DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	7/23/2019-8/14/2019* FEI NUMBER 3002754162

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joel J. Meyerson, President

FIRM NAME	STREET ADDRESS
Pure Source LLC	9750 NW 17th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Doral, FL 33172-2753	Contract OTC 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:
QUALITY SYSTEM

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your QCU did not properly assess a total aerobic microbial count failure at (b) (4) colony forming units (CFUs/g) with a specification of less than or equal to 100 CFU's/g test result with an identification of the organism as Bacillus spp. in Topiderm SPF-30 Face Cream lot G3P formula (b) (4) This was a retain sample that was tested to ensure that previous test methods and formulations comply with finished drug product specifications.

B. You did not reject and discontinue the use of your (b) (4) until it met your specifications when you obtained TOC and microbiological failures on 4/11/2018 (DEV#180404). You continued to use the component (b) (4) batches of OTC drug products and used the finished product test results for the release of these batches that were processed using the component ((b) (4))that failed your (b) (4) specifications.

C. Deviation 180910 covered the release of the active drug ingredient (b) (4)) (b) (4) . This deviation documentation identified that that no finished OTC drug products were made using this active drug substance. This deviation also states that all finished drug products require assay testing prior to release and this would ensure that no product is released to market that does not meet specification. There was no

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joanne E King, Investigator	X Joanne E King Investigator Signed By 1300174867 Date Signed 08-14-2019 16 12 44	8/14/2019

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FIRM NAME Pure Source LLC	STREET ADDRESS 9750 NW 17th St
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requirement for corrective and preventive action for how untested components may receive a released status by the QCU and be accessible to the production staff.

This is a repeated 483 item 3 from your 2/8/18 - 3/1/18 inspection.

PRODUCTION SYSTEM

OBSERVATION 2

Deviations from written production and process control procedures are not recorded and justified.

Specifically, in (b) (4) . The batch record did not identify the containers that are required for bulk storage and no deviation for using metal drums for (b) (4) , was documented.

MATERIALS SYSTEM

OBSERVATION 3

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, a review of your (b) (4) supplier questionnaire lacked information on the registration of the manufacturers. The regulatory history section 5.1 of this questionnaire identified that this supplier has been subject to periodic audits by competent authorities. Registration documentation provided to you by this supplier identified that it has only been evaluated as a food facility.

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This is a repeated 483 item 6 from your 2/8/18 - 3/1/18 inspection.

***DATES OF INSPECTION**

7/23/2019(Tue), 7/24/2019(Wed), 7/25/2019(Thu), 7/26/2019(Fri), 7/29/2019(Mon), 7/30/2019(Tue), 7/31/2019(Wed), 8/01/2019(Thu), 8/02/2019(Fri), 8/12/2019(Mon), 8/14/2019(Wed)

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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."