DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/16/2026-3/20/2026
	FEI NUMBER 3013559620

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pamela A. Liberto Clark, Head of Quality Assurance

FIRM NAME	STREET ADDRESS
Eosera, Inc.	5000 South Fwy Ste 110
CITY, STATE, ZIP CODE, COUNTRY Fort Worth, TX 76115-3912	TYPE ESTABLISHMENT INSPECTED 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:

QUALITY SYSTEM

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

a) Your firm failed to reject lot #(b) (4) of (b) (4) bottles after it was noted there were imperfections in the (b) (4) during incoming inspection of the lot. The lot was then used to fill Lot #(b) (4) of (b) (4) on (b) (4) and Lot #(b) (4) of (b) (4) on (b) (4). Lot #(b) (4) Lot #(b) (4) were distributed.

Lot #(b) (4) was placed on stability (b) (4) and long term) and was out-of-specification for (b) (4) assay at the (b) (4) timepoint for (b) (4) stability. The long term stability study was not continued after the (b) (4) timepoint. Your firm has no documentation addressing the cessation of the long term stability study for this lot.

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	Margaret M Annes, CSO Oluwasefunm Agbanigo, Investigator Milton J De Jesus Tavarez, Investigator X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 03-20-2026 16:39:10	3/20/2026

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NCR #HOMA-D8SPDK was initiated due to leaking bottles found during filling/packaging of Lot #(b) (4) The decision was made to release Lot #(b) (4) as "the risk is considered low since it would only cause inconvenience to the consumer if a leaking product were released to the market, without posing any safety issues".

Your firm has received approximately 23 complaints against lot #(b) (4) for issues such as empty bottle and difficulty opening bottle. In addition to the complaints received, your firm attributed the issue with the incoming bottles to the out-of-specification result received for lot #(b) (4) of (b) (4) at the (b) (4) timepoint for the (b) (4) stability study.

b) Lot #(b) (4) ((b) (4)) was placed on stability ((b) (4) and long term). The lot was not manufactured according to CGMPs. For example, your firm did not perform testing/examination of all raw materials and drug product containers and closures used to make the lot. Some of the raw materials used, including (b) (4) that is one of the active ingredients, as well as the drug product containers and closures were R&D samples received from a vendor. There is no batch record showing filling of this lot and the lot numbers of the components used.

c) Your firm does not have written procedures for the issuance, use, and reconciliation of

loose- leaf forms used for documentation. Examples include the following:

- Equipment usage and cleaning logs
- PH meter and calibration logs
- Issuance of the batch record for use in production

d) Drug product specifications do not always include the assigned expiration date for the product, including for the (b) (4) drug product ((b) (4)). Your firm did not create a change control to implement a change to the expiration date for the (b) (4) drug product from (b) (4) to (b) (4) sometime in 2025. There is only a note on an uncontrolled Excel spreadsheet what the first lot was with the new expiration date.

LABORATORY SYSTEM

OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

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a) Your firm has not established a specification for (b) (4) content nor are you testing for(b) (4) content in any of your drug products, including (b) (4) ((b) (4)), (b) (4) (b) (4) ((b) (4)), (b) (4) ((b) (4)) and (b) (4) ((b) (4)).

b) Your firm has no documentation to show that the test methods used for testing of stability samples for any of your drug products, including (b) (4) ((b) (4)), (b) (4) (b) (4) ((b) (4)), (b) (4) ((b) (4)) and (b) (4) ((b) (4)), are stability-indicating.

c) Your firm has no documentation to show that Method Suitability for the (b) (4) (b) (4) ((b) (4)) has been performed to show suitability of the test method used for USP <60>, USP <61> and USP <62> testing of the finished product and stability lots.

OBSERVATION 3

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, your firm received out-of-specification (OOS) test results for the following stability lots and timepoints for (b) (4) ((b) (4)):

- Lot #(b) (4) at (b) (4) ((b) (4))
- Lot #(b) (4) at (b) (4) ((b) (4))

Your investigation into the OOS's invalidated the test results based on the fact that the samples were tested more than 10 days and/or 6 weeks past the pull date. Your firm has no

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documentation to show that the delayed testing caused the OOS result.

PRODUCTION SYSTEM

OBSERVATION 4

Your firm failed to establish adequate 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, your firm failed to perform an adequate process validation for new products to ensure that the manufacturing process is in a state of control. No appropriate control strategy was established to guarantee the process consistently produces product that meets predetermined specifications before commercial distribution, including all stages of the process, new ingredients, and test methods.

Your firm manufactured and released (b) (4) batches of (b) (4) ((b) (4)) using only data from one batch, stating this constituted adequate process qualification for a new filling line. Also, your firm manufactured and released (b) (4) batches of (b) (4) ((b) (4)), stating the existing components and filling line support validation completion using only one batch.

All (b) (4) batches were released for commercial distribution under a concurrent approach prior to collecting sufficient data for statistical analysis of process performance, including (b) (4) (b) (4) lots (b) (4) distributed on (b) (4), and (b) (4) (b) (4) lots (b) (4) distributed on (b) (4).

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MATERIALS SYSTEM

OBSERVATION 5

Failure to reject any lot of drug product containers that did not meet the appropriate written specifications for identity, strength, quality, and purity.

Specifically, your firm failed to reject lot #(b) (4) of (b) (4) bottles after it was noted there were imperfections in the (b) (4) during incoming inspection of the lot. The lot was then used to fill Lot #(b) (4) of (b) (4) on (b) (4) and Lot #(b) (4) of (b) (4) on (b) (4). During filling of lot #(b) (4), leaking bottles were noted that were attributed to the imperfections found at the incoming inspection of the (b) (4) bottles.

OBSERVATION 6

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically, Your firm failed to ensure that all required compendial tests for materials used in the manufacture of OTC drug products are performed in accordance with USP monographs. Your firm conducts testing using a contract laboratory on each component received to support the supplier's CoA, however, the testing does not always include all compendial tests, and acceptance criteria are not always aligned. Examples include, but are not limited to:

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- (b) (4) (lot (b) (4)): The supplier's CoA does not include USP methods/compendial claims and lacks Identification A and Nonvolatile Residue tests. Additionally, acceptance criteria deviate from USP specifications for Assay ((b) (4)%–(b) (4)% vs. (b) (4)%–(b) (4)%) and Melting Temperature ((b) (4)°–(b) (4)° vs. (b) (4)°–(b) (4)°).

- (b) (4) (b) (4) (lot (b) (4)): The supplier's CoA does not include USP methods/compendial claims and lacks the Limit of (b) (4) test. The Assay test range ((b) (4)%–(b) (4)%) does not align with USP specifications ((b) (4)%–(b) (4)%). Testing performed by your contract laboratory does not include the Assay test, providing no assurance that the ingredient meets specifications.

- (b) (4) (lot (b) (4)): Testing performed by your contract laboratory failed the Particle Size Distribution specification, with results exceeding acceptable limits at 49.6% retained on the (b) (4) sieve (b) (4) and 43.8% retain on the (b) (4) sieve (b) (4) The supplier's CoA reported (b) (4) % for both parameters. Additionally, microbial testing was performed using USP <2021>, which is specific to dietary supplements, rather than USP <61> and <62> required for drug products.

(b) (4) and (b) (4) lots were used in the manufacture of (b) (4) lots (b) (4) , which were distributed on (b) (4) . (b) (4) (b) (4) lot was used in the manufacture of (b) (4) lots (b) (4) , which were distributed on (b) (4) .

FACILITIES AND EQUIPMENT SYSTEM

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OBSERVATION 7

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

a) The cleaning validation study protocol # QA.VA.106, performed for equipment used in batch formulation of (b) (4) over the counter (OTC) drug products is deficient in that:
   i. No documentation of microbiological examination testing to demonstrate that the cleaning procedure effectively removes microbial contamination.
   ii. The cleaning validation protocol and report fails to document the specific drug product(s) utilized during the validation study.
   iii. There is no scientific justification for the omission of direct surface sampling. The sampling methodology relies exclusively on rinse sampling to evaluate cleaning effectiveness.
   iv. While the protocol references SOP # HOMA-DKJKQP for the cleaning procedure, the execution records fail to document the specific cleaning steps performed, and the identity of the cleaning agents used.
   v. There is no evaluation of solubility of all material used in the manufacture of drug products. For example, (b) (4), an active ingredient in the (b) (4) ((b) (4)) is only slightly soluble in water.

b) Your firm uses (b) (4) Detergent for the cleaning of equipment used in batch formulation of (b) (4) OTC drug products. Your firm has no documentation to show that this product is appropriate for use in cleaning drug product contact surfaces.

OBSERVATION 8

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Individual equipment logs do not show time, date, product and lot number of each batch processed.

Specifically, your firm fails to record the actual cleaning date in the equipment cleaning documentation for equipment used in the manufacture of (b) (4) OTC drug products. Instead, production personnel only document the batch formulation start date, which can be several days before the equipment is cleaned. Furthermore, on 03/18/2026, your Head of Quality confirmed that cleaning records for cleaning performed following batch formulation lacked a second-person verification review.

OBSERVATION 9

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, you failed to perform re-qualification of your real time and (b) (4) stability chambers # (b) (4) respectively, after moving to your new suite #110 in August 2023.

OBSERVATION 10

Routine calibration of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, on 03/16/2026, I observed that your firm had not calibrated the in-line (b) (4) (b) (4) used to test (b) (4) in the manufacture of (b) (4) OTC drug products. The calibration was due in May 2025.

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X Oluwasefunm Agbanigo
Investigator
Signed By: OLUWASEFUNMI AGBANIGO -S
Date Signed: 03-20-2026 16:39:52

X Milton J De Jesus Tavarez
Investigator
Signed By: MILTON J. DE JESUS-TAVAREZ -S
Date Signed: 03-20-2026 16:40:30

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EMPLOYEE(S) SIGNATURE

Margaret M Annes, CSO
Oluwasefunm Agbanigo, Investigator
Milton J De Jesus Tavarez, Investigator

X Margaret M Annes
CSO
Signed By: Margaret M. Annes -S
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3/20/2026

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."