DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 26, 2011

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 August 23, 2011, FDA received via UPS your "Revised Remediation Plan for Finished Product and Condemned Ingredient Materials" ("revised reconditioning plan"). The 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 revised reconditioning plan replaced a "Remediation Plan for Finished Product and Condemned Ingredient Materials" that you submitted on June 16, 2011, supplemented on July 29, 2011, and which was the subject of a July 29, 2011, conference call between representatives of H&P Industries, Inc., and FDA.

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, including recurring process deviations, lack of process controls, incomplete process validation, inadequate handling of out-of-specification test results, insufficient environmental monitoring, and the failure to have and to follow a written stability plan.

Although the Decree permits the defendants to submit for FDA review a reconditioning plan with respect to the condemned articles, Paragraph 8 of the Decree clarifies that the reconditioning proposal must include an acceptable plan for bringing the condemned articles into compliance with the law, and must specifically identify which corrective measures apply to which condemned articles. As we discussed during our conference call on July 29, 2011, to bring the condemned into compliance with the law, the process in your revised reconditioning plan must establish when implemented that the condemned articles will no longer be adulterated.

FDA has reviewed your revised reconditioning plan and determined that it is not approvable as submitted. With respect to chemical raw materials, we believe that reconditioning may be appropriate if additional information and clarification is provided.

With respect to finished and in-process products, however, FDA has determined that your revised reconditioning plan is not approvable because it does not ensure that the condemned articles comply with the law.

Proposed Reconditioning of Chemical Raw Materials

FDA agrees in principle that unopened, unexpired chemical raw materials may be suitable for return to the vendor, or qualified for use in manufacturing, as identified in Appendix VI of your revised reconditioning proposal. However, FDA requires additional information and clarification before it can determine whether to approve your proposal to recondition these condemned articles.

1. Your revised reconditioning plan states that "*material to be returned to vendors will undergo a limited review, to include* b(4) [redacted] b(4) [redacted] The revised plan, however, does not set out a procedure for this limited review.

2. Your revised reconditioning plan references a two-step process for qualification of unopened containers for use by H&P Industries in future manufacturing. The first step involves a review of b(4) [redacted] b(4) [redacted] and FDA 483 observations that pertain to the material being evaluated. Although you indicate that a checklist (HP-001-A2) will be used in the evaluation process, neither the checklist nor your reconditioning plan explain what will disqualify an article. For example, if the checklist shows that a condemned article lacks a certificate of analysis, it should be clear that the article is not eligible for reconditioning. Moreover, to the extent the checklist contains language specific to opened raw materials, such provisions are unnecessary since the reconditioning proposal only applies to unopened raw materials.

   The "second step" referenced in your reconditioning plan describes additional testing that will be performed on unopened chemical raw materials. This additional testing, however, appears to take place after H&P resumes manufacturing. Because manufacturing will not be permitted until other requirements of the Decree are satisfied, including the injunctive provisions set forth in Paragraph 19 of the Decree, the subsequent testing described in your second step should not be a component of your revised reconditioning plan. Rather, such testing should be incorporated into your manufacturing processes, which FDA will be reviewing in accordance with Paragraph 19 of the Decree.

These deficiencies must be corrected if you choose to submit a revised reconditioning proposal for chemical raw materials that you intend to return to vendors or intend to use in future manufacturing.

Proposed Reconditioning of Finished Products and In-Process Materials

Upon reviewing your proposal for reconditioning condemned finished products and in-process materials, FDA has concluded that even if you evaluated these products as described in your revised reconditioning plan, they still would be adulterated.

Specifically, the process outlined in your revised reconditioning plan will not bring the violative articles into compliance with the law.

Your revised reconditioning plan, which is limited to condemned articles manufactured in February and March, 2011, references many operational SOPs and quality system improvements that you have implemented subsequent to recent FDA inspections. Although these are important and related to your compliance with CGMP, you do not have sufficient supporting evidence that these changes to the SOPs and quality system improvements corrected the underlying CGMP violations that caused the drug products you manufactured to be adulterated. The persistent CGMP violations observed included those documented and cited on the Form FDA 483 which FDA issued at the close of the March 21 to 28, 2011, inspection, shortly before the condemned articles were seized.

Because the retrospective review of records described in your reconditioning proposal does not mitigate the environmental, procedural, and equipment deficiencies that caused your drug products to be adulterated during their manufacture, and your revised reconditioning plan does not vitiate that adulteration, FDA disapproves your revised reconditioning plan to the extent the plan seeks to recondition finished products and in-process material.

Products Designated for Destruction

As mentioned during the July 29, 2011, conference call, it is important for H&P Industries to have in place a detailed plan for the destruction of condemned articles. Your revised reconditioning plan identifies (b) (4) (b) (4) as the firm you intend to use for managing the destruction. The proposal, however, does not describe how you plan to coordinate the destruction with (b) (4) (b) (4) Nor does it contain details about the final disposition of the articles to be destroyed. FDA expects you to have the coordinated plan ready for implementation upon release of the condemned articles scheduled for destruction. Even though the date of release is unknown at this time, this does not preclude you from having a final plan ready to implement.

If you have questions about this letter, please respond to Dr. Brian D. Garthwaite, Compliance Officer, directly at (612) 758-7132 or to Dr. Garthwaite through your Counsel.

Sincerely,

Gerald J. Berg
Director
Minneapolis District

GJB/rfk

xc:

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