

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768		DATE(S) OF INSPECTION 3/12/2025-3/20/2025* FEI NUMBER 3007209985			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Daniel A. Bashour, Site Head					
FIRM NAME CoreRX Inc.		STREET ADDRESS 14205 Myerlake Cir			
CITY, STATE, ZIP CODE, COUNTRY Clearwater, FL 33760-2824		TYPE ESTABLISHMENT INSPECTED Biologic 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 WE OBSERVED: OBSERVATION 1 Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically, A. Your (b)(4) process is not required to run continuously and is allowed to be completed over multiple (b)(4). The (b)(4) and other (b)(4) materials such as (b)(4) are held (b)(4) or for (b)(4) at (b)(4) until the (b)(4) process is finished. For example, the (b)(4) process for Palforzia batch (b)(4) began on (b)(4), the (b)(4) batch (b)(4) were held (b)(4) on (b)(4), before resuming (b)(4) on (b)(4). Due to a power outage, the (b)(4) was paused on (b)(4), the (b)(4) along with other (b)(4) materials were placed on hold from (b)(4). Your (b)(4) process for batch (b)(4) resumed on (b)(4), and was completed on (b)(4). Palforzia batch (b)(4) was released to your (b)(4) for further (b)(4) to the U.S market. Your firm has not established an appropriate hold time or validated the non-continuous					
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manufacturing process to support the (b)(4) storage of the (b)(4) (b)(4) and other (b)(4) materials (b)(4) or for (b)(4) process has begun. B. There are no established written procedures for how to store and monitor the (b)(4) materials, including (b)(4) when held (b)(4) or for (b)(4) the (b)(4) process. C. You have not established procedures for resumption of the (b)(4) process after (b)(4) materials have been held (b)(4) or for (b)(4).			
OBSERVATION 2 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. Incident No. INC-24-00219, was initiated on July 8, 2024, for a site wide unplanned power outage that occurred on July 3, 2024. During this outage, manufacturing of Palforzia 20mg batch number (b)(4) was interrupted during the (b)(4) process. The (b)(4) process for Palforzia batch (b)(4) was placed on hold for (b)(4) and completed on (b)(4). Additionally, the (b)(4) experienced a temperature excursion due to the outage. Your investigation concluded that there was no product impact; however, no product impact assessment or risk assessment was conducted for Palforzia batch (b)(4), or for the products stored in the (b)(4). Palforzia batch (b)(4) was released to your client for further			
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processing and distribution to the U.S market. B. Incident No. INC-24-00034, was initiated on January 24, 2024, for missing Environmental Monitoring (EM) samples for viable and non-viable particulates in the GMP manufacturing areas for (b)(4). Your investigation concluded that there was no product impact, but no product impact assessment was conducted. During this period, (b)(4) Palforzia batches were manufactured and subsequently released to your client for distribution.					
OBSERVATION 3 Written procedures are not established and followed for the cleaning and maintenance of equipment, including (b)(4), used in the manufacture, (b)(4) of a drug product. Specifically, A. On March 12, 2025, multiple dissembled equipment parts of the (b)(4) (b)(4), including the (b)(4) of a (b)(4) were observed to have visible (b)(4). B. You failed to establish cleaning instructions and documentation logs for the (b)(4) connecting to the (b)(4) used in the (b)(4) of excessive (b)(4) during the production of finished drug product. C. On March 12, 2025, (b)(4) was used in multiple location on (b)(4) surfaces of production equipment including: i. (b)(4) of the (b)(4) ii. (b)(4) of the (b)(4)					
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iii. (b)(4) D. On March 12th, 2025, we observed that you have not performed the verification of major clean activities in (b)(4) following the manufacturing of finished drug product Palforzia batch # (b)(4) conducted on (b)(4), documented in (b)(4) Room (b)(4) issued on (b)(4).			
OBSERVATION 4 The responsibilities and procedures applicable to the quality control unit are not in writing. Specifically, you fail to establish a procedure to adequately address the control of documents in your manufacturing suite when not in use. The following blank documents and records were observed in the common support area of the manufacturing suites during the walkthrough on March 12th, 2025 i. -0147 "Line Clearance Form for Manufacturing Operations" ii. Attachment 3 of SOP-0342 " Operation, Maintenance, and Calibration of the (b)(4) System, including (b)(4) Page 29-44 iii. Attachment 2 of SOP-0368 " Cleaning of (b)(4), for the (b)(4)", Major Cleaning of (b)(4) (Page 1-3)			
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OBSERVATION 5

Buildings used in the manufacture, (b)(4) of drug products are not maintained in a clean and sanitary condition.

Specifically, during our inspection walkthrough on March 12th, 2025, we observed the following deficiency:

A. Multiple cracks on the (b)(4) on the -- were observed in production suite --, used for the (b)(4) for the manufacturing of 0.5mg, 10mg, and 20mg of finished drug product Palforzia.

B. A hole on the (b)(4) of the (b)(4) of the (b)(4) and no work order having been initiated for repair.

C. Paint peeling off the -- inside production suite --, which is used for the (b)(4) used for the manufacturing of 20mg and 100mg of finished drug product Palforzia.

OBSERVATION 6

Written procedures are not followed for the storage of components and drug product (b)(4)

Specifically,

A. On March 18, 2025, we observed that material was placed in the incorrect location in the (b)(4), including:

Material Name and Batch Number	Location Assigned in	Location observed in
Microcrystalline Powder	(b)(4)	(b)(4)

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Batch:	(b)(4)														
Colloidal Silicon Dioxide	(b)(4)	(b)(4)													
Colloidal Silicon Dioxide	(b)(4)	(b)(4)													
B. You failed to assign corresponding (b)(4) in the finished product (b)(4) used to store active pharmaceutical ingredient (API) and finished drug product following - implementation on August 17th, 2022. On March 18, 2025, your team failed to identify the location of API Peanut Allergen Powder Partially Defatted (b)(4) Batch (b)(4) with assigned - location (b)(4) without more than (b)(4) firm employees searching the entire finished product (b)(4).															
*DATES OF INSPECTION 3/12/2025(Wed), 3/13/2025(Thu), 3/14/2025(Fri), 3/17/2025(Mon), 3/18/2025(Tue), 3/19/2025(Wed), 3/20/2025(Thu) X Thai D Truong Investigator Signed By: 0014274389 Date Signed: 03-20-2025 15:39:39															
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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."