VIA UNITED PARCEL SERVICE AND
ELECTRONIC MAIL

November 23, 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:

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 revision of the Revised Reconditioning plan is being submitted as a response to FDA correspondence received November 10, 2011 and the meeting with the agency on November 21, 2011.

H&P Industries has retained (b) (4) (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 resumes were previously provided in the submission dated October 4, 2011.

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, resume previously submitted in the October 4, 2011 submission, as the Chief Operating Officer effective August 29, 2011. In addition, H&P Industries has hired (b) (6) resume previously submitted in the October 4, 2011 submission, as an Analytical Method Development Chemist. Furthermore, H&P Industries has hired (b) (6) resume Attached as Appendix I, as a Quality Assurance Internal/External Auditor and a Quality Control Manager, Paavan Trivedi, resume Attached as Appendix II. H&P Industries continues to recruit and interview for permanent resources including Quality Control, Quality Control Laboratory, Quality Assurance, and Operational candidates.

EVALUATION PROCESS

The raw chemical lots proposed for reconditioning for use or return to vendor will be reviewed by (b) (4) upon FDA's approval of this plan in accordance with paragraph 8 of the Consent Decree and (b) (4) procedure BC-002 Rev A (THIRD PARTY REVIEW AND RELEASE/DISPOSITION OF UNOPENED CHEMICALS FOR RETURN TO VENDOR OR MANUFACTURING) HP-001-A5 (Unopened Chemical Checklist to Recondition), and HP-001-A6 (Unopened Chemical Checklist for Return to Vendor) attached as Appendix III. Copies of the completed signed checklists 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). A copy of the completed checklist will be provided along with the "return to vendor" shipment if it requested by the receiving company.

H&P Industries is proposing to recondition unopened raw chemicals for both future use in manufacturing and return to or described in Appendices IV and V.

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. The lots of a chemical or a chemical container which are defined as "unopened" are those in which the factory seal is still intact.

In order to recondition an unopened 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 (*Sampling, Testing, Approval, and Release of Incoming Chemicals*) at the time of receipt. b(4) [redacted] b(4) [redacted] (b) (4) [redacted] review.

b(4) [redacted] b(4) [redacted] All reconditioned chemicals will be held and maintained in quarantine until these lots are qualified per SOP-QA-010 (*Supplier Qualification and Management Program*), later approved for use per WI-QC-0203, 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 HP-001-A6 checklist. b(4) [redacted] b(4) [redacted] In addition to labeling, the chemical lots to be reconditioned and returned to vendor will be physically segregated in clearly identified locations or "stations" marked with signage and chain enclosures.

Should a chemical to be reconditioned for use 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, as determined either by H&P or (b) (4) [redacted] the chemical will be rejected and destroyed. Once all lots of chemicals to be reconditioned have been reviewed by (b) (4) [redacted] moved to

quarantine, or designated to be returned to the vendor, 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 (including those only opened for QC Laboratory sampling), bulk chemicals, expired raw chemicals, and opened, partially used components will be destroyed per SOP-QA-017 (*Notice of Destruction Procedure*). Those items identified to be destroyed are listed in Appendices VI-IX.

This Reconditioning Plan has (b) (4) Teams performing all of the reconditioning and destruction activities simultaneously for 10 to 15 consecutive working days. See Table 1 below for a summary of teams and responsibilities.

Team	Staffing	Priority
(b) (4)		

H&P Industries has worked with (b) (4) and (b) (4) to profile all materials for destruction. (b) (4) landfill sites and all specified destruction sites listed below have perimeter fencing with 24 hour video surveillance. These facilities are also not accessible without an appointment. Additionally, each facility maintains the required regulatory agency permits. As part of the profile evaluation process, H&P Industries was responsible for sending MSDSs, labels, specifications, and/or formulation documents to (b) (4) (b) (4) used the profiles to 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) landfill sites include (b) (4) (b) (4) will coordinate the destruction of bulk liquids at (b) (4) In addition, (b) (4) will also coordinate the destruction of chemicals through:

(b) (4)

For all chemicals, the destruction service, destination and method of destruction are identified in Appendices VI and VII.

H&P Industries has provided all of the pertinent information, to (b) (4) and (b) (4) in order to accurately determine the waste profile for each chemical to be destroyed. All of the waste profiles have since been completed and returned to H&P Industries.

(b) (4)

Products Designated for Landfill

(b) (4)

b(4) [redacted] It is estimated to take (b) (4) [redacted] to compete the landfill portion of product destruction. H&P Teams (b) (4) [redacted] will prepare the loads, load the trucks, witness/verify, and document these activities.

Products Designated for Incineration

Once H&P has approval to begin destruction of these items, (b) (4) [redacted] to schedule the destruction. Trucks will be loaded to a target weight of (b) (4) [redacted] lbs which will equal approximately (b) (4) [redacted] truck loads. These loads will be processed (b) (4) [redacted] of the destruction schedule and will fit into the product destruction schedule of (b) (4) [redacted] H&P Teams (b) (4) [redacted] will prepare the loads, load trucks, witness/verify, and document these activities.

Bulk Liquids

After H&P obtains approval to begin destruction, (b) (4) [redacted] will coordinate the scheduling of the destruction of these items with (b) (4) [redacted] This destruction will require (b) (4) [redacted] tanker trucks. (b) (4) [redacted] to schedule the tankers so the (b) (4) [redacted] trucks will be loaded on (b) (4) [redacted] total destruction schedule. H&P Team (b) (4) [redacted] will work with (b) (4) [redacted] to transfer the bulk liquids into the tankers and witness the transfer activities.

Chemicals

Upon approval to begin the destruction, (b) (4) [redacted] will coordinate the schedule with (b) (4) [redacted] will have a crew on site which will include a chemist to supervise the combining of chemicals into destruction containers for transportation. H&P Team (b) (4) [redacted] will pick the chemicals from the racks; stage them for packing, and witness the packaging. (b) (4) [redacted] will (b) (4) [redacted] per day and transport the load for destruction on the next day. (b) (4) [redacted] H&P Team (b) (4) [redacted] will witness the packaging of chemicals on (b) (4) [redacted] and the loading of the truck will be conducted on (b) (4) [redacted] for each load. These loads will take approximately (b) (4) [redacted] to load.

(b) (4) [redacted]

b(4)

[redacted]

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 issued 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 H&P Industries' (b) (4) (b) (4) H&P has an Industrial Service Agreement for Wastewater Discharge in place with the (b) (4) The current agreement is effective April 1, 2011 through June 30, 2012. In order for H&P Industries to discharge wastewater, the requirements set forth in the service agreement must be met. The service agreement ensures that the (b) (4) reatment facility will be able

to process the wastewater discharged from the H&P treatment system. In addition, the service agreement includes monitoring requirements to ensure the discharged wastewater quality requirements are met as defined. The monitoring requirements include, but are not limited to, a (b) (4) (b) (4) H&P Industries has notified the (b) (4) on 11/11/20011 in regards to the plan of starting up the treatment system and the disposal of some of the bulk liquids through the treatment system. Per the attached Bulk liquids inventory, bulk liquids which would not meet the requirements of our service agreement, after in-house treatment, are planned for disposal using (b) (4)

The condemned articles designated for treatment will be treated in (b) (4) gallon batches in the (b) (4) Upon treatment of the batch, the treated liquid will be (b) (4) (b) (4) facility for further treatment. The amount of material batched into the (b) (4) will be (b) (4) (b) (4) so a final reconciliation maybe completed. (b) (4)
(b) (4)
(b) (4)

H&P Industries trusts that FDA will find this revised plan meets the agency's concerns communicated in correspondence dated November 10, 2011 and the meeting with FDA on 11/21/11.

Thank you for your consideration.

Respectfully submitted,

Allison Stray

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

cc: b(4)
David L. Rosen, Foley & Lardner LLP

Enclosures

LIST OF APPENDICES

APPENDIX I	Resume - (b) (6)
APPENDIX II	Resume- Paavan Trivedi
APPENDIX III	(b) (4) 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 VIII	Finished Product for Destruction
APPENDIX IX	Bulk Liquids for Destruction