DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
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Memorandum of Meeting

Date: July 29, 2011

Firm: **H & P Industries, Inc.**
700 West North Shore Drive
Hartland, Wisconsin 53029
2128643

Between: **H & P Industries, Inc.**
Eric Haertle, President
Allison Stray, QA System Manager
Jeremy Cramey, QC Laboratory Manager
Michael McIntosh, Engineering Manager
David Rosen, Counsel, Foley and Lardner, LLP
b(4) Consultant,
Consultant, (b) (4)

Center for Drug Evaluation and Research
David Jaworski, Team Leader, DCMB Team II
Tamara Ely, Compliance Officer, DCMB Team II

Office of Chief Counsel
Michael Shane, Attorney

Minneapolis District Office
Brian Garthwaite, Compliance Officer

Subject: **Civil No. 2:11-cv-00317-AEG**
Reconditioning Plan submitted June 16, 2011
Supplement to Reconditioning Plan submitted July 29, 2011

FDA convened this teleconference with H & P Industries, Inc., ("the firm") to give the firm opportunity to explain the reconditioning plan (the firm used the term "remediation plan") submitted on June 16, 2011, in advance of the firm's posting of the bond on July 22, 2011. The firm submitted on July 29, 2011, a supplement to their reconditioning plan. The supplement contained an agenda, a process map, a spreadsheet containing remediation summary charts, a list of finished articles slated for reconditioning, and a list of raw ingredients slated for reconditioning.

FDA's opening statement defined the purpose of the teleconference, and identified points of focus that FDA expects in a reconditioning plan. FDA expects a reconditioning plan that describes in detail the reconditioning process and how the reconditioning process identifies, removes, and mitigates the GMP deficiencies under which the firm manufactured the drugs. FDA's expects that the reconditioning process yields reconditioned drugs that FDA, the firm and its

consultants, and customers for which the firm manufactured drugs can verify safety and effectiveness for the intended use.

Mr. Haertle stated that he shared FDA's concerns about reconditioned products, and that safety is paramount. Mr. Haertle then summarized how the firm devised the reconditioning plan. (b) (4)

(b) (4)

FDA asked whether the lists of drugs the firm submitted on July 29, 2011, represented the final lists of drugs that the firm slated for reconditioning. The lists in the July 29, 2011, submission contained fewer lots than did the lists in the June 16, 2011, submission. Mr. Haertle stated that the lists represent "as of today" what the firm wanted to recondition, b(4)

b(4)

FDA asked how the firm intended to recondition raw chemical ingredients. The reconditioning plan did not describe reconditioning or final disposition of raw chemical ingredients. Mr. Haertle stated that (b) (4)

(b) (4)

FDA disagreed with the firm's approach for identifying lots slated for reconditioning. FDA stated that the firm must establish a deadline for customers to notify the firm whether the customer accepts reconditioned products. FDA pointed out that the reconditioning plan lacks detail about how the firm will handle reconditioning of raw chemical ingredients.

FDA told the firm that the reconditioning plan did not contain any details about the destruction of articles that the firm will not recondition, and that this information is needed in a reconditioning plan.

(b) (4) then described the process that the consultants and the firm developed for identifying articles for reconditioning. She stated that there was no way to devise a specific reconditioning plan that would cover all products to be reconditioned. She discussed the process flow chart, the remediation summary chart, and the checklists in Appendix VI in the June 16, 2011, submission.

FDA commented that the process flow chart, remediation summary chart, and checklists may be useful for assessing the firm's documentation practices, but they do not address the GMP deficiencies that existed during the time the firm manufactured the drugs. FDA used as an example the firm's lack of a supplier qualification system, which FDA identified during inspections of the firm. FDA commented that the reconditioning procedure outlined by (b) (4) does not consider that the firm has been cited for many quality control and quality assurance deviations, and such deficiencies need to be mitigated as part of the reconditioning process.

FDA described another example of a GMP deficiency that the reconditioning plan does not cover. The investigators observed bare-handed employees packaging hemorrhoid wipe material into containers. The firm identified microbial contamination in hemorrhoid wipes, but the firm did not investigate the cause of the contamination. This was one example where the firm did not explain in their reconditioning plan how the firm corrects GMP deficiencies FDA investigators observed during inspections. FDA mentioned also the GMP deficiencies with manufacturing equipment, particularly with the glycerin suppository press.

FDA informed the firm that the reconditioning plan submitted on June 16, 2011, did not meet FDA's expectations, and that the firm's next effort needs to include a final list of finished goods the firm plans to recondition, a detailed plan for destroying goods the firm will not recondition, and a detailed plan for reconditioning raw chemical ingredients.

The firm committed to "rethinking and redoing" the reconditioning plan with the assistance of their consultants. The firm stated their intent to submit a revised plan within a week.

The teleconference adjourned.

Brian D. Garthwaite, Ph. D.
Compliance Officer
Minneapolis District

BDG/bdg

Attachment: Meeting Notes