

**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		04/13/2011 - 04/20/2011*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER
TO: Mr. Robert P. Reichman,, VP World Wide Quality / Regulatory Affairs,		2411192

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 whether or not the batch has been already distributed. Specifically, approximately 16 batches of PDI Alcohol Swabs were tested in duplicate, for finished product release. This duplicate testing was not investigated. The following are some examples of the lots that were tested in duplicate Lot# 11100348, 11100368, 11005558, 11100500 and 11100390.

OBSERVATION 2

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

Specifically, SOP No WI QAS-058 entitled *Chain of Custody Procedure for QA Lab Samples*. The section 3.5.6 states that the (b)(4) (b)(4) . This procedures were not followed by the laboratory analysts.

*** DATES OF INSPECTION:**

04/13/2011(Wed), 04/14/2011(Thu), 04/15/2011(Fri), 04/20/2011(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sony Mathews, Investigator 	04/20/2011