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	10/14/2010 - 10/21/2010* FEI NUMBER 2411192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mrs. Melanie M. Leibowitz, Senior Director 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 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 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 fails to follow the written standard operating procedure (SOP) which requires all Investigation to; sufficiently explain the discrepancies being investigated, assess the impact of discrepancy on product quality, contain root cause analysis, contain corrective action and preventive action, and assess the need to expand investigation to other batches of same drug product. As a result numerous investigations were found to be inadequate. The following are some examples of inadequate non conformance investigations reviewed during the inspection:

- Non conformance report (b)(4) for Sani Hands ALC 135, Lot# 9F027BBR, for too low % of Ethyl Alcohol.
- Non conformance report (b)(4) for Sani Hands Kids 50 ct, Lot# 9F027FDC, for too low % of Ethyl Alcohol.
- Non conformance report for PDI BZK Twilt Bulk, Lot# 9B284GD1, for too low % of Benzalkonium Chloride.
- Non conformance report (b)(4) for PDI BZK Twilt Bulk, Lot# 9B284FR1, for too low % of Benzalkonium Chloride.
- Non conformance report (b)(4) for (b)(4) BZK Twilt, Lot# (b)(4) , for too low % of Benzalkonium Chloride.
- Non conformance report (b)(4) for PDI BZK Twilt Bulk 3's, Lot# 9C036GD1, for too low % of Benzalkonium Chloride.
- Non conformance report (b)(4) for PDI BZK Twilt Bulk 1's, Lot# 9C036FR1, for too low % of Benzalkonium Chloride.
- Non conformance report (b)(4) for PDI BZK Antiseptic Twilt Bulk, Lot# 9C036ED1, for too low % of Benzalkonium Chloride.

Note: This is repeat observation from last inspection ending on 10/29/2008.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sony Mathews, Investigator	10/21/2010

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OBSERVATION 2

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

Specifically, Report (b)(4) for PDI PVP Duo Swab, Lot# 11001553, for incorrect liquid used in manufacturing, the firm failed to follow SOP WI OPS I-21, entitled, ~~Iodine or PVP~~ Line Clearance Checklist OP 501 500 A 500 09/21/2010, when they fail to check drum label as Iodine (b)(4) Scrub before continuing filling process.

OBSERVATION 3

Procedures describing the warehousing of drug products are not established and followed.

Specifically, The firm failed to follow the section 7.9.1.3 " (b)(4) (b)(4) of SOP QAS -004, entitled, *Receiving, Inspection, Sampling, Release, and or Rejection of Materials Incoming Procedure* and during the walk thru, QA released incoming raw material such as (b)(4) b)(4) were observed in designated quarantine area.

* DATES OF INSPECTION:
10/14/2010(Thu), 10/15/2010(Fri), 10/19/2010(Tue), 10/21/2010(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sony Mathews, Investigator	10/21/2010