clinical Center suspended operations of its Pharmaceutical Development Section after the discovery of serious manufacturing problems and lack of compliance with standard operating procedures. This followed an inspection conducted by the FDA from May 19-29, 2015, which found a series of deficiencies in the PDS physical facility. In addition, two vials of albumin, used for administration of the drug interleukin in experimental studies, were found to have fungal contamination. Hundreds of participants in 46 studies were potentially affected by the contamination, and six patients were administered drugs from vials made from the contaminated batch. The severity of the deficiencies, the disruption of ongoing studies, and the resulting suspension of PDS operations raise serious questions about the management of the NIH PDS for the last several years.

The current PDS facility was opened in 2010. FDA officials have told committee staff that the NIH PDS facility was not inspected prior to May 2015. However, a May 1, 2010 article in the American Journal of Health-System Pharmacy (AJHP) quoted the NIH Clinical Center Director as saying that "the new PDS area will be fully GMP-compliant and subject to inspection by FDA."

FDA officials told committee staff that the FDA was not required to conduct a cGMP (current Good Manufacturing Practices) inspection of the NIH PDS facility in 2010 because FDA does not conduct routine inspections of facilities that manufacture or process drugs solely for use in research. Generally, FDA would not conduct routine inspections of such a facility, but

would conduct a for-cause inspection in response to a complaint, if warranted. However, this facility was making experimental drugs for FDA-regulated clinical trial research with human subjects. FDA's response raises questions about how human subjects in these clinical trials were protected without an inspection to ensure there was sufficient information to assess the risks to subjects, or if the subjects would be exposed to unreasonable and significant risk.

FDA officials also reported to committee staff that FDA staff visited the NIH PDS in 2012 to explore the possibility of a training audit at the PDS. Based on conditions observed during the visit, FDA staff prepared a draft inspection assignment, but the assignment was never finalized or issued, and no inspection of the facility was conducted.

To assist the committee's inquiry, please provide the following documents and information by August 14, 2015:

1. All documents since January 1, 2015 related to communications from NIH personnel or NIH contractors about any allegations connected to NIH PDS or any information about adverse events and/or contaminated products at NIH PDS.
2. All attachments to the FDA's May 2015 inspection of the NIH PDS.
3. All documents related to the 2012 Center for Drug Evaluation and Research (CDER) staff visit of the PDS facility, including the draft inspection assignment.

Please also respond to the following questions by August 14, 2015:

1. Did FDA have the legal authority to conduct a routine inspection of the current PDS facility before May 2015? Please provide the policy and the legal opinion related to this authority.
2. Did FDA ever conduct an inspection of the NIH PDS prior to 2010? If so, when? What were the findings?
3. Did FDA ever receive any information about adverse events or known contamination of products produced at the NIH PDS prior to April 2015? If so, when? What was the nature of the information? What was FDA's response to the allegations?
4. How many Investigational New Drug (IND) submissions using drugs made from the NIH PDS were filed with the FDA? Did any of these IND submissions make statement(s) relating to quality control, sterility, and/or cGMP-compliance? If so, please provide these IND submissions. Out of the IND submissions reviewed by FDA, how many did FDA place on clinical hold? Out of these IND submissions reviewed by FDA, for how many did FDA find evidence of inadequate quality control procedures that would compromise the safety of IND product? Out of these IND submissions reviewed by FDA, how many were found by FDA to expose human subjects to unreasonable and significant risk?

5. Why was the 2012 CDER inspection assignment not finalized or issued? Was there a decision not to inspect? If so, please provide documentation of the decision. If there was no decision, was the inspection assignment still under consideration at the time of the for-cause inspection in May 2015?

Your prompt assistance is appreciated. An attachment to this letter provides additional information on how to respond to the committee's request. If you have any questions, please contact Alan Slobodin of the majority committee staff at (202) 225-2927 and Una Lee of the minority committee staff at (202) 225-3641.

Sincerely,



Fred Upton  
Chairman



Frank Pallone, Jr.  
Ranking Member



Tim Murphy  
Chairman  
Subcommittee on Oversight  
and Investigations



Diana DeGette  
Ranking Member  
Subcommittee on Oversight  
and Investigations

Attachment