DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
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Telephone: (612) 334-4100
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December 14, 2011

Via CERTIFIED MAIL and e-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 November 25, 2011, FDA received via UPS your "Revised Reconditioning Plan for Condemned Ingredient Materials and Destruction of Finished Goods and Materials" ("third revised reconditioning plan") dated November 23, 2011. The third 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 "Decree"). The third revised reconditioning plan replaces a "Revised Reconditioning Plan for Condemned Ingredient Materials and Destruction of Finished Goods and Materials" dated October 4, 2011, that was the subject of FDA's letter to you dated November 10, 2011, and discussed with you during a meeting with FDA on November 21, 2011.

On December 1, 2011, Dr. Garthwaite from our office and Ms. Stray from your firm discussed deficiencies and items needing clarification in your third revised reconditioning plan. On December 5, 2011, FDA received via UPS Ms. Stray's letter dated December 2, 2011, which provided additional clarification with respect to the third revised reconditioning plan and contained revised Appendices III-VII and IX. On December 7, 2011, Dr. Garthwaite and Ms. Stray discussed your proposed disposition of [(b)(4)] totes of [b(4)] solution, some of which you proposed to recondition by return to the vendor, and some of which you designated for destruction by incineration. On December 8, 2011, Ms. Stray informed Dr. Garthwaite by voicemail that all [b(4] totes of [b(4)] solution, including the containers, will be destroyed. FDA concurs with your decision to destroy the [(b)(4)] totes of [b(4)] solution and containers.

FDA has reviewed your third revised reconditioning plan and the materials dated December 2, 2011, and has determined that the procedures described therein are acceptable and satisfy the requirements of Paragraph 8 of the Decree. Therefore, your third revised reconditioning plan as clarified and amended in your letter dated

December 2, 2011, is approved.

We remind you, however, that FDA's approval of your third revised reconditioning plan does not authorize release of the condemned articles, which remain in the custody of the United States Marshal. Pursuant to paragraph 9 of the Decree, the United States Marshal, after receiving notice from the United States Attorney or FDA, shall release the condemned articles from his custody to the custody of the Claimants for the sole purpose of attempting to bring the condemned articles into compliance with the law in accordance with the reconditioning proposal. FDA is coordinating the release of the condemned articles with the United States Attorney and the United States Marshal.

Furthermore, pursuant to paragraph 10 of the Decree, until the condemned articles have been released in writing by an FDA representative, you shall retain the condemned articles intact for examination and inspection by the FDA representative. Under paragraph 10 of the Decree, FDA will issue to you a separate letter that releases the condemned articles to you for purposes of reconditioning and destruction as outlined in the approved, third revised reconditioning plan, as amended in your December 2, 2011, submission. Until such time as you receive the written notification of release from FDA, the condemned articles are not released for reconditioning and destruction.

Finally, nothing in this letter in any way vitiates any of the other requirements of the Decree, including, but not limited to, the injunctive provisions set forth in paragraphs 19(A)-(J).

Dr. Garthwaite will work with you to coordinate the scheduling of FDA's supervision of the reconditioning and destruction of condemned articles. If you have questions about this letter, please respond to Dr. Garthwaite directly at (612) 758-7132.

Sincerely,

Elizabeth Waltrip

Elizabeth A. Waltrip
Acting Director
Minneapolis District

BDG/ccl

xc:

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