~~DD~~
ADCB

VIA FEDERAL EXPRESS AND
ELECTRONIC MAIL

August 19, 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 REMEDIATION PLAN FOR FINISHED PRODUCT AND CONDEMNED INGREDIENT 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 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. This revised plan is submitted as a follow-up to the FDA and H&P Industries' teleconference on July 29, 2011.

H&P Industries has (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 capabilities brochure and representative CVs are attached as **Appendix I**. H&P Industries has also engaged the services (b) (4), Principal Consultant and Owner (b) (4) for expert assistance and consulting advice on 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 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. Current and future organizational charts are included as **Appendix III**. Mr. (b) (6) , CV attached as **Appendix IV**, has been acting as interim Quality Lead since July 18, 2011. H&P Industries has been recruiting and interviewing for permanent resources including Plant Manager, Quality Control, and Quality Assurance candidates (b) (4)

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

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 Qualification and Management System	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

SOP Number	SOP Title	New SOP / Revised SOP	Revision / Effective Date
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-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
SOP-QA-007	Internal Audit Procedure	Revised	7/19/2011

QUALITY SYSTEM IMPROVEMENTS

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

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) [redacted]

3) H&P Industries' compilation and review of process validations, cleaning validations, and test method validations. Relevant validations, i.e., those affecting processes going forward, will be reviewed and evaluated by Third Party reviewers.

4) An environmental monitoring program to assess viable organisms and nonviable particulates in the air and on surfaces has been implemented in specified manufacturing areas. In addition to environmental monitoring, employee awareness has been increased though good hygiene training and the revision of the gowning procedures and policies to reduce the risk of contamination from personnel.

5) H&P Industries' review of deviations, corrective and preventive actions (CAPAs), supplier qualifications, complaints, out of specification (OOS), and failure investigations for all products will be assessed for trends, potential risks, and product impact, as 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 the present indicates that there are no significant or 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. The DI water system is also in the process of being upgraded and revalidated.

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) [redacted] In addition, HVAC supply ducts were cleaned by a Third Party contractor in March of this year.

10) The following programs were initiated: overhaul of the document control system, document control rooms were established 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. Nasal product process validations performed in 2011 include DOE elements.

11) A comprehensive review and audit of all operations by (b) (4) [redacted] has been initiated under the H&P Industries' internal audit program, SOP-QA-007 Internal Audit Procedure. Results of these audits will be included as part of the remediation review along with the prior Form FDA 483 observations matrix.

12) A supplier qualification program has been initiated. Audits of some suppliers/ manufacturers have been performed and other audits are scheduled. Questionnaires have been sent to identified raw material manufacturers. Supplier performance histories are being compiled and will be reviewed as part of the remediation effort. These actions, along with testing verifications, and reducing the numbers of approved suppliers should produce a robust overall program.

13) Stability-indicating test method development has been initiated for nasal products. b(4) [redacted].

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

Eligibility for Remediation

H&P Industries conducted a review of the seized product inventory to identify products and lots that may be eligible for remediation. This review considered (b) (4) [redacted]s. All products listed for remediation were manufactured after January 1, 2011 when many of the revised procedures and processes had been implemented. The revised lists, attached as **Appendices V, VI,** include products to be remediated. In addition the chemicals list has been segregated into products for return to suppliers and those that H&P Industries will utilize for manufacturing operations.

Products for remediation have been broken down into (b) (4) [redacted] for remediation as discussed in Consent Decree paragraph 9 (A-C). These Lots are summarized by product categories below.

(b) (4) [redacted]

(b) (4) [redacted] and H&P Industries have compiled a comprehensive matrix of all Form FDA 483 observations, including system deficiencies and product specific observations. (b) (4) [redacted] will review the comprehensive matrix to ensure that the Form FDA 483 observations have been addressed for each product family manufactured and scheduled for

remediation. (b) (4) will also review internal audit findings for each family in this manner.

b(4)
b(4) This information will be included in an executive summary per product family, matched with the reviews documented in the individual (b) (4) checklists, and will be available for FDA review: HP-001-A1 (Finished Products Checklist), HP-001-A2 (Products Checklist), and HP-001-A3 (In-Process Material Inventory Checklist). The review will be performed in addition to the product-specific items listed on the three aforementioned checklists, attached as **Appendix VII.**

H&P Industries has, since product acquisition and transfer to the Hartland 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) . Both laboratories were qualified in accordance with SOP-QA-010. The qualification process included on-site audits of the laboratories with a review of the Quality Systems and controls. Finished product manufactured and analyzed prior to initiation of outside microbial laboratory testing will not be remediated and will be destroyed.

As indicated earlier, since the November 29, 2010 - January 7, 2011 FDA inspection, H&P Industries has made significant improvements to its Quality Systems. Based on the aforementioned improvements implemented by H&P Industries, H&P Industries is proposing to recondition the listed finished products, in-process materials, and chemicals/components described above and compiled in **Appendices V, VI.**

Evaluation Process

The finished products, in-process materials, and chemicals/components lots intended for remediation will be reviewed by (b) (4) in accordance with (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 VII.** Copies of the completed signed checklists and executive summary will be attached to the batch/lot records and maintained as part of the lot history in accordance with H&P Industries' retention policy (POL-QA-003).

b(4)
b(4) This information will be included in an executive summary per product family and matched with the reviews documented in the individual (b) (4) checklists.

Finished Products

Following the H&P Industries' product disposition process, batches determined acceptable by H&P Industries will be reviewed by (b) (4) . Records for finished products in

closed shipping containers will be reviewed using (b) (4) checklist HP-001-A1 (Finished Products Checklist). This review will consider b(4) In addition, Form FDA 483 observations will be reviewed to ensure they have been addressed for each product lot. b(4) . This information will be complied in an executive summary and matched with the review documented in the individual (b) (4) checklists.

In-Process Materials

Open in-process materials, and open finished products in tanks and drums will be destroyed. In-process packaged product lots in shipping cartons will be reviewed and documented by H&P Industries according to currently established procedures. Records for in-process materials in closed containers will be evaluated using (b) (4) HP-001-A3 (In-Process Material Inventory Checklist). In addition, Form FDA 483 observations will be reviewed to ensure they have been addressed for each material lot. b(4) ill be reviewed, as appropriate to each material. Inventory quantities will be verified, accounted for, and recorded.

Chemicals and Components

Open containers of chemicals and components and expired chemicals and components, will be destroyed. Unopened containers and bulk tank materials will be evaluated to determine if they can be remediated. Unopened, unexpired materials have been segregated into two categories: those to be qualified for use or those to be returned to the vendor.

Material to be returned to vendor will undergo a limited review, to include (b) (4) b(4) These records will be available for FDA review and the completed return records will be reviewed and approved by b(4) b(4)

Qualification of unopened containers for use in manufacturing will proceed following a two-step process. The first step will be to review b(4) Form FDA 483 observations will be reviewed as they pertain to the material being evaluated. b(4) will be required for the material to be eligible for release under the H&P Industries' SOP.

(b) (4) will review the documentation in accordance with the (b) (4) checklist HP-001-A2 (Products Checklist). Lots of materials meeting requirements will be placed in quarantine. Lots that are not eligible for release will be slated for destruction.

The second step of the remediation process is required at Phase II for materials to be released for use. Each lot will undergo (b) (4) [redacted] Lots meeting all specifications may be released following the H&P Industries' disposition procedure with final review and approval from (b) (4) [redacted]

Identification of Lots to be Remediated

b(4) [redacted] All materials will be segregated by category and tagged "Pending FDA Approval" to await FDA review, decision, and disposition.

Products for Destruction

Products, where deficiencies are identified, will be reviewed in accordance with current H&P Industries' procedures to determine whether remediation can proceed. Products that fail remediation review will be identified as such, held for FDA review, and destroyed in accordance with H&P Industries destruction plans. These products have been segregated into two categories, those requiring incineration and those that can be destroyed in a landfill. All product destructions will be completed in accordance with all state and local requirements. Destruction of all items will be managed by (b) (4) [redacted] Formulations of all products to be disposed of will be forwarded to (b) (4) [redacted] who will determine, based upon environmental regulatory requirements, whether the products will be sent to the (b) (4) [redacted]

****

H&P Industries trusts that FDA will find this revised plan meets the agency's concerns discussed during the teleconference on July 29, 2011.

Thank you for your consideration. We are prepared and would be pleased to discuss this remediation plan at your earliest convenience. We will call your office next week to schedule a mutually convenient date and time for the meeting.

Respectfully submitted,

Eric Haertle
President
H&P Industries, Inc.

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

Enclosures

LIST OF APPENDICES

APPENDIX I	(b) (4) **Capabilities Brochure and Representative CVs**
APPENDIX II	(b) (4) **CV**
APPENDIX III	**Current and Future Organizational Charts**
APPENDIX IV	(b) (4) **CV**
APPENDIX V	**Hemorrhoidal Wipes and Pads, Nasals, Glycerin Suppositories, and Cough and Cold Products to be Remediated**
APPENDIX VI	**Chemical Raw Materials to be Remediated and Destroyed**
APPENDIX VII	(b) (4) **SOP and Checklists**