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	06/22/2011 - 07/05/2011* FEI NUMBER 2411192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. 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	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

Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically, MedWatch# 456119 was filed on a patient with hemophilia who developed Bacillus spp bacteremia after receiving Factor 8 infusion. The hospital reported to find Bacillus spp in PDI alcohol prep pads, Lot# 11100055. Your company confirmed such finding and also found the same species, Bacillus cereus, in additional PDI Alcohol Prep Pad finished product, Lot# 11100515, 11003269, 11003222 and 11002166. Your root cause analysis for Alcohol Prep Pad Product family dated 06/24/11 demonstrated that Bacillus cereus was recovered from the applicator used to manufacture the alcohol prep pads. However, your corrective action and prevention action from your non-conformance report# NYH-11-0131 addressing the recovery of Bacillus cereus in the non-sterile PDI Alcohol Prep Pads does not propose any necessary changes to include microbiological testing on each lot of applicator used in the production of both non-sterile and sterile alcohol prep pads as your Work Instruction QAS-012 approved in July 2008, entitled, "QA Raw Material Inspection Testing and Disposition" 3.1.13 states, (b)(4) [redacted] As the result, none of the applicator lots used in the production of PDI Alcohol Prep Pad finished product, Lot# 11100055, 11100515, 11003269, 11003222 and 11002166, had a microbiological testing performed prior to making into the finished product.

OBSERVATION 2

The written stability program for drug products does not include test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability.

Specifically, your Standard Operating Procedure (SOP) QAS-017, entitled, "Marketed Product Stability Program" 7.1.7 states, (b)(4) [redacted] Such SOP is found to be deficient for it fails to monitor the microbiological aspects of the drug products

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Alice S. Tsao, CSO	07/05/2011

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throughout the proposed shelf life. As the result, any possible out-of-specification microbiological testing results that could occur after product release and during stability will not be captured until after expiry.

*** DATES OF INSPECTION:**
06/22/2011(Wed), 06/23/2011(Thu), 06/24/2011(Fri), 06/29/2011(Wed), 06/30/2011(Thu), 07/05/2011(Tue)

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	Alice S. Tsao, CSO	07/05/2011