

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

158-15 Liberty Ave.
Jamaica, NY 11433
(718) 340-7000 Fax: (718) 662-5661
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

06/22/2011 - 07/05/2011*

FBI NUMBER

2411192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

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

FIRM NAME

Professional Disposables International, Inc.

STREET ADDRESS

2 Nice Pak Park

CITY, STATE, ZIP CODE, COUNTRY

Orangeburg, NY 10962-1317

TYPE ESTABLISHMENT INSPECTED

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)

(b)(4)

(b)(4)

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)

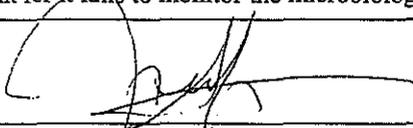
(b)(4)

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

Alice S. Tsao, CSO



DATE ISSUED

07/05/2011

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FOOD AND DRUG ADMINISTRATION**

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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)

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