



**VIA UNITED PARCEL SERVICE AND
ELECTRONIC MAIL**

December 2, 2011

Brian D. Garthwaite
Compliance Officer, Minneapolis District Office
Food and Drug Administration
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401

RE: CONSENT DECREE CORRESPONDENCE

**REVISED RECONDITIONING PLAN FOR CONDEMNED INGREDIENT
MATERIALS AND DESTRUCTION OF FINISHED GOODS AND MATERIALS**

Dear Dr. Garthwaite:

This amendment is in response to the H&P Industries, Inc. (H&P Industries) Revised Reconditioning Plan submitted on November 23, 2011 and our telephone conversation on December 1, 2011.

H&P Industries is providing clarification and additional information regarding the specific items described below.

1. Per our telephone conversation on December 1, 2011, (b) (4) will begin the review process for Unopened Chemicals to Recondition using checklist HP-001-A5 (Unopened Chemical Checklist to Recondition), and for Unopened Chemicals for Return to Vendor using checklist HP-001-A6 (Unopened Chemical Checklist for Return to Vendor) prior to receiving approval from the agency on the Revised Reconditioning Plan. (b) (4) will begin the review process the week of December 5, 2011. We expect all paperwork for both chemicals to be reconditioned and chemicals to be returned to the vendor be completed on or before December 14, 2011.

2. H&P Industries understands the approval of the Revised Reconditioning Plan does not grant permission or approval to use unopened raw chemicals for future use in manufacturing. The unopened raw chemical containers will be qualified per SOP-QA-010 (*Supplier Qualification and Management Program*) as described in H&P Industries' Work Plan.
3. Raw chemical materials not accepted by a vendor for return will be destroyed during reconditioning per SOP-QA-017 (*Notice of Destruction Procedure*).
4. If a vendor accepts and receives an unopened chemical raw material and later decides to return the material due to shipping damage, changed interest in acceptance, etc., H&P Industries will not accept the material for future use and will destroy the material per SOP-QA-017 (*Notice of Destruction Procedure*).
5. H&P Industries has clarified the statement "Once all lots of chemicals to be reconditioned have been reviewed by (b) (4) moved to quarantine, or designated to be returned to the vendor, the reconditioning of the chemicals will be complete."

H&P Industries expects to have all materials proposed for return to vendors shipped on or before December 31, 2011. If a vendor has not communicated a response regarding acceptance of chemicals to be returned, the chemicals will be destroyed per SOP-QA-017 (*Notice of Destruction Procedure*).

Upon further review, (b) (4) teams are not necessary for the destruction of finished goods. Team (b) (4) which was previously assigned as a finished goods team has been reallocated to Team (b) (4) to provide additional support for the return to vendor process. The plan has been revised from (b) (4) teams to (b) (4) teams total.

Team	Staffing	Priority

6. Based on discussions with (b) (4) H&P Industries expects the destruction paperwork will be received one week after each truck leaves H&P

Industries' facility. Both (b) (4) understand the urgency in forwarding the required paperwork to H&P Industries and have communicated their willingness to cooperate.

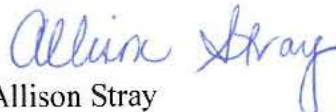
7. The statement "(b) (4)" has been removed from item 9a in HP-001-A5 (Unopened Chemical Checklist to Recondition) and also item 2 in HP-001-A6 (Unopened Chemical Checklist for Return to Vendor). Refer to the revised Appendix III (b) (4) SOP and Checklists).
8. The footnote in Appendix IV (Raw Chemicals Proposed for Reconditioning) has been revised to a note at the top of the Appendix. A limitation resulting from the seizure is that seized product may not be moved within the facility. This constraint has made the objective to obtain all product information required for the inventory lists very difficult. Once permission is granted to move the previously seized materials, the container quantities may change. Although the container quantities may change, the proposed chemical types to be reconditioned will not change. Refer to the revised Appendix IV.
9. The question marks in Appendices V, VI, VII, and IX have been changed to an asterisk with a note on each page. A limitation resulting from the seizure is that seized product may not be moved within the facility. This constraint has made the objective to obtain all product information required for the inventory lists very difficult. Once permission is granted to move the previously seized chemicals, the pertinent information will be recorded and documented on the appropriate (b) (4) (b) (4) consulting checklist. Refer to the revised Appendix V.
10. Per our telephone conversation on December 1, 2011, H&P Industries proposes to recondition a bulk tank of (b)(4) (b)(4) will be reconditioned per HP-001-A5 (Unopened Chemical Checklist to Recondition) and qualified for future use in manufacturing under the Work Plan per SOP-QA-010 (*Supplier Qualification and Management Program*).

H&P Industries trusts that FDA will find these clarifications acceptable.


Dr. Brian Garthwaite
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Thank you for your consideration.

Respectfully submitted,




Allison Stray
Quality System Manager
H&P Industries, Inc.

cc: 
David L. Rosen, Foley & Lardner LLP

Enclosures

LIST OF APPENDICES

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| APPENDIX III |  SOP and Checklists |
| APPENDIX IV | Raw Chemicals Proposed for Reconditioning |
| APPENDIX V | Raw Chemicals Proposed for Return to Vendor |
| APPENDIX VI | Raw Chemicals for Destruction-QC Sampled |
| APPENDIX VII | Raw Chemicals for Destruction-Open and Expired |
| APPENDIX IX | Bulk Liquids for Destruction |