DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

November 10, 2011

**VIA CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Eric C. Haertle
President
H&P Industries, Inc.
700 West North Shore Drive
Hartland, Wisconsin 53029

Re: United States of America v. 169/50kg drums. . . et. al., (E. D. Wis.), Civil No. 2:11-cv-00319-AEG

Dear Mr. Haertle:

On October 5, 2011, FDA received via UPS your "Revised Reconditioning Plan for Condemned Ingredient Materials and Destruction of Finished Goods and Materials" ("second revised reconditioning plan"). The second revised reconditioning plan was submitted under Paragraph 8 of the Consent Decree of Condemnation, Forfeiture, and Permanent Injunction entered in the Eastern District of Wisconsin on June 13, 2011. The second revised reconditioning plan replaces a "Revised Remediation Plan for Finished Product and Condemned Ingredient Materials" dated August 19, 2011, that was previously reviewed by FDA and the subject of FDA's letter to you dated September 26, 2011.

Pursuant to Paragraphs 3 and 4 of the Decree, all articles seized by the United States on April 4 and 5, 2011, are adulterated and condemned by virtue of the CGMP deficiencies documented during FDA's inspections of the H&P Industries facility. Paragraph 8 of the Decree permits claimants to submit an initial reconditioning plan, subject to FDA approval, to bring the condemned articles into compliance. Paragraph 8 also permits claimants to submit for FDA review a revised reconditioning plan for condemned articles for which the initial plan was unacceptable, and provides for destruction under Paragraph 15 condemned articles for which FDA determines the revised reconditioning plan is unacceptable.

FDA has reviewed your second revised reconditioning plan and determined that limited deficiencies still remain. With respect to unopened chemical raw materials, reconditioning may be appropriate if additional information and clarification is provided, but we disagree with your definition of "unopened." With respect to finished goods, open in-process finished goods, in-process materials in tanks and drums, opened raw chemicals, expired and rejected raw chemicals, and opened components, destruction is necessary and appropriate. However, the destruction

procedure outlined in the second revised reconditioning plan needs additional information and clarification.

**Proposed Reconditioning of Chemical Raw Materials**

Although unopened, unexpired chemical raw materials may be suitable for return to the vendor, or qualified for use in future manufacturing, your second revised reconditioning plan is not yet acceptable and needs to address the following issues and comments:

1. We disagree with your inclusion of chemicals ". . . *appropriately sampled for release testing. . .* " in your definition of "unopened." The second revised reconditioning plan does not contain evidence that your sampling technique has not contaminated the contents of the container. In the absence of such evidence, your second revised reconditioning plan should provide for the destruction of raw chemical ingredients that have been opened for sampling.

2. Items 6 and 7 in checklist HP-001-A5 reference (b) (4)
(b) (4)

3. Item 8 in checklist HP-001-A5 queries whether the (b) (4)
(b) (4)

4. Item 11.a. in checklist HP-001-A5 queries whether (b) (4)
(b) (4)

5. The instructional paragraph after item 12 in checklist HP-001-A5 references the (b) (4)
(b) (4)

6. Item 2.a. in checklist HP-001-A6, used for (b) (4)
(b) (4)

7. Page 3 of your second revised reconditioning plan states in several places that FDA will issue final "review and approval" with respect to particular articles released for reconditioning. While FDA may review whether you follow your procedure, or may, at its discretion during supervision of reconditioning, deem a chemical unsuitable for use, FDA will not "approve" such use. If reconditioning is deemed acceptable, your firm is responsible for final review and approval of whether a chemical is suited for return to the vendor or reserved for use in future manufacturing, and your firm assumes all liability for such products.

**Materials Designated for Destruction**

FDA concurs with your decision to destroy all condemned finished goods, open in-process finished goods, in process materials in tanks and drums, opened raw chemicals, expired raw chemicals, and opened components. Although you have made progress with the destruction component of your second revised reconditioning plan, the plan still requires some additional information and detail before it can be approved.

8. The second revised reconditioning plan describes a waste profile that will be used to determine the destination and method for destruction of the material. You state that you have provided to (b) (4) and to (b) (4) (b) (4) An approvable plan, however, needs all of the waste profiles determined and completed.

9. The second revised reconditioning plan describes that (b) (4) (b) (4) (b) (4) While FDA may, during supervision of the destruction, periodically audit the loading of a trailer, your firm is responsible for verifying the inventory of material loaded onto each trailer.

10. The second revised reconditioning plan describes a process for (b) (4) (b) (4) (b) (4) The plan, however, does not explain the steps you will take if the seal numbers do not match, or the seal is broken.

11. The plan does not describe whether you notified the (b) (4) (b) (4)

We look forward to receiving and reviewing a revised version of your second revised reconditioning plan. If you have questions about this letter, please respond to Dr. Brian D. Garthwaite, Compliance Officer, directly at (612) 758-7132.

Sincerely,

Elizabeth R Waltip

for Gerald J. Berg
Director
Minneapolis District

GJB/ccl

xc:

David L. Rosen, Esq.
Foley & Lardner LLP
3000 K Street N.W.
Suite 600
Washington, DC 20007-5109

Max B. Chester, Esq.
Foley & Lardner LLP
777 East Wisconsin Avenue
Milwaukee, WI 53202-5306

Scott Campbell
Assistant United States Attorney
517 East Wisconsin Avenue
Suite 530
Milwaukee, WI 53202

Timothy Finley
Trial Attorney
Office of Consumer Protection
Litigation
Department of Justice
Civil Division
P.O. Box 386
Washington, DC 20044

Michael Shane
Associate Chief Counsel
U.S. Department of Health and Human Services
Office of the General Counsel
White Oak 31 Room 4554
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002