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	08/06/2008 - 08/12/2008* 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	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

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy and completeness.

Specifically, a review of the microbiological testing conducted by the firm on their purified water revealed that the firm failed to follow *SOP WI QAS-028,* entitled, *How to Issue, Maintain, Use & Archive Lab Notebooks and Logbooks*, in that, there is a lack of a review of the firm's microbiology laboratory's testing by Quality personnel. This may have contributed to the firm's reporting of results as negative where in fact the results were out of specification on several different occasions.

For example, on 7/14/08, the firm reported negative results for samples drawn from Port (b)(4) Port (b)(4) and (b)(4) Purified Water use points and stated the water met release specifications in their Water Analysis Logbook; however the actual results recorded in Laboratory Notebook (b)(4) showed positive results for Pseudomonas and other bacteria. The water was subsequently released for use in manufacturing and no investigation was conducted into the OOS results.

OBSERVATION 2

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, the firm failed to follow *SOP QAs-001*, entitled, *Customer Complaint Coordination and Documentation* and *SOP QAS-027*, entitled, *Complaint Handling Procedure,* in that:

a. Numerous complaints reviewed were not completed within the required timeframes and there was no written justification explaining the lateness in the complaint record as required by the SOP. For example, some complaints which should have been closed out in (b)(4) working days were as much as (b)(4) months late without a written justification.

b. Several investigations conducted into complaints received were inadequate. For example, retain samples were not checked, or, in another case the complaint was closed out without attempting to retrieve further information about a possible serious adverse event.

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OBSERVATION 3

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

Specifically, during a walkthrough of both warehouses the following was observed:

a. There are no written procedure in place describing procedures for the firm to follow to ensure appropriate storage conditions of drug products are maintained. For example, the firm does not monitor or record the temperature in both warehouses where finished drug products that are labeled with temperarure storage requirements are stored.

b. The firm failed to follow *SOP OPS-027*, entitled, *Control of Monitoring and Measuring Devices*, in that, the (b)(4) (b)(4) temperature monitoring devices in the firm's quarantine room of the firm's distribution warehouse had not been calibrated. Specifically, both recorders were observed to have been out of calibration since 4/2008. In addition, the chart not been replaced on 8/2/08, so the results were being recorded over the previous month's data.

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*** DATES OF INSPECTION:**
08/06/2008(Wed), 08/07/2008(Thu), 08/08/2008(Fri), 08/12/2008(Tue)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Demitria J. Argiropoulos, Investigator

SEE REVERSE OF THIS PAGE	DATE ISSUED
	08/12/2008