DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	10/21/2008 - 10/29/2008* FEI NUMBER 2411192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Robert P. Reichman, Vice President, Worldwide Quality/Regulatory Affairs

FIRM NAME	STREET ADDRESS
Professional Disposables International, Inc.	2 Nice Pak Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orangeburg, NY 10962-1317	Pharmaceutical 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 I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, the firm lacks a written standard operating procedure (SOP) which requires all investigations to: sufficiently explain the discrepancy being investigated, assess the impact of the discrepancy on product quality, contain a sufficient root cause analysis, contain corrective and preventative actions, assess the need to expand to other batches of the same drug product (or other drug products), and be completed in a timely manner. As a result, numerous investigations reviewed during the inspection were found to be inadequate. The following are a small sample of inadequate non-conformance investigations reviewed during the inspection:

a. Report (b)(4) for Sani Hands for Adults Wipes, lot # 7M163RUF, for incorrect lot code on packets
b. Report (b)(4) for (b)(4) Hand Sanitizer, lot (b)(4) for low packet weights which failed AQL limits
c. Report (b)(4) for Sand Hands ALC, lot #8A327RBG, for incorrect packet weights due to incorrect weight specification in batch record
d. Report (b)(4) for Alcohol Sterile Prep Pads, lot #8C034BEA, for leaking packets which failed AQL limits

OBSERVATION 2

Written procedures are not followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

Specifically, the firm failed to follow SOP #Corp Prac-001, entitled, *Annual Product Review*, in that, the firm has not conducted, and documented, Annual Product Reviews for any of their drug products, since 2005.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Paul C. Mouris, Investigator 	10/29/2008

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OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, SOP #WI QAS-010, entitled, *Investigating Analytical OOS Results*, is not in compliance with cGMP's, in that, it allows the firm to invalidate an initial Out of Specification (OOS) result with (b)(4) in-specification, retest result. The SOP should require the firm to retest in, at least, (b)(4) (i.e. (b)(4) the number of OOS results) in order to invalidate an initial OOS result. Additionally, the SOP should require the firm to document their attempt to determine an assignable cause for the initial OOS result, even after duplicate retests results are found to be within specification. The following are examples of OOS investigations in which the firm invalidated an initial OOS result with only (b)(4) retest result, which met specification:

a. OOS Investigation (b)(4) for PDI Duo Swab, lot #7K035ABC, for low Iodine assay (via titration method)
b. OOS Investigation (b)(4) for PDI Medium Alcohol Pads, lot #8B086EFC, for low alcohol assay

OBSERVATION 4

Master production and control records lack a statement of theoretical yield including the maximum and minimum percentages of theoretical yield beyond which investigation is required.

Specifically, master packaging/batch records of numerous drug products, manufactured and packaged by the firm, fail to contain actual yield *specifications*, beyond which investigation is required. The following are a small sample of drug products manufactured and packaged by the firm; yet, have no actual yield specifications in their master packaging records:

a. (b)(4)
b. PDI Povidone Iodine Prep Pads
c. Sani-Hands II Hand Sanitizer Wipes, 220 count

* DATES OF INSPECTION:
10/21/2008(Tue), 10/22/2008(Wed), 10/27/2008(Mon), 10/29/2008(Wed)

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	Paul C. Mouris, Investigator	10/29/2008