VIA UNITED PARCEL SERVICE AND
ELECTRONIC MAIL

October 4, 2011

Gerald J. Berg
Director, 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 Mr. Berg:

H&P Industries, Inc. (H&P Industries) in accordance with the Consent Decree of Permanent Injunction dated June 13, 2011 in the United States District Court Eastern District of Wisconsin, Case No. 11-C-0319 hereby submits the following revised reconditioning plan for Condemned Ingredient Materials seized on April 4, 2011 for the Food and Drug Administration's (FDA) review and approval. This revised plan is being submitted as a response to FDA correspondence received September 26, 2011.

H&P Industries has retained (b) (4) located in (b) (4) as Third Party Good Manufacturing Practice (GMP) experts. (b) (4) has been qualified in accordance with H&P Industries' Supplier Qualification Procedure (SOP-QA-010 effective September 30, 2010). A (b) (4) capabilities brochure and representative CVs are attached as Appendix I.

H&P Industries' reconditioning plan is comprised of a two-phase approach in accordance with the Consent Decree: Phase I – Condemned Ingredient Materials Reconditioning and Destruction, as detailed in this plan, and Phase II – a Quality Systems Approach to Enhanced cGMP Compliance and Start-up of Manufacturing Operations, to be covered in a subsequent plan.

CURRENT STATUS

It is important to note that in conjunction with the November 29, 2010 - January 7, 2011 FDA inspection, H&P Industries reorganized its Quality Unit effective December 30, 2010. H&P Industries has hired Mr. Eamonn Vize, CV attached as Appendix II, as the Chief Operating Officer since August 29, 2011. In addition, H&P Industries has hired (b) (6), CV attached as Appendix III, as an Analytical Method Development Chemist. b(4)

b(4)

EVALUATION PROCESS

The raw chemical lots proposed for reconditioning and return to vendor will be reviewed by (b) (4) in accordance with (b) (4) (Third Party Document Chemical Review and Release/Disposition), HP-001-A5 (Unopened Chemical Checklist to Recondition), and HP-001-A6 (Unopened Chemical Checklist for Return to Vendor) attached as Appendix IV. Copies of the completed signed checklists and executive summary will be attached to the raw chemical lot paperwork and maintained as part of the permanent records in accordance with H&P Industries' retention policy (POL-QA-003).

H&P Industries is proposing to recondition raw chemicals for both future use in manufacturing and return to vendor as described in Appendices V and VI.

RAW CHEMICAL MATERIAL RECONDITIONING

All unopened chemicals currently under seizure in H&P Industries' inventory have the opportunity to be "reconditioned" as defined in this Reconditioning Plan. Those lots of chemicals which are defined as "unopened" are those in which the factory seal is still intact or have been appropriately sampled for release testing as outlined in H&P Industries' procedure WI-QC-0203 (Sampling, Testing, Approval and Release of Incoming Chemical Materials). In order to recondition a chemical or bulk tank chemical for use in manufacturing, H&P Industries will perform a full documentation and data review as outlined in the (b) (4) checklist HP-001-A5. The procedure of documentation, testing and data review will ensure the chemical was approved and released per WI-QC-0203 at the time of receipt.

When a lot of chemical meets the requirements specified in the HP-001-A5 checklist, the checklist, incoming inspection report, and supporting documentation will be held for a representative o(b) (4) to perform a secondary review, also with respect to HP-001-A5.

Upon meeting the requirements of the (b) (4) review, each chemical lot to be reconditioned will be b(4) b(4) b(4) All reconditioned chemicals will be held and maintained in quarantine until these lots are qualified per SOP-QA-010 (Supplier Qualification and Management Program) and later approved for use and moved into inventory as outlined in the manufacturing process (as referenced in the agency's correspondence dated September 26, 2011).

The chemical lots to be reconditioned and returned to the vendor will be reviewed with respect to the (b) (4) HP-001-A6 checklist. b(4) b(4) (b) (4) b(4) b(4) b(4) b(4) In addition to labeling, the chemical lots to be reconditioned and returned to vendor will be physically segregated.

Should a chemical to be reconditioned or returned to vendor not meet the criteria outlined in HP-001-A5 or HP-001-A6, the supporting documentation cannot be obtained, e.g. manufacturer's COA, or does not meet H&P Industries' specifications the chemical will be rejected and destroyed. Once all lots of chemicals to be reconditioned have been reviewed by (b) (4) (b) (4) approved by FDA and moved to quarantine, the reconditioning of the chemicals will be complete. Rejected chemical materials will be inventoried and added to the destruction list.

MATERIALS DESIGNATED FOR DESTRUCTION

All finished goods, open in-process finished goods, in process materials in tanks and drums, opened raw chemicals, expired raw chemicals, and opened components will be destroyed per SOP-QA-017 (Notice of Destruction Procedure).

Finished goods, open in-process finished goods, opened raw chemicals, expired and rejected raw chemicals, and opened components

H&P Industries is working with (b) (4) and (b) (4) to profile all materials for destruction.

(b) (4) landfill sites have perimeter fencing with 24 hour video surveillance. As part of the profile evaluation process, H&P Industries is responsible for sending MSDSs, labels, specifications, and/or formulation documents to (b) (4) (b) (4) The profile will determine whether the material can be sent to a landfill or must be processed as hazardous waste. All material destruction will be completed in compliance with state and local requirements.

(b) (4)

(b) (4)

H&P Industries has sent (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Once the destruction service has completed the destruction of the products or materials in each load they will provide a certificate of destruction to H&P Industries. The certificate of destruction must include a description of the material destroyed, the method of destruction, acknowledgement that the seal number on the trailer matched the seal number on the destruction inventory sheet, and that the seal was intact when the load arrived at the destruction facility.

H&P Industries' Quality Assurance will review the certificate of destruction from the destruction service and file it with the H&P Industries' notice of destruction.

In process materials in tanks and drums

In process materials in tanks and drums will be destroyed using (b) (4)

(b) (4)

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H&P Industries trusts that FDA will find this revised plan meets the agency's concerns communicated in correspondence dated September 26, 2011.

Thank you for your consideration.

Respectfully submitted,

Eric Haertle
President
H&P Industries, Inc.
cc: b(6)
David L. Rosen, Foley & Lardner LLP

Enclosures

LIST OF APPENDICES

APPENDIX I	(b) (4) Capabilities Brochure and Representative CVs
APPENDIX II	Eamonn Vize's CV
APPENDIX III	(b) (6) CV
APPENDIX IV	(b) (4) SOP and Checklists
APPENDIX V	Raw Chemicals Proposed for Reconditioning
APPENDIX VI	Raw Chemicals Proposed for Return to Vendor
APPENDIX VII	Raw Chemicals for Destruction
APPENDIX VIII	Finished Product for Destruction