VIA UNITED PARCEL SERVICE (UPS) AND
ELECTRONIC MAIL

June 16, 2011

Mr. Gerald J. Berg
Director, Minneapolis District Office
Food and Drug Administration
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401

RE: CONSENT DECREE CORRESPONDENCE

REMEDIATION PLAN FOR FINISHED PRODUCT AND CONDEMNED INGREDIENT MATERIALS

Dear Mr. Berg:

H&P Industries, Inc. (H&P Industries) in accordance with 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 remediation plan for Finished Product and Condemned Ingredient Materials seized on April 4, 2011 for the Food and Drug Administration's (FDA) review and approval.

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 Process (SOP-QA-010 effective September 30, 2010). A (b) (4) capabilities brochure and representative CVs are attached as Appendix I. H&P Industries has also engaged the services of (b) (4) Principal Consultant and Owner, (b) (4) (b) (4) for expert assistance and consulting advice on all microbiological matters. (b) (4) CV is attached as Appendix II.

H&P Industries' remediation is comprised of a two-phase approach in accordance with the Consent Decree: Phase I – Finished Product and Condemned Ingredient Materials Remediation, detailed in this plan, and Phase II – Quality Systems (GMP), a systemic approach to cGMP enhancement for manufacturing processes.

It is important to note that since the November 29, 2010 – January 7, 2011 FDA inspection, H&P Industries reorganized its Quality Organization on December 30, 2010. Current and future organizational charts are included as Appendix III. Additionally, significant improvements to

GMP processes and procedures have been implemented and were underway during the March 21-28, 2011 FDA inspection. All procedures identified in this plan will be reviewed by Third Party consultant, prior to use in this plan. Table 1 provides an overview of new and revised procedures.

TABLE 1
New and Revised Procedures

SOP Number	SOP Title	New SOP / Revised SOP	Revision / Effective Date
SOP-LAB-009	Environmental Monitoring Program	New	1/28/2011
SOP-QA-010	Supplier Management	New	9/30/2010
SOP-WH-001	Warehouse Storage and Distribution	New	2/25/2011
SOP-QA-019	Quality Unit Responsibilities	New	2/16/2011
SOP-VL-001	Equipment Qualification	New	3/7/2011
SOP-VL-002	Process Validation	New	4/8/2011
SOP-RD-001	Writing Manufacturing Batch Records	New	2/25/2011
SOP-QA-020	Drug Adverse Event Reporting	New	3/31/2011
WI-PUR-0001	Product Labeling Artwork Approval Process	Revised	5/17/2011
WI-PM-0138	HVAC Duct Cleaning - Annual PM	New	3/29/2011
WI-MFG-0121	Production Room Cleaning	New	3/19/2011
SOP-QA-002	Reporting, Tracking and Management of Deviations	Revised	1/26/2011
SOP-QA-017	Notice of Destruction Procedure	Revised	1/24/2011
SOP-QA-005	Record Review and Product Disposition	New	3/7/2011
SOP-QC-001	Nonconforming Materials Procedure	Revised	2/14/2011
SOP-QA-018	Training Program	Revised	2/18/2011
SOP-LAB-001	Out of Specification Investigations	Revised	2/15/2011
SOP-QA-014	Management Review	Revised	10/14/2010

SOP Number	SOP Title	New SOP / Revised SOP	Revision / Effective Date
SOP-QA-011	Complaint Handling System	Revised	3/31/2011
SOP-LAB-010	Water System Monitoring Procedure	Revised	4/1/2011
POL-SF-001	Personal Protective Equipment (PPE), Cleanliness and Dress Policy	Revised	3/7/2011
SOP-QA-001	Reporting, Tracking and Management of CAPAs	Revised	1/24/2011
SOP-QA-006	Preparation, Management and Change of GMP Documents	New	2/11/2011

Quality Improvements impacting Phase I remediation are discussed within this plan. Enhancements appropriate to Phase II Quality System will be discussed in detail in a separate submission.

PRODUCTS SPECIFIC REMEDIATION (FINISHED PRODUCT, CHEMICAL, COMPONENT, CONTAINER, CLOSURE, AND LABELING)

H&P Industries conducted a review of the seized product inventory to determine products and lots potentially subject to remediation. b(4) b(4) b(4) The lists (product and materials remediation), attached as Appendices IV and V, include products and materials H&P Industries proposes to recondition in accordance with the following plan.

Products for remediation have been broken down into (b) (4) (b) (4) as discussed in Consent Decree paragraph 9 (A-C). These Lots are summarized by product categories below. A comprehensive list of products by Lot is attached as Appendix IV.

(b) (4)

H&P Industries has, since product acquisition and transfer to our facility, submitted all Cough and Cold and Nasal products to outside laboratories for microbial testing b(4) In addition,

effective December 2, 2010, H&P Industries outsourced all microbial testing to (b) (4) (b) (4). Both laboratories were qualified in accordance with SOP-QA-010. Qualification included on-site audits of the laboratory, the Quality Systems and controls in place. All finished product manufactured and analyzed prior to outside microbial lab testing will not be remediated and will be destroyed.

Since the November 29, 2010 - January 7, 2011 FDA inspection, H&P Industries has made significant improvements to its Quality Systems. Based on the following improvements implemented by H&P Industries and discussed below, H&P Industries is proposing to recondition the listing of finished, in-process product, raw materials, and component materials described above and attached as Appendices IV and V.

QUALITY SYSTEM IMPROVEMENTS

1) Implementation of Quality Unit oversight and manufacturing lot review release. SOP-QA-005 was effective on March 7, 2011.

2) Outsourcing of all microbiology testing to (b) (4) (b) (4)

3) H&P Industries' compilation and review of process validations, cleaning validations, and method validations. The appropriate validations will be reviewed and verified by Third Party reviewers.

4) An environmental monitoring program to assess viable air and surface particulates has been implemented throughout the facility. In addition to environmental monitoring, a reinvigorated awareness has been initiated though the revision of the proper gowning techniques procedure and policy along with communicating the importance of good hygiene through training to eliminate any potential for contamination from personnel.

5) H&P Industries' review and trending of deviations, CAPAs, supplier qualifications, complaints, OOS, and failure investigations for all products will be assessed for trends, product impact, and potential investigations if appropriate.

6) Annual Product Reviews have been completed for 2010, covering products manufactured between April 2010 and April 2011.

7) Review of DI water system microbial testing results from 2010 to present demonstrates no significant and repetitive microbial issues with the water in the facility. As of December 2, 2010, all DI Water microbial testing has been outsourced to a qualified Third Party laboratory (b) (4) and will continue to be outsourced moving forward.

8) Prior to start-up, a thorough review of the calibration and maintenance programs will be performed to ensure all equipment is calibrated and in compliance.

9) The floors, ceiling, walls, and equipment in all of the production rooms were cleaned with (b) (4) In addition, all air ducts were cleaned by a Third Party contractor.

10) The following new programs were initiated: Overhaul of the document control system, document control rooms set up for control of records, overhaul of the stability program, implementation of design of experiments (DOE) for all new products and product transfers, a revised validation master plan, and restructuring of operations by product family.

11) A comprehensive review and audit of all operations has been initiated.

All condemned finished batches, in process materials, and raw materials (chemicals/components) will be reviewed by outside consultants in accordance with (b) (4) procedure (b) (4) (Third Party Document, Finished Product, Raw Material, and/or Chemical Records Review and Release/Disposition), HP-001-A1 (Finished Products Checklist), HP-001-A2 (Products Checklist), and HP-001-A3 (In-Process Material Inventory Checklist) attached as Appendix VI. Copies of the completed signed checklist will be attached to the batch records and maintained as part of the lot history in accordance with H&P Industries' retention policy (POL-QA-003).

Any products which have not yet undergone microbial testing performed by an outside laboratory will be sampled, tested by (b) (4) and the results will be reviewed. If a product should report results exceeding H&P Industries' current specifications while meeting the requirements specified by the USP, based on intended use, will be reviewed and evaluated by H&P Industries, (b) (4) for remediation and/or destruction per Out of Specification SOP, SOP-LAB-002, and Notice of Destruction SOP, SOP-QA-017.

IN-PROCESS MATERIALS

In-process packaged product lots in shipping cartons will be reviewed and processed by H&P Industries according to currently established procedures. After the H&P Industries' acceptance process, the batches will be reviewed as per above by (b) (4) Open in-process or finished products containers or tank materials will be destroyed. All product yields will be calculated for this material.

Deviations from Quality Systems and product specifications will be reviewed and managed under the current implemented (reviewed and revised) SOP-QA-002 (Reporting, Tracking and Management of Deviations) implemented January 26, 2011.

Products that meet the above remediation criteria will be reviewed by the Third Party reviewers per (b) (4) attached as Appendix VI. Reviewed products will be identified and held per the Consent Decree requirements paragraph 10 for FDA review, evaluation, and decision.

Products, where deficiencies are identified, will be reviewed in accordance with current H&P Industries' procedures to determine whether remediation can proceed. Products that will not be remediated will be segregated and held for FDA review prior to destruction in accordance with the Consent Decree paragraph 11.

IDENTIFICATION OF LOTS FOR REMEDIATION

All lots or batches to be remediated will be b(4) [redacted] in accordance with SOP-QC-001 (Nonconforming Materials Procedure). b(4) [redacted] in accordance with H&P Industries' procedure SOP-QA-007 (Record Review and Product Disposition). b(4) [redacted] b(4) [redacted] All materials will be segregated by category and tagged "Pending FDA Approval" to await FDA review, decision, and disposition.

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H&P Industries trusts that FDA will promptly review and approve the proposed remediation plan. We are available to meet and discuss the plan at any time. Please do not hesitate to call me at (262) 538-2908 (office), (b) (4) [redacted] (b) (4) [redacted] to discuss the proposed plan.

Thank you for your consideration.

Respectfully submitted,

Eric Haertle
President
H&P Industries, Inc.

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

Enclosures