DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	6/1/2026-6/3/2026
	FEI NUMBER 3004875840

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jack V. Smith, Director Operations

FIRM NAME	STREET ADDRESS
Sciteck Diagnostics	317 Rutledge Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fletcher, NC 28732-9328	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

Records do not identify the test equipment used to perform product measurement activities.

Specifically,

Production records for finished (b) (4) were reviewed lacked identification of the specific test equipment used during measurement activities associated with product release. The firm uses multiple pieces of equipment of the same type (e.g., multiple volumetric flasks in various sizes, multiple megaohm meters) but does not record equipment IDs, serial numbers, or asset references in the batch record at the time of use. Specific examples observed include:

- Batch record for (b) (4) with batch number (b) (4), prepared on (b) (4) does not identify the specific scale used in the addition of chemical ingredients weighed out in the quantity of (b) (4), nor does it identify the volumetric flask used. Your Manufacturing Manager stated that your firm utilizes multiple volumetric flasks in various sizes, with no means to determine from the record which was used.
- Batch record for (b) (4)) with batch number (b) (4) prepared on (b) (4)

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references a pH reading taken during batch formulation, but no equipment ID is recorded for the pH meter used.

This deficiency was observed across all reviewed production records reviewed during the inspection.

OBSERVATION 2

Production controls do not include documentation of procedures and methods for the control of production and implementation of monitoring and measurement of process parameters and product characteristics.

Specifically,

A review of the firm's production and service provision activities revealed that documented procedures and methods governing key production and monitoring activities are absent or inadequate. Specific examples observed include:

- There is no documented procedure directing the (b) (4) or (b) (4) -making/assembly process. Additionally, your firm relies on an informal lot tracking document referred to as a "(b) (4) lot tracker" or "lot tracking sheet," which is an uncontrolled Excel spreadsheet that serves as the production record, but is not directed by any procedure.
- Your firm maintains a (b) (4) QC tracking chart used to monitor product quality, however no procedure exists according to your Manufacturing Scientist and Manufacturing Manager that directs or describes this monitoring activity, defines the process parameters to be documented as part of the test (such as the lot number of the (b) (4) being assessed), or what should happen to convey the acceptance/rejection of the finished lot upon completion of the QC test.
- Your procedures that directs the general manufacturing and batch mixing process do not specify

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storage conditions for finished bulk batches of your (b) (4) mixtures.

OBSERVATION 3

Documents required by the quality management system have not been controlled.

Specifically,

A review of the firm's documents, labels, and production records revealed that multiple document types are missing document control numbers and/or revision numbers, indicating that the firm's document control system is not effectively implemented. Specific examples observed include:

- Instructions for Use (IFU) for your medical device (b) (4) does not contain a revision number, control number, or an effective/release date, making it impossible to determine which version is current or authorized for use.
- IFU for your medical device (b) (4) does not contain a control number, revision number, or release date.
- For-3 (Standard Batch Filling Form) used for batch filling operations, does not contain a revision number or a release date.
- For-12 (Fill Record) used for filling operations that was reviewed in connection with batch number (b) (4) ((b) (4) , filled (b) (4)) does not contain a revision number or a release date.

The absence of revision numbers and control numbers on these documents prevents the firm from ensuring that personnel are using current, authorized versions of controlled documents, and prevents traceability of document history.

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: 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."