DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	09/03-18/2024
	FEI NUMBER 3017473850

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lyndon R. Leitner, CEO

FIRM NAME	STREET ADDRESS
Staska Pharmaceuticals, Inc.	742 Evergreen Dr.
CITY, STATE, ZIP CODE, COUNTRY Bennet, NE 68317	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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:

Observations for the Quality System

OBSERVATION 1

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,
During your firm's visual inspection of Buffered Lidocaine HCl USP 2% 20mg/mL, 50mL Vials for injection Lot (b) (4) MFG 08/30/2022, (b) (4) vials were rejected due to defects including particles, package defects, sealing defects and abnormal fill volume. Deviation DR/PD/22/09/004 determined the root cause for the defects was contamination and damage incurred during transportation. However, the investigation wasn't expanded to determine if other lots using Lot (b) (4) were affected. CAPAs included (b) (4) vials to prevent rattling and post-cleaning inspections by the vial manufacturer. The batch was rejected but no CAPA's were implemented by your firm, and no effectiveness check was conducted. A second deviation occurred on July 19, 2024.

During your firm's visual inspection of Ascorbic Acid 500mg/mL 50mL Vials for sterile injection Lot (b) (4), BUD 12/31/2024, you initially identified (b) (4) vials containing glass particles. As a result, deviation DR/PD/24/07/006 was initiated. After testing Amber Vials Lot (b) (4) the root cause was identified as glass contamination. However, the other (b) (4) amber vial lots used in filling batch (b) (4) were not tested and the investigation was not expanded to determine if Lots (b) (4), (b) (4) were affected. CAPAs included implementing an in-house testing procedure

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2024.09.26 10:30:22 -05'00'	09/26/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	09/03-18/2024
	FEI NUMBER 3017473850
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lyndon R. Leitner, CEO	
FIRM NAME Staska Pharmaceuticals, Inc.	STREET ADDRESS 742 Evergreen Dr.
CITY, STATE, ZIP CODE, COUNTRY Bennet, NE 68317	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

to test for particles prior to approval of the vials. No effectiveness check was conducted. The testing procedure has been implemented practically but the SOP remains in the draft phase. Additionally, since there are no established limits or rejection rates for defects identified during the visual inspection process, (b) (4) vials of Ascorbic Acid 500mg/mL 50mL Vials for injection Lot (b) (4) , BUD 12/31/2024 were released and distributed.

OBSERVATION 2

Your firm failed to establish acceptance criteria for the sampling and testing conducted by the quality control unit that are adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release.

Specifically,
In regards to your 100% visual inspection of finished product vials and syringes:
Your firm has not implemented a clear classification scheme for defects, including critical, major, and minor categories nor have you established rejection rates to identify atypical lots. Furthermore, there is no SOP for this process.

OBSERVATION 3

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically,

A. Your firm has not implemented a clear classification scheme for defects, including critical, major, and minor categories. In addition, there is an absence of established, documented defect characterizations that detail defect size ranges, specific defect locations on containers, and where feasible, photographs of the defects to ensure consistency in defect identification during qualification visual inspections.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2024.09.26 10:31:01 -05'00'	09/26/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	09/03-18/2024
	FEI NUMBER 3017473850

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lyndon R. Leitner, CEO	
FIRM NAME Staska Pharmaceuticals, Inc.	STREET ADDRESS 742 Evergreen Dr.
CITY, STATE, ZIP CODE, COUNTRY Bennet, NE 68317	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

B. Your firm has not incorporated defect types routinely encountered during production into the training program. The absence of naturally occurring defects or production rejects in inspector training can limit an inspector's ability to detect actual production-related defects effectively during routine inspections.

C. Your firm has not established a limit for false rejection of acceptable vials during a visual inspection qualification.

D. There is no requirement to conduct a 360-degree visual inspection of each unit. Full rotation (360°) of the container during the container–closure defect inspection sequence is recommended for identifying small container defects such as cracks or chips.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

Observations for the Production System

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,
According to SOP MC010, Environmental Monitoring, Rev 06, microbial contamination recovery limits for the elbows or gowning elements of operators are set at Alert: NA and Action:(b) (4), while the limit for hands or gloves entering the Grade A area is Action (b) (4) However, when operators conduct interventions in which they open the (b) (4) door, both their elbows and hands/gloves enter the ISO 5 area.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2024.09.26 10:31:21 -05'00'	09/26/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	09/03-18/2024
	FEI NUMBER 3017473850
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lyndon R. Leitner, CEO	
FIRM NAME Staska Pharmaceuticals, Inc.	STREET ADDRESS 742 Evergreen Dr.
CITY, STATE, ZIP CODE, COUNTRY Bennet, NE 68317	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

During the filling of (b) (4), Buffered Lidocaine 1%, production technicians were observed reaching into the ISO 5 laminar flow hood past their elbows to clean the hangers for the suspension rod and placement of the settle plate. Additionally, viable air monitoring was conducted during the calibration of the repeater pump and not during routine filling.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. Your firm has not conducted a cleaning validation on product contact equipment including stainless steel mixing pots and mixing impellers to assure your cleaning process removes microbial content or chemical residues on the equipment used in your aseptic operations. (b) (4) stainless steel pots were used in batches including but not limited to:

- Methylcobalamin 1 mg/mL 30 mL Preserved Lot (b) (4)
- Methylcobalamin 5 mg/mL 30 mL Preserved Lot (b) (4)
- Buffered Lidocaine HCL 1% (10 mg/mL) Syringes Lot (b) (4)
- Buffered Lidocaine HCL 1% (10 mg/mL) Syringes Lot (b) (4)

B. The wet contact times specified in SOP PD016 Cleaning, Disinfection of ISO 5, ISO 7, ISO 8 Areas and Equipment, Rev 5 for cleaners and disinfectants are not consistently being met. During cleaning and disinfection of Room (b) (4) (ISO 8) on 09/09/2024, Room (b) (4) (ISO 7) on 09/09/2024 and left laminar flow hood (ISO 5) on 09/09/2024, the established (b) (4) wet contact time for (b) (4) was not met.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2024.09.26 10:31:39 -05'00'	09/26/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	09/03-18/2024
	FEI NUMBER 3017473850
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lyndon R. Leitner, CEO	
FIRM NAME Staska Pharmaceuticals, Inc.	STREET ADDRESS 742 Evergreen Dr.
CITY, STATE, ZIP CODE, COUNTRY Bennet, NE 68317	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 6

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 firm has not performed Process Validation (PV) for finished products. You have considered performance of stability studies suitable to satisfy PV requirements. There are no documented / established written PV protocols or reports.

From 2021 until the beginning of this inspection, the firm has made (b) (4) batches of products including but not limited to:

Product	Batches
Ascorbic Acid 500 mg/mL 10 mL Syringes	(b) (4)
Ascorbic Acid 500 mg/mL 50 mL vial	
Ascorbic Acid 500 mg/mL 50 mL vial Preserved	
B Complex	
Buffered Lidocaine HCL 1% (10mg/mL) 10 ml syringe	
Buffered Lidocaine HCL 2% (20 mg/mL) 50 mL	
Buffered Lidocaine HCL 2% (20 mg/mL) Syringes	
Glutathione injection (200 mg/mL)	
Glutathione injection (200 mg/mL) 30 mL Preserved	
Methyl Cobalamin 5 mg/mL 30 mL preserved	
Methylcobalamin 1 mg/mL Preserved 30 mL vial	
Methylcobalamin 25 mg/mL Preserved	

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2024.09.26 10:31:59 -05'00'	09/26/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	09/03-18/2024
	FEI NUMBER 3017473850
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lyndon R. Leitner, CEO	
FIRM NAME Staska Pharmaceuticals, Inc.	STREET ADDRESS 742 Evergreen Dr.
CITY, STATE, ZIP CODE, COUNTRY Bennet, NE 68317	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

B. An unapproved ingredient, (b) (4) that was not part of the approved formulation, batch record, or product label was added to the following batches:

- Batch (b) (4), Ascorbic Acid Preserved BUD: 07/07/2023
- Batch (b) (4) Methylcobalamin 25 mg/mL BUD: 10/21/2023
- Batch (b) (4) Methylcobalamin 25 mg/mL BUD: 06/30/2024

C. Hold times for in-process bulk material have not been established or validated. For example:

- Batch (b) (4) Ascorbic Acid Preserved BUD: 05/24/2024 – bulk solution was covered and held for (b) (4) due to a "stuck syringe" on the (b) (4) filling line.
- Batch (b) (4) Ascorbic Acid Preserved BUD: 08/02/2024 – bulk solution was covered and held for (b) (4) due to a "stuck syringe" on the (b) (4) filling line.

OBSERVATION 7

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established or followed.

Specifically,

A. Your aseptic personnel practices and interventions are not scientifically justified or documented.

1. Corrective and inherent interventions are not documented in your batch record.
2. You do not document the amount of time each operator participates in or the activities they perform as part of the media fill for the (b) (4) fill line.
3. Interventions performed during media fills do not reflect routine production.

B. Media fills do not document:

1. Aseptic assembly of equipment (e.g., at start-up, during processing)
2. Time personnel participate and their activities

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2024.09.26 10:32:20 -05'00'	09/26/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	09/03-18/2024
	FEI NUMBER 3017473850
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lyndon R. Leitner, CEO	
FIRM NAME Staska Pharmaceuticals, Inc.	STREET ADDRESS 742 Evergreen Dr.
CITY, STATE, ZIP CODE, COUNTRY Bennet, NE 68317	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

3. Representative number of aseptic additions (e.g., charging containers and closures as well as sterile vials) or transfers
4. Raw data results of all media vials incubated (results for unknown number of vials or vials associated with interventions only)

C. Growth promotion is not conducted on every lot of (b) (4) received and data loggers are not used to document the conditions of shipping. SOP MC015, Growth Promotion Test of Microbiological Media Effective 1/13/2022 does not require growth promotion to be performed on each batch of purchased (b) (4) received. The (b) (4) is used for cleaning validation conducted from 12/7/2021 through 1/20/2022 as well as routine environmental and personnel monitoring in the ISO 5 and ISO 7 manufacturing rooms.

To date, no gram negative bacteria or yeast have been recovered at this facility and there is no growth promotion data showing that agar used at this facility can recover either gram negative bacteria or yeast.

D. ISO-5 classified areas were not adequately certified under dynamic conditions. For example:
1. The smoke study labeled ISO5 Syringes fails to incorporate all aseptic operations used in routine production that can potentially disrupt unidirectional airflow within the ISO5 laminar flow hood.
2. Smoke study ISO5 Syringes and ISO5 (b) (4) were not informative as the generated "smoke" was not robust, widespread or continuous to demonstrate airflow on your (b) (4) line or in ISO 5 laminar flow hood.
3. Your smoke study, ISO5 Syringes shows an influx of poor quality air from ISO7 Room (b) (4) into the ISO5 laminar flow hood.

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2024.09.26 10:32:39 -05'00'	09/26/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	09/03-18/2024
	FEI NUMBER 3017473850
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lyndon R. Leitner, CEO	
FIRM NAME Staska Pharmaceuticals, Inc.	STREET ADDRESS 742 Evergreen Dr.
CITY, STATE, ZIP CODE, COUNTRY Bennet, NE 68317	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 8

The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, your containers do not include the following information:

a. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088;

Examples of your container labels that do not contain this information:
Ascorbic Acid Inj. Solution (Preserved, Non-corn) 25,000mg/50mL (500mg/mL)

- (b) (4) Solution
- Glutathione Inj. Solution (Preservative free) 2,000mg/10mL (200mg/mL)
- Lidocaine 2% Buffered Inj. Solution (PF) 1000mg/50mL (20mg/mL)

b. Directions for use, including, as appropriate, dosage and administration.

Examples of your container labels that do not contain this information include:

- Ascorbic Acid Inj. Solution (Preserved, Non-corn) 25,000mg/50mL (500mg/mL)
- Lidocaine 2% Buffered Inj. Solution (PF) 1000mg/50mL (20mg/mL)

OBSERVATION 9

Bulk drug substances used by your outsourcing facility to compound drug products are not manufactured by an establishment that is registered under section 510 as required by section 503B(a)(2)(C).

Specifically,
The bulk drug substance, (b) (4) is manufactured by, (b) (4)., an establishment that is no longer registered under section 510 as required by section 503B(a)(2)(C).

SEE REVERSE OF THIS PAGE	Lisa L. Flores, Investigator	Lisa L. Flores -S Digitally signed by Lisa L. Flores -S Date: 2024.09.26 10:33:02 -05'00'	09/26/2024

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."