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	04/19/2010 - 05/18/2010* FEI NUMBER 2128643

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED 5/18/10

TO: Eric C. Haertle, ~~CEO~~ COO

FIRM NAME	STREET ADDRESS
H & P Industries, Inc. dba Triad Group	700 W North Shore Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hartland, WI 53029-8358	Drug, Medical Device, and Cosmetic 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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

MEDICAL DEVICES

OBSERVATION 1

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, the firm could not provide documentation for the validation of the sterilization process for the lubricating jelly products labeled as sterile.

Additionally, evidence indicates the currently used (b) (4) sterilization cycle may not be adequate to sterilize the lubricating jelly. The current sterilization cycle specifies acceptance of material that receives between a minimum of (b) (4) and a maximum o(b) (4)

- As part of a follow-up to on-going CAPA H-10-001, a post-sterilization sample of Sterile Lubricating Jelly from lot 9M172 was tested and showed growth of (b) (4) (b) (4)
- Each lot of post-sterilization Lubricating Jelly is tested for (b) (4) In a review of testing done from September 2009-April 2010 growth in post-sterilization samples was initially indicated in the following lots:

Micro ID #	Lot	Date Read	Results
512J	9H195	09/30/09	(b) (4)
211K	9J175	10/15/09	

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363K	9K03	10/26/09
62L	9K104	11/06/09
64L	9K133	11/06/09
66L	9K181	11/06/09
183L	9K190	11/12/09
189L	9K165	11/12/09
147M	9L144	12/09/09
161M	9L137	12/09/09

(b) (4)

- During the currently on-going validation, VAL-PQ-Steril-002, for sterility of the Lubricating Jelly, which began in December 2009, high bioburden results were obtained for the pre-sterilized Sterile Lubricating Jelly. Samples results are an average of a total of (b) (4) samples that were collected from the (b) (4) production lot.

Pre-sterilized lubricating jelly in 4oz tubes:

Date Sample Completed	Lot	Average Bioburden
12/15/09	9L186	(b) (4)
12/15/09	9M111	
12/15/09	9M100	
4/06/10	0B163	
4/06/10	0C164	
4/06/10	0C165	

Pre-sterilized lubricating jelly in 4oz bottles:

Date Sample Completed	Lot	Average Bioburden
12/15/09	9M08	(b) (4)
12/15/09	9M18	
12/15/09	9M12	
4/06/10	0C12	
4/06/10	0C19	
4/06/10	0C20	

Pre-sterilized lubricating jelly in 3 gram packets:

Date Sample Completed	Lot	Average Bioburden
12/15/09	9L123	(b) (4)
12/15/09	9L137	
12/15/09	9L162	

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1/08/10	9M172	(b) (4)
4/06/10	0C172	
4/06/10	0B128	
4/06/10	0C218	

Validation protocol VAL-PQ-Steril-002 calls for the use of the average bioburden from (b) (4) lots to be used to set (b) (4) The dosage from (b) (4) only provides dosage levels for a maximum average bioburden of (b) (4) cfu. The dosage level for (b) (4) to sterilize at a Sterility Assurance Level (SAL) of (b) (4) Your current sterilization cycle specification allows for an acceptance of material that receives a minimum of (b) (4).

Per (b) (4) a minimum dose of (b) (4) would be sufficient to sterilize a product with an average bioburden of (b) (4) The lowest average bioburden result from a single lot you have is (b) (4)

The lots sampled for this protocol and other lots that were being manufactured during this same time period were released for distribution based on the current sterilization cycle specifications.

OBSERVATION 2

Procedures for finished device acceptance have not been adequately established.

Specifically;

- Finished device acceptance procedures do not ensure that finished devices are quarantined or otherwise adequately controlled until acceptance criteria are met. Sterile Lubrucating Jelly, lot 9M172 was packaged for [redacted] customers. The finish product testing for customers (b) (4) passed and product was distributed. The finished product testing for customer [redacted] failed Post Sterile Viscosity, but product was still distributed starting 01/11/10. A statement to the batch record on 01/28/10 by the Regulatory Affairs Manager states "*released by D. Haertle on 01/28/10". (D. Haertle is the CEO of H&P). On 02/01/10 an OOS was initiated to address the failed results. On 02/04/10, the decision to release this product per D. Haertle was revised per reconsideration. The remaining (b) (4) cases were scrapped. However (b) (4) cases had already been distributed and no action was taken on the distributed cases.

- There is no procedure addressing the "confirmatory testing" currently being implemented during microbiological testing. Currently, Sterile Lubricating Jelly is being tested for (b) (4) post-sterilization. The specification is listed as no growth for both tests. Since September of 2009, ten lots have shown growth on the initial test as described in Observation #1. In each case, a second sample was checked and found negative for growth. The passing results were reported and the failed results were not addressed. No OOS Investigation was initiated to investigate the failing results.

- The post-sterilization testing of Sterile Lubricating Jelly for (b) (4) does not neutralize the preservatives in the product. WI-LAB-0011 revision F - Testing for Microbiological Contamination

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in Samples, effective 12/21/09 has not been updated to include the (b) (4) (b) (4) during the post sterilization testing for lubricating jelly. On-going CAPA H-10-001 initiated 01/22/09, states in the follow-up, "(b) (4) (b) (4) (b) (4) "

OBSERVATION 3

Complaints involving the possible failure of a device and labeling to meet any of its specifications were not evaluated and investigated where necessary.

Specifically, but not limited to:

- Complaint ID 12007/Call ID 8851, dated 08/27/09 concerning Sterile Lubricating Jelly 4 oz. tube, lot 9F131, states, "***Product is sub standard. When the doctors use it, it runs right off their gloves and onto the floor. It is too runny.***" During the investigation, H&P tested [redacted] pre-sterilization retains and [redacted] post sterilization retains for viscosity. These samples were all produced from the same batch of product, but were packaged for different customers. All (b) (4) pre-sterilization retains failed viscosity and (b) (4) post-sterilization samples failed. The only sample that passed was packaged for the customer that made the complaint. After reporting the one passing result to the complainant, the complaint was closed without investigating the affect of the failed results on product currently on the market. H&P has received 11 viscosity related complaints from July 2009 to present.

- Complaint ID 13100/Call ID 9688, dated 03/11/10 concerning Sterile Lubricating Jelly, 4 oz. tube, lot 9L186, states high rate of abnormal paps. Hospital lab confirms that the jelly was to blame. H&P has gotten 6 similar complaints regarding this issue from July 2009 to present.

OBSERVATION 4

A baseline report on FDA Form 3417 or approved electronic equivalent was not submitted following the first MDR report on a device model.

Specifically, the firm failed to report an adverse event related to complaint ID 13012 dated 2/17/2010 alleging over 30 patients having contracted vaginal irritation after a physician used the sterile lubricating jelly. The complaint alleged that patients were switched to a different lubrication jelly product and treated with a prescribed medication. The complainant alleged that some patients cleared of symptoms within nine days and the remaining patients exhibited symptoms for about three weeks and beyond.

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OBSERVATION 5

Written MDR procedures have not been developed and implemented.

Specifically, the firm has no MDR procedures.

OBSERVATION 6

Corrective and preventive action activities and/or results have not been adequately documented.

Specifically, CAPA H-10-001 opened Jan 22, 2010, has yet to address high microbial bioburden levels in pre-sterile lubricating jelly products. Procedure 01-013, revision B - Corrective and Preventive Action Procedure (CAPA) which states in section 5.6 "***(b) (4) [redacted] (b) (4) [redacted] ***" has not be followed.

DRUGS

Production System

OBSERVATION 7

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, there is no validation of the (b) (4) [redacted] sterilization process for the Alcohol Swabstick products labeled as sterile.

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OBSERVATION 8

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically, the validation for the sterilization of alcohol pads VAL-0007-PQRPT-002, approved on 3/12/10 states the minimum sterilization dose to sterilize alcohol pad products to a SAL of [redacted] would be (b) (4) Your current specifications for your contract sterilizer, updated 4/14/10, specify you will accept product that receives a minimum dosage of (b) (4) A minimum dosage specification of (b) (4) is what you have used for the product you currently have on the market.

OBSERVATION 9

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

- Procedure WI-LAB-0040, revision A - Laboratory Out Of Specification (OOS) Investigations

  The Purpose and Scope states, "(b) (4) (b) (4) ". In the following cases, no OOS was initiated, the productwas retested and the initial result dropped:

Batch	Product Code	Failed Test
9A440B	PL-1450	(b) (4)
9A131B	10-5201 ([redacted]	
9H104	11-PZ32	

  Section 3.3.1 states, "***(b) (4) (b) (4) ***". Batch OB103B does not allow for adjustment, however during the review of the raw data for the (b) (4) HPLC analysis it was noted that (b) (4) sets of samples were tested prior to getting passing results. Only the final passing results were recorded in section VI. Quality Assurance Batch In-Process Analysis & Approval sheet. No OOS was generated. Quality stated this is a common practice when dealing with suspensions.

- Procedure WI-LAB-0063, revision C - Stability Study Program states in section 3.6.1, "(b) (4) (b) (4) (b) (4) " This

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procedure was not followed when failures occurred during the following stability studies:

Formula	Lot	Formula	Lot
04-136	8G172	04-201	7H05
04-132	8J123	04-193	7E68
04-084	7G22	04-112	8F133
04-132	7K63	10-5102	9A135
04-098	8E53	04-148	8J144
04-158	7D04		

- Procedure 01-013, revision B - Corrective and Preventive Action Procedure (CAPA) states in section 5.6 "***A (b) (4) (b) (4) ***" This was not followed for the following CAPAs:

CAPA No.	Request Date	Update Provided
H-10-001	01/22/10	undated, provided after inspection was initiated.
H-10-002	02/02/10	04/26/10, provided after inspection was initiated.
H-10-003	02/19/20	04/26/10, provided after inspection was initiated.

- Procedure WI-LAB-0094, revision B - General Rejection Procedure states in section 3.2.7.1, "(b) (4) (b) (4) (b) (4)" This procedure was not followed for the following OTC batches:

Lot Code	Product Code	Date	Defect	Reject Level	Defects Recorded
9J17	10-3532	09/09/09	Weight within spec.	(b) (4)	(b) (4)
OC137	33-14906-TP	03/01/10	Weight within spec.		

OBSERVATION 10

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

- No documentation exists to support that the methods used in stability testing are stability indicating.

During the tour on 4/19/10 and 4/20/10, several activities were observed that were not controlled by procedures:

- Repacking of product was taking place in the warehouse in an unsegregated area.
- Rechecking of material on the packaging lines when defects are noted during the finish product inspection are not

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documented or controlled by a procedure.

- "Hold" stickers are being used by Quality during an OOS investigation.
- "Return to Inventory" tags.
- Receiving material under quarantine from the New Jersey plant prior to all testing being completed.

Quality System

OBSERVATION 11

Drug products failing to meet established specifications are not rejected.

Specifically:

- Triad Plus BZK Prep Pads have a BZK, wt% specification of (b) (4) Batches of this product were released outside of this specification range as follows:

Date	Lot Number	Finished Product Results	Quantity	Released Under Deviation
08/26/09	9H104	(b) (4)	(b) (4) cases	NO DEV/OOS WRITTEN
02/01/10	0A38/0A38B		(b) (4) cases	(b) (4)

- Hemorrhoid Cream has a phenylephrine specification of (b) (4) Batches of this product were released outside of this specification range as follows:

Date	Lot Number	Finished Product Results	Quantity	Released Under Deviation
11/05/09	9J140B/9J140	(b) (4)	(b) (4) gallons	(b) (4)
09/18/09	9K213/9K213B		(b) (4) cases	

OBSERVATION 12

Results of stability testing are not used in determining expiration dates.

Specifically, numerous OTC batches involving various products failed during the annual stability studies. Data obtained during stability testing is not used to determine if expiration dates need to be adjusted.

Formula Date	Lot	Mo. Failed	Exp. Date	Formula	Lot	Mo. Failed	Exp.
10-5102	9A135	(b) (4)	01/12	04-112	8F133	(b) (4)	06/10
04-132	8J123		09/11	04-193	7E68		05/10
04-148	8J144		09/11	04-158	7D04		04/10

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04-098	8E53	(b) (4)	05/11	04-132	7K63	(b) (4)	10/09
04-201	7H05		08/10	04-084	7G22		07/09
04-136	8G172		07/10				

OBSERVATION 13

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.

Specifically,

- Numerous OTC batches involving various products failed during the annual stability studies. No investigation was documented determining the affect of these failures to product currently on the market as listed in Obervation 12.

- The firm identified (b) (4) and (b) (4) suppositories in the following batches of infant and adult glycerin suppositories:

Lot#	Mfg. Date	Contamination description	Infant/Adult
OD100	04/01/2010	(b) (4)	Adult
OD118	04/05/2010		Infant
OD119	04/06/2010		Infant
OD120	04/07/2010		Adult
0D121	04/08/2010		
0D158	04/13/2010		Adult
0D160	04/15/2010		Adult
0D161	04/16/2010		Adult
0D173	04/19/2010		Infant
0D196	04/27/2010		Infant
0D197	04/27/2010		Infant
0D174	04/28/2010		Adult
0D175	04/29/2010		Adult

*0D121 - the Notice of Destruction for this batch states that "(b) (4) (b) (4) " Per the batch records and the Production Manager, no suppositories were manufactured from this batch.
**0D173 - the Nonconformance report identifies contamination and discoloration of this batch.
***0D197 - a portion of this lot was destroyed. Per your production manager, the remainder of the bulk batch for this lot was destroyed as it was late in the production day. Holding the bulk product longer than necessary causes the product to discolor. Therefore, the decision was made to discard the remainder of the bulk batch.

In-process CAPA-H-10-007 dated 4/7/10 states that during quality control inspection of Glycerin suppository batches,

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(b) (4) the suppositories. The CAPA also identifies a (b) (4). Your firm's production manager (b) (4) (b) (4). There is no description of the contamination identified as (b) (4) in the CAPA, batch records, or nonconformance reports, or whether the (b) (4) contamination differs from the contaminants identified as (b) (4)

Firm management said that the (b) (4) examination documented on Work Instruction WI-QC-0028, page 3 of 3 ("(b) (4)") is sufficient to identify contaminated batches. However, lots 0D100 and 0D119 both show no findings of contamination in the (b) (4) examinations, but nonconformance reports documenting (b) (4) contamination were later included in the records for both batches.

In response to the contamination concerns, use of (b) (4) (b) (4) (b) (4) as part of the in-process and finished product inspection as this has been deemed sufficient to identify contamination. An (b) (4) was conducted to determine if the (b) (4) (b) (4)

There is no documentation available to determine when and how the (b) (4) will be used. For example, the entire lot of (b) (4) totes from 0D100 was placed on hold pending (b) (4) In comparison, only (b) (4) of the (b) (4) totes from infant suppository lot 0D196 were initially placed on hold for (b) (4) prior to management placing the entire lot on hold following this observation.

In addition to the (b) (4) were implemented beginning with batch OD160. No documentation was provided to demonstrate how (b) (4) upon finding contamination in a batch.

There is no documented use of the (b) (4) or any other investigation into the potential for (b) (4) contamination in infant suppository lot 0D118. This lot of infant suppositories was manufactured chronologically between two lots in which (b) (4) contamination was found (0D100 and 0D119). Lot 0D118 was distributed. Lot 0D158, in which (b) (4) suppository had been identified was partially distributed. Firm management conducted additional (b) (4) examinations of product that was in-house in response to this observation.

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OBSERVATION 14

Written procedures are not drafted, reviewed and approved by the appropriate organizational units.

Procedure WI-LAB-0123, revision A - Analytical Method Validation and Verification states in 3.1, "A(b) (4) (b) (4) " During the review of various validation methods, it was observed that the validation protocols were not signed off prior to the execution of the validation.

Protocol	Effective Date	Execution Date
VAL-P-0092	12/08/09	12/01/09
VAL-P-0171	02/04/10	12/30/09
VAL-P-0011	12/23/09	07/06/09
VAL-P-0084	12/08/09	11/17/09

OBSERVATION 15

Deviations from written specifications are not justified.

Specifically:

- Deviation Form 01-019, rev. C, attachment II states in the corrective action section, "(b) (4) (b) (4) (b) (4) " No corrective actions/justifications were written for deviations H0210.001 dated 02/01/10 and H1109.007 dated 11/5/09.

- Deviation P0207.008 dated 02/16/07 concerning towelettes states, "*** (b) (4) (b) (4) (b) (4) *** " CAPA H-10-002 concerning the failing (b) (4) in finished goods and stability samples was not issued until 02/02/10.

OBSERVATION 16

Employees engaged in the manufacture and packing of a drug product lack the training required to perform their assigned functions.

Specifically,

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H & P Industries, Inc. dba Triad Group	700 W North Shore Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hartland, WI 53029-8358	Drug, Medical Device, and Cosmetic Manufacturer

Temporary employees do not receive formal training before they operate production lines.

- On 04/19/10, during the packaging of product PL-5104B, Lot OD143, on line CB4, temporary employee (b) (6) (b) (6) was documenting the Top Seal Temperature at (b) (4) °F for the [redacted] checks taken (b) (4) The specification for the top seal is (b) (4) °F.

- On 04/19/10, during the packaging of product 11-SP03, Lot OD15, on line HB5, temporary employee (b) (6) (b) (6) documented the Top Seal Temperature at (b) (4) The specification for the top seal is (b) (4) (b) (4) °F. The top seal temperature was observed running at (b) (4) °F during our observation of line HB5 at ~3:30pm on 04/19/10.

Training did not appear adequate for the regular employees due to the numerous documentation errors noted throughout this inspection. These include, but are not limited to:

- On 04/13/10, batch OD153B, the incorrect lot number was documented and verified by a second employee for the Cocoa Butter NF. This error was not caught until an investigator noted it during the inspection on 04/21/10.
- On 01/26/10, for specification 04-132, step (b) (4) the step was performed by [redacted] but was never verified.
- The batch records state do not run outside of process parameters, however multiple instances were documented where production lines were being run outside of operating parameters.

OBSERVATION 17

Reprocessing was performed without the review of the quality control unit.

Specifically, the Infant and/or Adult Glycerin Suppositories, formula 04-144, are manufactured using (b) (4) (b) (4) are 'approved' by Quality, no specification for (b) (4) or documented criteria for what Quality is looking for could be provided.

Laboratory System

OBSERVATION 18

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically, some OTC drug products are currently being released for distribution prior to the completion of all release testing.

- One batch can be used to package several packaging configurations. Testing is required (b) (4) each packaging run. (b) (4) (b) (4)

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	Sandra A Hughes, Investigator SAH Joel D. Hustedt, Investigator JDH Justin A. Boyd, Investigator JAB	05/18/2010

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	04/19/2010 - 05/18/2010* FEI NUMBER 2128643

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(b) (4)
testing is required.

Sample	Testing Required
(b) (4)	(b) (4)

Batch	Product	Samples Tested	Date Released	# Cases
OB166	(b) (4) Glycerin Suppositories	(b) (4)	03/05/10	(b) (4)
OB166	(b) (4) Glycerin Suppositories		03/04/10	
OB166	(b) (4) Glycerin Suppositories		03/15/10	

Assay testing was approved by Quality for (b) (4) Glycerin Suppositories for (b) (4) sample on 03/09/10. (b) (4) (b) (4) Glycerin Suppositories were released before Assay testing, (b) (4) sample.

- Testing was completed for (b) (4) sample on 08/17/10 for BZK product 9H104. (b) (4) testing was completed on 08/26/10 with **failing** results for BZK, (b) (4) Assay. The first pallet containing (b) (4) cases was released into inventory for shipping on 08/14/09. The second pallet containing (b) (4) cases was released into inventory for shipping on 08/19/09. Product was shipped as follows:

Dated	#Cases
08/14/09	(b) (4)
08/19/09	(total)

No investigation occurred when failed results were documented for the End Sample for product already in inventory. The remaining cases were released into inventory and shipped.

OBSERVATION 19

The written stability testing program is not followed.

Procedure WI-LAB-0063, revision C - Stability Study Program states in section 3.4.1, "***(b) (4) (b) (4) (b) (4) ***" Numerous test points were missed during the execution of stability protocols with no deviations being written.

Solution #	Lot #	Missed time point(s)	Solution #	Lot #	Missed time point(s)

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04-011B	9A135	(b) (4)	04-112	8F133	(b) (4)
04-132	8J123		04-193	7E68	
04-148	8J144		04-158	7D04	
04-098	8E53		04-132	7K63	
04-201	7H05		04-084	7G22	
04-136	8G172				

OBSERVATION 20

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically, no raw data could be provided to support the Cleaning Validation Report for the Glycerin Suppository Press dated 12/29/09.

Facilities and Equipment System

OBSERVATION 21

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,

- The Infant and Adult Glycerin Suppository filling line is not appropriate for the manufacture of the OTC drug products in that there were cracked ejector pins on the glycerin press. The production work order for Specification 07-SOL-04-144IN, batch OB166B states in section IX, "***Check the Glycerin Press for broken pins; if any broken pins are observed, alert Production Supervisor.***" There is no additional information documented as to what steps were taken to correct the problem or whether the production supervisor was contacted and if so, if any follow up occurred.
- The foam punches used to cut the pads used in drug and cosmetic products manufactured by the firm are not easily cleanable and were patched with tape.
- The tank used to manufacture the oatmeal products had holes in the bottom that were patched using tape. This tape has contact with product.

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OBSERVATION 22

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

- The fans used in the Swab room to dry the swabs were observed on 04/19/10 to have accumulation of debris.
- The wire baskets used in the Swab room to hold the swabs while they are drying were observed to have frayed wires and an accumulation of grey fuzz.
- The plastic scraper used in the manufacturing of the oatmeal products was chipped. The wooden handle was broken and taped together and was not easily cleanable.

OBSERVATION 23

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,

- Procedure WI-PM-0056, revision B - Cleaning and Sanitizing Batching Equipment, Tanks and Totes states the following:

  Page 5: Glycerin Suppositories/Clean and Sanitize Between Batches. Section 7 states, "***(b) (4) (b) (4) ***. The Lab Manager stated this process is currently (b) (4) (b) (4) as shown by the log for tank 61.

  Page 4: Ointment and Suppository Products/ (b) (4) (b) (4) The log for tank 44 and 42 shows batch information not being documented and cleanings not being performed (b) (4) batches.

- Procedure WI-PM-0113, original - Performing Daily Calibration on (b) (4) Suppository Machine Scales states in section 3.1.14, "(b) (4) (b) (4) " Lot OB132 dated 02/12/10 documents the scale reading at [illegible]% for (b) (4) scales.

- Procedure WI-PM-0090, original - Assigning Status Tags to Batch Tanks states the following:

  Section 3.1.2, "(b) (4) ." Although tank 44 was in use, no batch information was recorded for tank 44 for the following dates: 3/19/10, 3/23/10, 3/24/10, 3/25/10, 3/29/10, 3/31/10, 4/09/10, 4/12/10, 4/19/10.

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Section 3.1.3, "(b) (4) (b) (4) ." It was observed during the walk through on 04/20/10 the incorrect batch number was recorded on the 'IN USE' tag and no start date was documented.

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Observation Annotations

Observation 1:	Promised to correct by 6/15/2010.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.

*** DATES OF INSPECTION:**
04/19/2010(Mon), 04/20/2010(Tue), 04/21/2010(Wed), 04/22/2010(Thu), 04/23/2010(Fri), 04/27/2010(Tue), 04/28/2010(Wed), 04/30/2010(Fri), 05/03/2010(Mon), 05/04/2010(Tue), 05/05/2010(Wed), 05/10/2010(Mon), 05/18/2010(Tue)

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