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	07/15/2009 - 07/17/2009
	FEI NUMBER 3003710670

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eric C. Haertle, Chief Operating Officer

FIRM NAME	STREET ADDRESS
H & P Industries, Inc. dba Triad Group	700 West North Shore Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hartland, WI 53029	OTC 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:

Quality System

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

OBSERVATION 2

GMP training is not conducted with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

OBSERVATION 3

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, multiple Out of Specification investigations into Hemrrhoidal Suppositories with Phenylephrine were not extended to other products containing Phenylephrine i.e. Hemrrhoidal Cream and Ointment with Phenylephrine.

OBSERVATION 4

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

Specifically, the Infant and/or Adult Glycerine Suppositories, formula #04-154, are manufactured using (b) (4) (b) (4) The quality control unit does not approve the reprocessing of the batches prior to production.

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	Marie A Fadden, Consumer Safety Officer MAF Joel D. Hustedt, Consumer Safety Officer JDH Sandra A. Hughes, Consumer Safety Officer SAH	07/17/2009

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OBSERVATION 5

Rejected in-process materials are not identified and controlled under a quarantine system to prevent their use in manufacturing or processing operations for which they are unsuitable.

Specifically, Glycerine Suppository lot #9C150B was observed in the Glycerine Suppository room with a "QA Accepted Material" tag on it. The material was in a corner of the room with items around it. The material was dispositioned on 7/16/09 after we observed it stored in the corner.

OBSERVATION 6

Drug products failing to meet established specifications are not rejected.

Hemrrhoidal Suppository with Phenylepherine has a Phenylephrine specification of (b) (4) multiple batches of this product were released outside of the specification range as follows:

Lot number	finished product test results
8K100	(b) (4)
8K151	
8L200	
8M101	
8M166	
8M186	
8H234	
8K101	

OBSERVATION 7

Deviations from written specifications are not justified.

a) No Out of Specification investigation was documented for Out of Specification finished product assay for Hemrrhoidal Suppositories with Phenylephrine lots 8K100 and 8K151.

b) The procedure "Laboratory Out of Specification (OOS) Investigations" #WI-LAB-0040 effective 6/17/09 section 3.3.10 requires approval by Quality Unit Managers. Nine out of eleven OOS investigations did not have Director of QA/QC/RA and Technical Services signature. According to the Lab Manager this should have been signed.

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OBSERVATION 8

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

OBSERVATION 9

Procedures describing the warehousing of drug products are not followed.

Specifically, the finished product reject storage area described in the procedure "General Rejection Procedure" #WI-QC-0094 effective 5/06/09 section 3.2.7.3 is not indicated by signs or other designation and is not spacially separated from acceptable material.

Facilities and Equipment

OBSERVATION 10

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.

a) The Starch Hemorrhoid Suppositories operators utilize a plastic five gallon bucket to transfer product from the mixing vessel to the suppository forming and packaging machine.
- the plastic bucket is not easily cleaned and sanitized and it is not documented
- the plastic bucket has not been evaluated for cross contamination with the product

b) the Infant and Adult Glycerin Suppository filling line is not appropriate for the manufacture of OTC drug products in that:
- the scraper used to remove material from the molds is (b) (4) a plastic like material, with noticable chips and scratches. It is not easily cleanable and is a direct product contact surface. It is not inspected periodically to ensure that it is safe for use.
- the pins used to force the suppositories out of the molds are (b) (4) It is not easily cleanable and is a direct product contact surface. Several pins were observed to be missing. The pins are not inspected periodically to ensure that it is safe for use.
- the ejector bin in which the suppositories are placed to ensure they are cool is plastic with clear plastic tape holding a piece of what appeared to be heavy paper inside of it. This is not easily cleanable and is a direct product contact surface.

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- the funnel hopper in which the suppositories flow is plastic with several scratches and is not easily cleanable. This is a direct product contact surface.

OBSERVATION 11

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.

a) in the suppository mixing room the spatula, with product residue on it, that is used to scrape in process product off the sides of the wall of tank 51 was observed during the manufacture of lot #9G115B to be sitting on the portable metal steps that the operator steps on to access the tank.

b) the fans used in the Infant and Adult Glycerine Suppository room to cool the suppository molds were observed on 7/16/09 to have accumulations of debris.

OBSERVATION 12

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, during a tour of the facility on 7/15/09 the following deviations from the procedure "Cleaning and Sanitizing Batching Equipment, Tanks and Totes" #WI-PM-0056 effective 4/06/09 were observed:
a) mixing tank #50 had a "ready for use" sign affixed to it, the "in use" tag was not completed, the tank was observed to have product in it. According to management the next suppository batch had been started, lot #9G123B was in the melting phase of production.
b) the "Tote or Tank Activity Record" for tanks 50 and 51 did not have any entries for the use of those tanks after 7/2/09.
c) mixing tank #40 was observed to have a "ready for use" sign affixed to it, the "in use" tag was not completed. We were informed by the operator that Hemorrhoid Cream, lot #9G109B was in the mixing tank.
d) the "Tote or Tank Activity Record" for tank #41 was observed with the entry "7/15/09 Hem Oint 9F109B" - as mentioned above that product was observed in tank #40.
e) the "Tote or Tank Activity Record" for Tank #40 did not have any entries after 6/29/09.

OBSERVATION 13

Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used and description in sufficient detail of the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically, the procedure "Cleaning and Sanitizing Batching Equipment, Tanks and Totes #WI-PM-0056 effective 4/06/09

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does not include instructions specific to differently designed pieces of equipment i.e. Infant and Adult Glycerine suppository filling line, (b) (4) suppository filling line, alcohol prep pad filling line, bottle filling line and tube filling line.

OBSERVATION 14

Records of the inspections of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically, the Infant and Adult Glycerin Suppository Molding Press Machine and the (b) (4) Scale Automatic Weighing Machine (used for packaging the Glycerin Suppositories) have no records of qualification.

Laboratory

OBSERVATION 15

The number of containers to be sampled is not based upon appropriate criteria.

Specifically, the procedure "Sampling, Testing, Approval and Release of Incoming Chemical Materials #WI-QC-0203 effective 7/14/08 does not specify the number of containers within a lot of raw material to sample.

OBSERVATION 16

The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established and documented.

a) As the method "HPLC Analysis - Phenylephrine HCl Content for Gel, Suppositories, Ointment #WI-LAB-0117 effective 5/28/08 is currently being run, it has not been validated.
b) The method HPLC Analysis - Phenylephrine HCl and Pramoxine HCl Content #WI-LAB-0120 effective 6/15/07 has not been validated.

OBSERVATION 17

The use of instruments not meeting established specifications was observed.

Specifically, the (b) (4) HPLC was used for assay of several OTC finished products prior to the PM/OQ/PV being completed.

Production

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OBSERVATION 18

All major equipment used during the production of a batch of drug product is not properly identified at all times to indicate contents.

a) tank #50 was observed with a "Ready for Use" tag on it. The tank contained the product Hemorrhoidal Suppository with Phenylepherine, lot #9G123B.

b) mixing tank #40 was observed to have a "ready for use" sign affixed to it. We were informed by the operator that Hemorrhoid Cream, lot #9G109B was in the mixing tank.

OBSERVATION 19

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, this firm has not validated any of their manufacturing processes for OTC drug products. Examples of OTC drug products currently manufactured under contract and/or their own label include Infant Hemorrhoidal Suppositories, Adult Phenylepherine and other active ingredient Hemorrhoid Suppositories, Mouthrinse products, Antibacterial towelettes, Sterile Lubricating Jelly, Sterile Alcohol Wipes, Cold Sore Medication, Acne pads and Lice Kits.

OBSERVATION 20

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established.

a) operators were observed carrying the Infant and Adult Glycerin Suppository (b) (4) from the suppository mold machine over to the mixing vessel. The operators touched (b) (4) after touching the movable metal steps, (b) (4) touched their clothes and were exposed to the air.

b) (b) (4) were observed in the Glycerin Suppository room. (b) (4) have been sitting there for up to four weeks. Some are covered by a thin plastic bag, some are not covered at all and some of the bags have holes in them.

OBSERVATION 21

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically, labels were observed unattended in the staging area. According to management this is standard procedure for all products and the labels can be left unattended in the area from 1 hour up to 2 days.

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