DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Michael F. Bennet
United States Senate
Washington, D.C. 20510-0609

JUN 0 9 2011

Dear Senator Bennet:

Thank you for your letter of March 31, 2011, cosigned by Senator Lamar Alexander, regarding the recall of products manufactured by H & P Industries, Inc. of Hartland, Wisconsin, due to contamination and sterilization problems in the manufacturing process. The Food and Drug Administration (FDA or the Agency) shares your concern and we are actively evaluating information received as part of our ongoing investigation of H & P Industries and its related firm, Triad Group (Triad). We would like to clarify that Triad and H & P Industries are owned and managed by the same party.

As you know, on April 4 and 5, 2011, U.S. Marshals, at FDA's request, executed a seizure of products distributed by Triad at its Hartland facility. The seized articles included a variety of finished drug products, raw materials, and in-process drug products. Through this seizure, FDA prevented the company from distributing product that was manufactured in violation of federally mandated manufacturing requirements. Seizure of drug products is an effective remedy when there is evidence of continued poor compliance with current Good Manufacturing Practice (GMP) requirements. Following a drug product seizure, companies often agree to a wide range of changes and improvements to the drug manufacturing practices at their facilities. Shortly before the seizure, FDA took the unusual step of asking the company to cease manufacturing drug products. On April 18, 2011, Triad notified FDA that it had voluntarily ceased all manufacturing and distribution operations.

FDA based its request for the seizure on Triad's continued failure to comply with FDA's GMP regulations, which are intended to ensure the safety, quality, and purity of manufactured drugs; escalated oversight of the Hartland facility, including two inspections within two years and a regulatory meeting with Triad in August 2010 to discuss the firm's ongoing corrective actions. Regulatory meetings with companies are used in exceptional cases where FDA management, at its discretion, believes it would be beneficial to meet with responsible individuals or firms to communicate how one or more products, practices, processes, or other activities are considered to be in violation of the law.

FDA's review of Triad continues, but, as you note in your letter, there have already been several product recalls, numerous press releases, and updates to FDA's Internet page in an effort to remove potentially unsafe products from the market and inform consumers and health care professionals.

We have also initiated an internal retrospective review of Triad's compliance history and the adequacy of FDA's oversight of the company, consistent with our mission to ensure the safety of all medical products. We have concluded that FDA's decision to hold a regulatory meeting with Triad's management to discuss the inspection findings/corrective actions associated with the 2010 inspection should have been augmented with a formal Warning Letter to reinforce FDA concerns about the GMP deviations.

In addition, we are in contact with your staff to schedule a briefing to further discuss this matter.

Thank you again for contacting us concerning this matter. Please let us know if you have any further questions. The same letter has been sent to Senator Alexander.

Sincerely,

Jeanne Ireland

Jeanne Ireland
Assistant Commissioner
for Legislation