DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	03/21/2011 - 03/28/2011
	FEI NUMBER 2128643

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eric C. Haertle, Chief Operating Officer

FIRM NAME	STREET ADDRESS
H & P Industries, Inc.	700 W North Shore Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hartland, WI 53029-8358	Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

1. A microbial out of specification (OOS) result, dated 1/19/11, for (b) (4) in lot 0M172 of BZK Towelettes occurred. The OOS investigation identified the organism *B. cereus*. The product was rejected.

   Two additional microbial out of specifications for (b) (4) in BZK Towelettes lot 0L276 dated 1/3/11 and BZK Swabstick Solution lot 1A21B dated 2/1/11 were obtained. However, the investigations into the additional failures did not identify the organisms recovered and deviation PDV-11-002 was used to justify changing the specification. The batches were released under the adjusted specifications.

2. A recall was initiated on 3/16/11 of all lots of iodine prep pads due to the identification of *Elizabethkingia meningoseptica* in sample results reported on 3/11/11. No investigation has been conducted to identify the source of this contamination. The potential impact to similar drug products, including iodine swabsticks and iodine scrubs, has not been assessed.

3. An investigation into source of *B. cereus* contamination of sterile and non-sterile alcohol prep pads was conducted. The investigation identified the pad material and foil as potential contamination sources. The impact to other products manufactured with the same or similar pad and foil was not assessed.

4. The psyllium husk products could not be validated at this location due to microbial contaminants during finished product testing. All lots made at this facility are designated for destruction. An investigation determined the raw material as the source of microbial contamination. The same raw materials were used to make these products at the New Jersey HH&P location prior to being transferred to this location. All psyllium husk products manufactured at HH&P New Jersey that were transferred to this location were designated for destruction, but the investigation did not asses the product already on the market.

5. Since the previous inspection in January 2011, several OTC batches involving various products failed during (b) (4) stability studies. No investigations were documented determining the effect of these failures to product currently on

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the market.

Product	Lot	Date tested	Mo. Failed	Expiration Date
Hemorrhoidal Suppository	9M126	1/13/11	(b) (4)	12/2012
Hemorrhoidal Suppository	9K164	1/13/11		10/2012
Triad PVP Swabsticks	OD034	2/07/11		04/2013

- Stability samples for hemorrhoidal suppositories, lots 9M126 and 9K164 failed their active ingredient specifications for the (b) (4) test point on 01/13/11. These lots have been failing their active ingredients specification since October 2010. OOS Investigation OOS-11-010 and OOS-11-011 were opened on 1/13/11, but never completed. No root cause has been determined.
- Stability sample for Triad PVP Swabsticks was tested for its (b) (4) test point on 2/7/11. The sample failed its active ingredient assay. OOS-W11-026 was initiated on 02/07/11, but hasn't completed its phase II investigation.

OBSERVATION 2

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, a validation was conducted for the new high purity water system in early 2008. The validation was performed in several sections including (b) (4) followed by (b) (4) (b) (4). The duration was from (b) (4) Not every day was included in the testing but a total of (b) (4) days results are logged. The data reported included a series (b) (4) shows 1cfu), followed by another (b) (4) with some findings (including at least (b) (4) with TNTC data on (b) (4) samples collected that day and much lower amounts (b) (4) sample collected that day), and finally followed by (b) (4) days with no (b) (4) findings. Written into the report on the same day starting the final trend of non findings was (b) (4) which was thought to imply (b) (4) was performed. The TNTC data points reported were described away as anomalies due to (b) (4) and not included in the (b) (4) calculations with little or no substantive justification, possibly skewing statistical results. The validation was approved using the described figures and was certified for use in production. This validation does not include any long term sampling (one year) to monitor seasonal or other fluctuations.

None of the raw microbiological data generated from the validation is still available for review, only the reports.

The validation protocol stated that a revalidation must take place (b) (4) None has occurred to date.

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OBSERVATION 3

Drains are not provided with an air break or other mechanical device to prevent back-siphonage where connected directly with a sewer.

Specifically, the firm's wall mounted (b) (4) water tester unit is hard plumbed into a PVC pipe located along the wall and identified as "storm drain". It is plumbed into a position near the top of the vertical pipe. An air break device was noted atop this pipe, several inches above the described link. It was observed that this air break device was just set on top of the pipe in that position and actually there was a threaded plug in its place, beneath it. A backed up or overwhelmed storm sewer could possibly cause pressured back siphonage into the tester and into the High Purity water system by direct line.

OBSERVATION 4

Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, several leaks were noted in the high purity water system, including one from a sample port at (b) (4) which is hard plumbed to the wall mounted tester unit, dripping at an observed rate of several drops per second.

The (b) (4) log for the system specifically asks to check for leaks to the "piping". This leak is located just feet away from the wall mounted (b) (4) tester and location where the daily log is maintained, yet there was no indication of a leak recorded and no maintenance request for repair.

OBSERVATION 5

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically, an apparent dead leg was noted in the high purity water supply loop. This ~3' x 1.5" vertical pipe is just downstream from a (b) (4) inlet valve. The system has no stand or surge tank so any water used must be immediately replenished or damage to the system could occur. As described to me by the firm, when new DI water is needed (b) (4) also opens this inlet valve. Understandably this valve remains closed much of the time, including during operational down time. If the valve is closed, the described pipe section about three feet or so, likely will not drain because there appears to be no way to let air or vacuum break into the top of the pipe, allowing flow.

In addition, it appears that this could cause an issue during heat sanitation of the supply loop for the same reason. It appears that there would be no substantive circulation into and thru that portion of the tube to sanitize it without re-directed plumbing. This was not described to me as taking place.

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OBSERVATION 6

Procedures for the cleaning and maintenance of equipment are deficient regarding maintenance and cleaning schedules, including, where appropriate, sanitizing schedules.

Specifically,

- There is no written guidance in place regarding routine sanitization of the high purity water system distribution loop.
- There is no written guidance in place for the maintenance of HEPA filters and the HVAC system in the Environmentally Controlled Room, Red Batching Room, or Red Filling Room.

OBSERVATION 7

Records are not kept for the sanitizing of equipment.

Specifically, previous to March 2009 there was no apparent record of conducting any sanitization activity to the high purity water system. The new version of a (b) (4) log added a place for a check mark, but no additional information was included. At the start of 2011, they actually began writing in that a sanitization cycle was conducted ((b) (4)).

OBSERVATION 8

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically, (b) (4) water samples are not representative of the manufacturing process in that they are collected using (b) (4) (b) (4)

OBSERVATION 9

Equipment for adequate control over air pressure and dust is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, there is not adequate separation, procedures, or pressure differentials to prevent cross contamination in the red batching room. The room can be used to batch two different products at the same time.

OBSERVATION 10

Buildings used in the manufacturing of a drug product are not maintained in a good state of repair.

Specifically, on the afternoon of 3/24/11 both sets of the interlocking doors at the equipment pass through between the nasal

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fill line and a general batching area were observed to be damaged. The nasal fill line is in a HEPA filtered Environmentally Controlled Room and there is no air control system in the general batching area. The damage allowed both sets of the doors in the pass through to remain open at the same time.

An operator stated it was noticed there was a problem with the doors (b) (4) 3/23/11, but he didn't know how long the doors had been broken. Lot 1C225 was filled in this room (b) (4)

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