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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401

Memorandum of Meeting

Date: November 21, 2011

Firm: **H & P Industries, Inc.**
700 W. North Shore Drive
Hartland, WI
FEI 2128643

Between: **Eric Haertle**, President, H&P Industries, Inc.
Allison Stray, Quality System Manager, H&P Industries, Inc.
Eamonn Vize, Chief Operating Officer, H&P Industries, Inc.
David Rosen, Counsel (via phone)
Jeremy Cramey, QC Laboratory Manager, H&P Industries (via phone)
(b) (4)

Michael D. Shane, Office of Chief Counsel (GCF-1) via phone
Tamara L. Ely, Compliance Officer, DCB1/CDER (HFD-320) via phone
David J. Jaworski, Compliance Officer, DCB2/CDER (HFD-320) via phone
Elizabeth A. Waltrip, Acting Director, MIN-DO (HFR-CE800)
Cheryl A. Bigham, Director, Investigations Branch, MIN-DO (HFR-CE850)
Gregory W. Smith, Supervisor, Investigations Branch, MIN-DO (HFR-CE850)
Janis R. Armendariz, Acting Director, Compliance Branch, MIN-DO (HFR-CE840)
Brian W. Garthwaite, Ph.D., Compliance Officer, MIN-DO (HFR-CE840)
Catherine C. Leonard, Legal Instruments Examiner, MIN-DO (HFR-CE840)

Subject: **Reconditioning and Work Plans in light of Bond deadline (1/15/12)**

The firm requested this meeting to get a better understanding of their position with regard to CD requirements, work thus far on their reconditioning and work plans, and their bond deadline. Mr. Haertle stated his firm's commitment to full compliance and confidence in its attainment. He expressed some frustration that much communication to date has necessarily been routed through attorneys but hopes for more open dialogue going forward.

Ms. Stray reported on progress since the April 2011 seizure and shut-down. Emphasis has been for building quality into all systems. With (b) (4) on-site and comprehensive assistance, QC has been overhauled. Efforts include b(4) b(4) addition of QC and management staff, multiple training events for both management and full staff. These projects are focused toward corrective action. Mr. Haertle admitted the firm has done a poor job communicating their many efforts. Dr. Garthwaite emphasized that details such as these are key to FDA's understanding of the firm's status, and advised the firm that for the purpose of gaining FDA's confidence in

resumption of manufacturing, the firm should consider itself a "start-up company" providing all details.

Regarding return of product in its Reconditioning plan, the firm requested approval to return all unopened and QC-sampled (opened) containers based on b(4) b(4) Ms. Ely reiterated that because of both micro and cross-contamination concerns, FDA has no GMP assurance and is uncomfortable with introducing any potential risk back into the market via returns to vendors. Dr. Garthwaite stated that once a container is opened, it is open. Discussion ensued about focusing work on b(4) b(4) Dr. Garthwaite emphasized the need for and illustrated the specific kind of details needed to coordinate identification of products, logistics, certification by disposal firms, verification by FDA personnel, and transmission to the Marshall and Court. Ms. Stray offered that a new level of detail has been added to their plan and the firm believes it can accomplish the task in b(4) days. Ms. Bigham added that her investigative personnel want to work with the firm, and added that details such as dates, number of hours per day, etc. will be necessary to plan for efficient FDA oversight. b(4) b(4) In the end, they agreed to destroy all opened and QC-sampled (opened) containers and to make the appropriate changes to their Reconditioning plan which will be submitted b(4) Dr. Garthwaite declined to commit to a review timeframe, but promised diligence, work over the Thanksgiving holiday, and a status communication on 11/29/11.

Ms. Stray outlined its Work Plan methodology devised with (b) (4) See slides 8-9. b(4) She believes the end result will build quality through all the systems. Dr. Garthwaite informed her that new submissions could merely reference items left unchanged from prior submissions (such as (b) (4) CVs).

Discussion ensued regarding submission for drug or device combination products. Ms. Stray and Mr. Haertle stated that the current plan focuses only on b(4) b(4) (b) (4) Mr. Shane acknowledged the reasonability of pursuing b(4) b(4) The parties agreed to work through any questions about combination products (drug vs. drug/device delivery) as they arise.

In response to Dr. Garthwaite, Ms. Stray acknowledged that the firm's first priority is t b(4) Dr. Garthwaite explained that the Agency's review time will depend on the plans themselves, the details provided and other FDA workload. Ms. Ely cautioned that the firm's background work and detailed thoughts have not, as of yet, carried into its submitted versions. She underscored the importance of the firm communicating in its plans that it understands the interrelation of all the manufacturing systems in order to gain FDA's confidence that the firm's efforts will successfully address its problems.

Mr. Vize outlined a new protocol for batch certification. It includes previous items (e.g. b(4)), but adds (b) (4)

(b) (4)

Mr. Vize proposed a validation scheme for installation and operation qualifications b(4) Mr. Jaworski and Mr. Vize discussed the b(4) b(4) b(4) b(4) Dr. Garthwaite b(4) encouraged the firm to include corrections and improvements such as these in its work plan submissions and to keep these items in sight as the firm moves back into production.

Concluding remarks advised the firm to detail its complete plan before submission, and to use the consulting firm for its expertise. Ms. Ely wants the protocol to be free of assumptions, but instead laid out step-by-step with rationale. Dr. Garthwaite explained that the burden is on the firm; FDA cannot act as the firm's consultant but wishes to work forward. Mr. Haertle expressed appreciation for the meeting and promised to meet expectations.

The meeting began at 10:35 and concluded at 11:50 a.m.

Catherine Leonard

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Legal Instruments Examiner
Minneapolis District

/ccl

Attachments: slide presentation