

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER New York District Office 158-15 Liberty Avenue Jamaica, NY 11433 Phone 718-340-7000  Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 03/09/2026 - 03/11/2026
	FEI NUMBER 3031550350

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Raymond J. Davis - Chief Executive Officer / Managing Member**

FIRM NAME VET4U, LLC	STREET ADDRESS 4155 Route 31, Suite 2
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CITY, STATE AND ZIP CODE Clay, NY 13041	TYPE OF ESTABLISHMENT INSPECTED Distributor
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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 (I) (WE) OBSERVED:

**OBSERVATION 1**

Your firm does not have adequate systems and processes to enable compliance with the verification requirements of section 582(c) of Federal Food, Drug, and Cosmetic Act (FD&C Act, as amended by the Drug Supply Chain Security Act (DSCSA).

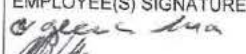


Specifically:

A. Your Quality Document 390, titled Suspect Product, last reviewed on 06/02/2025, and your Quality Document 470, titled Quality Management, last reviewed on 06/02/25, do not establish adequate systems and processes for identifying suspect product and conducting investigations of suspect product in coordination with trading partners.

B. Your Quality Document 440, titled Records, last reviewed on 06/02/2025, does not establish systems and processes to ensure records of suspect product investigations and records related to the disposition of illegitimate product are maintained for at least 6 years.

C. Your Quality Document 390, titled Suspect Product, last reviewed on 06/02/2025, does not establish systems and processes for responding to notifications of illegitimate product from FDA or trading partners.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE   	EMPLOYEE(S) NAME AND TITLE (Print or Type) Ogechi C. Nna, Investigator Sarah E. Venti, Regulatory Counsel Armen H. Youssoufian, Investigator	DATE ISSUED 03/11/2026
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**OBSERVATION 2**

Your firm failed to comply with the requirements of section 582(c) of the FD&C Act, as amended by the DSCSA.

Specifically:

A. Your firm failed to appropriately investigate suspect product in your possession or control as required by section 582(c)(4)(A)(i) of the FD&C Act, as amended by the DSCSA.

For example, on 07/11/2025, a representative from your firm learned from a draft indictment that (b)(6) your firm's primary contact at (b)(4), and (b)(4) were dealing in suspect and diverted product. Your firm failed to investigate product in your possession or control that had been received from (b)(4). This includes approximately (b)(4) units of suspect product which is still in your firm's possession or control.

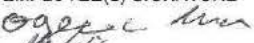

B. Your firm accepted and further distributed product purchased from (b)(4) without first receiving the corresponding Transaction Statement and Transaction Information.

Examples include but may not be limited to:

• On (b)(4), your firm received (b)(4) units of (b)(4) mg tablet (b)(4) lot# (b)(4) from (b)(4). On (b)(4) you then distributed (b)(4) units of product to (b)(4) located in (b)(4). Additionally, on (b)(4) you distributed (b)(4) units of product to (b)(4) located in (b)(4). You were not able to provide (b)(4) transaction statement and transaction information for these (b)(4) units.

• On (b)(4), your firm received (b)(4) unit of lot# (b)(4) ml (b)(4) product, from (b)(4). You then distributed that product to (b)(4) located in (b)(4) on (b)(4). You were not able to provide (b)(4) transaction statement and transaction information for this unit.

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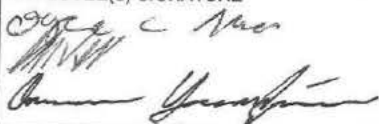
Distributor

• On (b) (4), your firm received (b) (4) units of lot# (b) (4) tablet (b) (4) from (b) (4).  
You then distributed that product to (b) (4) located in (b) (4) on (b) (4).  
You were not able to provide (b) (4) transaction statement and transaction information for these (b) (4) units.

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Sarah E. Venti, Regulatory Counsel  
Armen H. Youssoufian, Investigator

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