DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration 60 8th Street NE Atlanta, GA 30309 404-253-1171 Industry Information: www.fda.gov/oc/industry	2/18/2025, 2/21/2025, 2/24/2025
	FEI NUMBER 3018755991

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Anthony L. Bryant CEO & President

FIRM NAME	STREET ADDRESS
A2A INTEGRATED LOGISTIC INC	1830 Owen Dr Ste 10
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Fayetteville, NC 28304-3412	Wholesale Distributor

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 failed to have systems and processes in place to ensure compliance with the requirements of section 582 (c)(4) of the Food, Drug and Cosmetic Act, as amended by the Drug Supply Chain Security Act (DSCSA).

Specifically,

A. Your document "Pharmaceutical and Medical Surgical Equipment Standard Operating Procedure (SOP)," dated 30 July 2024 (Version 4.0), is inadequate, in part, because it fails to describe systems and processes for (1) identifying suspect product; (2) investigating suspect product in coordination with trading partners, which must include validating any applicable transaction history and transaction information in your possession and verifying the product identifier at the package level; (3) making notifications of suspect and illegitimate product to trading partners; (4) responding to notifications of illegitimate product; (5) making notifications of illegitimate product to FDA; and (6) otherwise investigating to determine whether a product is an illegitimate product.

B. The "Pharmaceutical and Medical Surgical Equipment Standard Operating Procedure (SOP)," dated 30 July 2024 (Version 4.0), defers to Trading Partner A and their compliance department's procedures for suspect and illegitimate product handling and to ensure that the FDA is notified (b) (4) after illegitimate product is identified. When asked for Trading Partner A's relevant procedures, your firm was unable to provide any documentation.

C. The "Pharmaceutical and Medical Surgical Equipment Standard Operating Procedure (SOP)," is limited in scope and, to the extent it does so, provides DSCSA required verification systems for when your trading partner is

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	Sonya M. Edmonds Kristle A. Green	Sonya M. Edmonds, Investigator Kristle A. Green, Consumer Safety Officer	02/24/2025

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Trading Partner A. The SOP does not account for the systems and processes to follow when working with A2A's other trading partners.

OBSERVATION 2

Your firm failed to maintain transaction information.

Specifically:
A. Adequate and complete transaction information was not received from upstream trading partners prior to, or at the time of, transactions. For example, the transaction information from Trading Partner B provided on February 21, 2025, lacked the drug strength and dosage form as well as the container size as required under section 581(26) of the FD&C Act, as amended by the DSCSA. Additionally, the transaction information provided on February 21, 2025, for Trading Partner A lacked the lot number, date of transaction and date of shipment. Also, on February 18, 2025, while conducting the inspection, FDA investigators witnessed boxes containing bottles of (b) (4) (b) (4) mg tablets being picked up by (b) (4) No transaction documentation was provided for this drug product for Trading Partner D when asked by FDA.

B. Your firm was not able to provide evidence that adequate and complete transaction information was provided to downstream trading partners prior to, or at the time of, transactions. For example, Trading Partner C received the transaction documentation only after contacting you on May 9th, 2024, when they informed your firm of concerns with the legitimacy of the drug product, (b) (4)

C. Your firm had product in your refrigerated finished drug product storage area and could not provide adequate transaction information from Trading Partner F when requested during the FDA onsite inspection. Mr. (b) (6) stated that Trading Partner F sent the drugs to him unprompted and did not provide any transaction documentation for (b) (4)

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OBSERVATION 3

Your firm failed to respond to a notification of illegitimate product and keep records regarding suspect product investigations and disposition of illegitimate product. [582(c)(4)(B)(iii), 582(c)(4)(A)(iii) and 582(c)(4)(B)(v)].

Specifically, on May 9, 2024, a meeting between your firm and Trading Partner D was held.

• Your firm was made aware that the packaging on (b) (4) distributed by your firm was not the standard for the product. The vials lacked a NDC and serialized barcode. The outer carton listed (b) (4) as the generic name in contrast to the accepted product which lists the name as (b) (4) Additionally, the (b) (4) unit vials and (b) (4) units vials for the lots (b) (4) respectively only contained linear barcode, foreign language on the box and an English language sticker placed over the foreign language on one side of the box. The package insert for these products were also printed with foreign language as the main language. The (b) (4) unit vial for lot (b) (4) did not contain any barcodes.

• Your firm was unable to provide records demonstrating that you identified additional illegitimate product in your possession or control, and appropriately handled and investigated such product in coordination with Trading Partners C and E.

OBSERVATION 4

Your firm failed to work with only Authorized Trading Partners as required by section 582(c)(3) of the FD&C Act, as amended by the DSCSA.

Specifically, your firm purchased product from Trading Partner E and distributed it to Trading Partner C by means of a drop shipment. Trading Partner E failed to provide Trading Partner C with complete Transaction Information. Trading Partner E is not authorized because they lack appropriate licensure and don't have current annual reporting to FDA.

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OBSERVATION 5

Your firm failed to appropriately identify suspect product. For example, you did not identify as suspect product, product purchased from a source that was new to your firm, that did not possess the necessary wholesale drug distribution state licensure, and where the new source provided incomplete and questionable documents, with the transaction origin listed as (b) (4)

OBSERVATION 6

Routine calibration of mechanical and electronic equipment is not performed according to a written program designed to ensure proper performance and ensure that storage and handling conditions to not adversely affect drug product.

Specifically, the drug receiving suite is not being monitored for temperature and the refrigerated (2-8°C) finished drug product storage area has had no record of calibration. Additionally, no temperature mapping studies have been performed, to ensure that the temperature readings are representative of the temperature throughout the refrigerated finished drug product storage area.

• Your firm failed to perform an initial calibration of your 2-8°C refrigerator's digital temperature monitoring system; therefore, there is no assurance that the refrigerator is used to store finished drug product is adequate.

• On February 18, 2025, we observed your firm stored (b) (4) Lot (b) (4) expiration: (b) (4) (b) (4) at the incorrect temperature. The (b) (4) was stored in the 2-8°C refrigerator while the box label states storage should be frozen at (b) (4) °C to (b) (4) °C.

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