

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

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661	DATE(S) OF INSPECTION 5/2/2019-5/28/2019*
	FEI NUMBER 2411192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Wendy F. Gould, Vice President, Quality and Regulatory Affairs

FIRM NAME Professional Disposables International, Inc.	STREET ADDRESS 2 Nice Pak Park
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CITY, STATE, ZIP CODE, COUNTRY Orangeburg, NY 10962-1317	TYPE ESTABLISHMENT INSPECTED Drug and Device Manufacturer
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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 WE OBSERVED:**

**OBSERVATION 1**

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, your high performance liquid chromatography (HPLC) data acquisition software, (b) (4), did not have sufficient controls to prevent the deletion or alteration of data files:

- (A) On 5/10/2019, it was observed that the Quality Control (QC) Manager has the ability to delete (b) (4) result files from the raw data file folder. The lead chemist also has the same access privilege as the QC Manager.
- (B) The sequence files and the report files audit trails are not enabled to ensure the integrity and reliability of the electronic data generated.
- (C) The Method Audit Trail covering the time period of 11/6/2007 to 5/7/2019 for test method # TM 233, which is used in assaying (b) (4) and related substances in the bulk solution, finished products and stability of Prevantics products, shows various changes were made to the test method. However, no justifications were documented for the changes that were made. For example, the method audit trail shows changes were made to the test method on 9/18/2018 including changed retention time, changed calibration factor, changed area, and replicate deleted with calibration time, replicate inserted with calibrate time.
- (D) The QC Manager stated the audit trail is not reviewed. The firm also does not have an established procedure governing review of audit trails.

**OBSERVATION 2**

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

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Specifically, analysis of test injections with actual samples using HPLC instrument is regularly performed for impurities testing in Prevantics products prior to official analysis/run. The results of the test injections are not always included in the official result packet for review. For example, test injections for the analysis of impurities in the Prevantics finished products listed below were performed prior to the official sample analysis. However, the test injections were not documented in the laboratory notebook and the results of the test injections were not reviewed. The following samples were analyzed under the same sequence run on 9/17/2018:

Product Name	Item #	Lot #	Product Category
Prevantics Device Swab	B19600	11801272	Device
Prevantics Device Swab Strip	B123ST	11801212	Device
Prevantics Device Swab Strip	B123ST	11801211	Device
Prevantics Swab	B10800	11801210	Drug
Prevantics Compact Swab	S42850	11801235	Drug
Prevantics Swab Bulk	B11400	11801226	Drug
Prevantics Swab Bulk	B11400	11801227	Drug

**OBSERVATION 3**

Written records are not made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically, according to Analytical Lab Logbook # 028 and the (b) (4) result folder, (b) (4) bulk solution (Lot # 9B020) was tested twice on 2/2/2019 for assaying the percentage of (b) (4). The initial result found at 8:29 AM was 39.7% w/w, which is outside of specification of (b) (4)% w/w. The sample was retested at (b) (4) PM and the result was found within specification. No documentation or investigation was initiated by the firm for the initial out-of-specification.

**OBSERVATION 4**

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Established test procedures are not followed.

Specifically,

- (A) Test method TM 370, entitled, "% CHG in Chlorascrub Products" requires the use o (b) (4) chromatographic method for assaying the (b) (4) in the bulk solution and finished products. However, the chromatographic method created in (b) (4) for the testing of Prevantics products was setup using isocratic condition.
- (B) Section 8.7.3 of test method TM 233, entitled, "Content of PCA and Related Substances in Chlorascrub™/Prevantics™ Products" states "Inject the Working Standard Solution (b) (4) times".

The sequence sample description for the following samples analyzed under the same sequence run on 9/17/2018 shows seven (7) working standard solutions were injected:

Product Name	Item #	Lot #	Product Category
Prevantics Device Swab	B19600	11801272	Device
Prevantics Device Swab Strip	B123ST	11801212	Device
Prevantics Device Swab Strip	B123ST	11801211	Device
Prevantics Swab	B10800	11801210	Drug
Prevantics Compact Swab	S42850	11801235	Drug
Prevantics Swab Bulk	B11400	11801226	Drug
Prevantics Swab Bulk	B11400	11801227	Drug

**OBSERVATION 5**

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, the following non-conformance investigations were not closed out in a timely manner and the recommended disposition were implemented without quality approval:

- Event Investigation # 17-0111-NY was initiated on 11/2/2017 for Sani-Hands Instant Hand Sanitizing Wipes, 220 ct (Item # P15984; Lot # 11701399) after finding that (b) (4) cases of the finished product was

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produced with the 11/19 expiration date while the rest of the lot was labeled with the 10/19 expiration date. The decision to release the subject lot with two expiration dates under one lot code was made without final approval by the quality unit. The investigation report was not signed by the quality unit until 5/10/2019. The lot of product was released in November 2017.

- Non-conformance Incident/Event # 17-0109-NY was initiated on 11/15/2017 to determine the disposition of expired raw materials used in the manufacturing of (b) (4). The Non-Conformance Incident Form was not signed by the quality unit until 5/2/2019. The expired materials were rejected and removed from inventory in April 2018.

**OBSERVATION 6**

Procedures describing the warehousing of drug products are not followed.

Specifically, applicator cloth (Item # 3OU351; Lot # 1900001750) used in the manufacturing of (b) (4) was shipped from your firm to your customer's warehouse on May 6, 2019 while the material was still in "Hold" status. This lot of material was shipped out of your facility without review or oversight by the Quality Unit.

**OBSERVATION 7**

Personnel training is not documented.

Specifically, in 10/2018, the firm initiated CAPA # NYC 18-012 (which is still open) to determine the root cause(s) for two products having finished units that were: a) "dry" - meaning that the finished packet pad or swab contained none or an insufficient amount of solution; or b) "empty" - that is having no product inside the sealed packet. The two products were: a) Item # B60307, PDI Sterile Alcohol Prep Pad - Medium, which is a drug, and b) Item # B16400, PDI Adhesive Tape Remover Pad, which is a medical device; and from 6/2017 to 10/2018, the firm received 10 complaints of dry units for the Sterile Alcohol Prep Pads, and 4 complaints for dry or empty units for the Adhesive Tape Remover Pads. The firm identified the root cause of the failure as due to improper set-up of the (b) (4) packaging line machine (b) (4) when the machine was changed-over for production of the Adhesive Tape Remover Pads after the machine had been used for production of the Sterile Alcohol Prep

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Pads or vice-versa. However, a review of the mechanics training records found that for three of the (b) (4) mechanics responsible for performing the machine set-up, there is no record or documentation that the mechanics were trained to perform this function.

**OBSERVATION 8**

Software used as part of the quality system has not been validated for its intended use according to an established protocol.

Specifically, the firm has two systems that are, at least in part, software controlled, but each has not been validated for its intended use according to an established protocol. The two systems are, as follows: a) the complaint handling system - which the firm noted is an Excel "spreadsheet", but this system is not used simply to "record information", because it actually generates the complaint numbers. Also, the complaint information is, initially, recorded electronically, and the individual entering the complaint information on the complaint intake form can delete the form (inadvertently or otherwise); and b) the (b) (4) asset management system - which is used, in part, to schedule preventive maintenance activities for production equipment, such as the (b) (4) packaging machine (b) (4) which is used to package a drug and a device.

**OBSERVATION 9**

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, with regards to the cleaning validation for the (b) (4) packaging machine (b) (4), the cleaning revalidation report was fully approved on 5/14/2019. However, the validation is inadequate, in that: the packaging machine when in operation has (b) (4) " nozzles, which dispenses solution, and each nozzle has (b) (4) channels for a total of (b) (4) channels. However, the firm swabbed from the exit point of only one channel to obtain the sample that was used for bacterial testing after the nozzles were cleaned. (The firm could

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not obtain a swab from the inside of the (b) (4) channel, because the diameter of the channels was (b) (4) inches which was much smaller than the diameter of the swab tip.) In short, the firm did not collect samples from enough channels to assert that this sampling was "representative". Hence, the conclusion that the cleaning method is adequate is not fully supported.

**OBSERVATION 10**

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been adequately established.

Specifically, on 5/14/2019, I (Investigator Joseph) observed that the reportedly "dedicated" nozzles (which the firm refers to as (b) (4) ) were held in storage in a sealed plastic bag, identified only with a stick-on label, noting the date of cleaning and the name of the equipment component ("5/02/19 nozzles"). The label did not identify for which product the nozzles are dedicated. The nozzle, which is a component of the (b) (4) packaging machine (b) (4) can be used to dispense the solution for two products: the PDI Sterile Alcohol Prep Pads (a drug product) or the PDI Adhesive Tape Remover Pads (a medical device).

**OBSERVATION 11**

Complaints involving the possible failure of to meet any of its specifications were not evaluated where necessary.

Specifically, the firm received two complaints with regards to leaking packets of the PDI Sterile Lubricating Jelly II, which is manufactured for the firm by a contract manufacturer (b) (4) , and the firm sent the complaints to the contract manufacturer for follow-up investigation. However, the firm recorded the complaints as closed, but there is no sign-off by QA, indicating that the contract manufacturer's respective investigation and corrective action were evaluated by QA and deemed adequate. The two complaints were: a) Complaint No.: NY180207 - dated 8/22/2018, and b) Complaint No.: NY180252 - dated 10/9/2018.

**OBSERVATION 12**

Requirements that must be met by suppliers have not been adequately established.

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Specifically, the firm's procedure, "Supplier Management", Revision Level: 9, Issue Date: August 2018, specifies that for a current supplier that is classified as a primary supplier - and from a quality perspective is deemed "critical" - that every (b) (4) the firm will perform a supplier survey or a Request for Information (RFI) Form completed and verified, or the supplier must submit to the firm an informative self-assessment document. However, the firm's procedure does not specify what actions, if any, the firm will take if any of the above information from the supplier is deemed inadequate.

**\*DATES OF INSPECTION**

5/02/2019(Thu), 5/03/2019(Fri), 5/06/2019(Mon), 5/07/2019(Tue), 5/08/2019(Wed), 5/09/2019(Thu), 5/10/2019(Fri), 5/13/2019(Mon), 5/14/2019(Tue), 5/15/2019(Wed), 5/16/2019(Thu), 5/17/2019(Fri), 5/28/2019(Tue)

X Gregson A Joseph  
Investigator  
Signed By: Gregson A. Joseph -S  
Date Signed: 05-28-2019 11:53:48

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**Annotations to Observations**

- Observation 1: Not annotated
- Observation 2: Not annotated
- Observation 3: Not annotated
- Observation 4: Not annotated
- Observation 5: Not annotated
- Observation 6: Not annotated
- Observation 7: Not annotated
- Observation 8: Not annotated

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**Annotations to Observations**

- Observation 9: Not annotated
  
- Observation 10: Not annotated
  
- Observation 11: Not annotated
  
- Observation 12: Not annotated

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."