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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 7/18/2022-8/5/2022*<br>FEI NUMBER<br>3011887629 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pejmon Jonathan Abrarpour, Chief Production Officer

| FIRM NAME | STREET ADDRESS |
|---|---|
| Empower Clinic Services LLC dba Empower Pharmacy | 5980 W Sam Houston Pkwy N Ste 300 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Houston, TX 77041-5251 | 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 WE OBSERVED:**

## OBSERVATION 1

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

Specifically, your Quality Unit (QU) failed to fulfill its duties and responsibilities. Examples include the following.

a) Failure to investigate and/or thoroughly investigate complaints, deviations/non-conformances, and out of specification results (OOS) in a timely manner.

b) Failure to report adverse events within timeframes to the FDA.

c) There is a lack of documentation to show that all active pharmaceutical ingredients (API) and excipients are suitable for use in drug products, including control for endotoxins.

d) Failure to have procedures in place for bringing ISO 5 and ISO 7 cleanrooms back to operating conditions following shut down of the air handling system, loss of differential pressure, and/or after maintenance/cleaning activities.

e) Failure to implement Corrective and Preventive Actions identified by your firm. For example, CAPA No. 112001 contains an investigation into endotoxin failures that were attributed to L-Citrulline. Testing conducted of L-Citrulline from several suppliers revealed high endotoxin levels for at least two of the suppliers. The corrective action stated "as part of the incoming raw materials process, endotoxin testing will be required for new lots of L-Citrulline before they can be released to production. Compendial testing for L-Citrulline has also been added to the incoming raw materials testing schedule". Your firm has not

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been testing lots of L-Citrulline for endotoxin received since this CAPA was approved 08/09/2021. Furthermore, your firm has received in lots from one of the suppliers noted in the investigation as the source of the endotoxin found in the finished product however, your firm has no documentation to show how this manufacturer was approved as a supplier of L-Citrulline. Lot #(b) (4) of Tri-Amino Injection was made with product from this manufacturer (batch #(b) (4) /supplier lot #(b) (4) ) and distributed.

## OBSERVATION 2

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

Specifically, your firm has no procedure in place for returning the ISO 5 and ISO 7 cleanrooms to operating conditions following shut down of the air handling system and/or after maintenance activity. For example,

a) On July 5, 2021, your firm noted a power outage had occurred that resulted in the HEPA filters for the ISO 5 and ISO 7 cleanroom suites being shut down with "no active air supply to the classified area". HEPA filter replacement and room certification was performed on July 2, 2021. At some point on July 3, 2021, the power went out as indicated by the loss of positive differential pressure between the cleanrooms. Your firm estimates the outage lasted for (b) (4) hours. The same roof top unit (RTU) that had lost power again malfunctioned later in the day on July 5, 2021. A sterility failure occurred for lot #(b) (4) of Ascorbic Acid Preservative Free 500 mg/mL (30mL vial) that was filled on July 8, 2021. Your firm did not complete the investigation into the sterility failure in a timely manner however, your firm has determined that the root cause of the sterility failure is (b) (4)

b) Your firm has no documentation to demonstrate that the process for the use of (b) (4) has been validated and the process for bringing the ISO 5 and ISO 7 cleanrooms back to operating conditions after application is adequate and appropriate.

## OBSERVATION 3

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

Specifically, your firm has no documented justification for not monitoring all critical sites within the ISO 5 cleanroom where drug products are aseptically filled and/or (b) (4), ensuring the location monitored is providing a meaningful sample, and ensuring all locations are sampled at appropriate frequencies. For example,

SOP T05.14 Environmental Monitoring of Cleanrooms, version 03 effective 04/15/2021, is for the environmental monitoring that occurs during the production of a specific batch or lot of drug product.

For product that is aseptically filled using the filling machine, viable active air sampling is not performed within the (b) (4) where open vials (b) (4) and are filled and (b) (4). The sample is taken from a table (b) (4) the filling machine. One surface sample is taken of one of (b) (4) sampling sites identified within the ISO 5 filling machine (b) (4). The procedure does not define how to choose which site to sample. Your firm has no documented justification for sampling only one site.

For product that is (b) (4) such as Methylcobalamin (B12) Injection and Sermorelin Acetate Injection, your firm is not performing viable active air sampling at the point where open vials (b) (4) and are then placed on a tray and carried across the room to the table where filling will occur. Your firm is not consistently performing viable active air sampling at the site (table) where the open vials are filled and (b) (4). For example, the viable active air sample for lot #(b) (4) of Sermorelin Acetate Injection was taken from the table (b) (4).

In addition, there is no non-viable particle monitoring in the vicinity of the table where open vials are filled and (b) (4) products). Your firm is relying on the non-viable particle counter for the ISO 5 cleanroom, which is located approximately (b) (4) from where the filling of the (b) (4) products occurs.

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## OBSERVATION 4

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 no documented justification for not (b) (4) the (b) (4) used to hold sterilized (b) (4) for (b) (4) aseptically filled drug products that are filled using the (b) (4) filler. Your firm is only wiping the (b) (4) with (b) (4) before use.

b) We observed rust and/or discoloration that appeared to be rust on the shelves and wheels of carts and the tables located in the ISO 5 Cleanroom where aseptic drug products are filled.

c) The legs of the tables located in the ISO 5 cleanroom are not a smooth cleanable surface. The height of the tables can be adjusted using (b) (4)

## OBSERVATION 5

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 is not performing investigations into all deviations (non-conformances), out of specification (OOS) results, and complaints received. Your firm is also not retaining all correspondence received and sent to the complainant. For example,

a) Since August 2021, your firm has received at least seven (7) complaints regarding drug products that were received without labels. Your firm has no documented investigation into any of these complaints.

b) Since September 2021, your firm has received at least 12 complaints regarding particles/particulates, crystallization, and/or precipitate found in several lots of Coenzyme Q-10 (Ubidecarenone) Injection. Your firm has not performed an investigation into the majority of these complaints and has advised the complainants to re-warm the product to see if the precipitate goes back into solution. Your firm has no written procedures for performing this re-warming or any documented evidence that crystallization or

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precipitation in the Coenzyme Q-10(Ubidecarenone) Injection product is expected. In addition, emails containing photographs sent by the complainant were not maintained. The photographs were extracted from the emails and uploaded to your system but the emails themselves were not retained. In addition, in some instances where the product was returned to your firm for evaluation, your firm either could not locate the returned product and/or did not perform a review of the returned product (INC-00000-17345, INC-0000018733 and INC-0000019223).

c) Your firm has had at least three (3) lots of Vitamin B-Complex Injection with potency failures for Riboflavin since March 2022 (lots (b) (4), (b) (4), and (b) (4)). Investigations have not been performed and/or completed for these failures. The Certificates of Analysis (CoA) from the manufacturer of the Riboflavin 5' -Phosphate do not show testing to the USP monograph. For example, the specification for assay (dry basis) listed on the CoA from the manufacturer is (b) (4) %. USP monograph specification for assay is 98.0%-102.0% on the dried basis.

## OBSERVATION 6

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, your firm has no procedure for integrity testing and replacement, including frequency, of the (b) (4) used to (b) (4) the (b) (4) and (b) (4) used during (b) (4) of aseptically filled drug products. The last time the (b) (4) was replaced was September 3, 2019. Your firm has no documentation of any integrity testing of the (b) (4) when it was changed. (b) (4) products include Methylcobalamin (B12) Injection and Sermorelin Acetate Injection.

## OBSERVATION 7

Written procedures are not established and followed that describe the in-process controls, tests and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically,

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a) Your firm has no written procedures for performing a supplemental visual inspection of drug products where the drug products and/or the container closure system permits limited inspection of the contents. Your firm (b) (4) several products including Methylcobalamin (B12) Injection and Sermorelin Acetate injection and fills many drug products into (b) (4) vials. Products filled in (b) (4) vials include Lipo-B Injection (30mL), Cyanocobalamin (B12) Injection, (B12) Injection, Methylcobalamin (B12) Injection, Tri-Amino Injection, and Vitamin B-Complex Injection.

Your firm has no justification for the sample size of (b) (4) vials no matter the batch size to perform the reconstitution and visual inspection of (b) (4) products. In addition, your procedures do not require extraction of product from a representative sample of products filled into (b) (4) vials such as Methylcobalamin, which is a (b) (4) when reconstituted, for supplemental visual inspection.

On July 26, 2022, we watched the supplemental visual inspection of lot #(b) (4) of Methylcobalamin (B12) Injection. The employee did not perform the visual inspection of the reconstituted product against a (b) (4) background, they did not measure and verify the light intensity, and they did not extract the (b) (4) from the (b) (4) vial.

b) Your firm is not conducting an AQL sampling and inspection of containers after 100% visual inspection.

## OBSERVATION 8

Written procedures are lacking which describe in sufficient detail the receipt, handling, sampling, testing, approval and rejection of components.

Specifically,

a) Your firm has no documentation to show that all bulk drug substances and excipients are appropriate for use in drug products. All lots listed have been released and distributed. For example,

- Mecocobalamin (Methylcobalamin) lot (b) (4) - Certificate of Analysis (CoA) from manufacturer states "Not for Drug Use". This lot was used to make lot #s (b) (4), (b) (4) and (b) (4) of

Methylcobalamin (B12) Injection - 10,000 mcg/vial on (b) (4) (mixing), (b) (4) (filling and (b) (4)), and (b) (4) ( (b) (4)).

- Cyanocobalamin (Vitamin B12) batch #(b) (4) - CoA from manufacturer states "Not for Drug Use". This product is used to make sterile drug products such as lot #(b) (4) of Lipo-B Injection made on (b) (4) and lot #(b) (4) of Cyanocobalamin (B12) Injection 2,000 mcg/mL made on (b) (4).
- Ascorbic Acid USP (b) (4) Source) lot #(b) (4) used to make lot #(b) (4) of Ascorbic Acid Injection Preserved 500mg/mL. The Certificates of Analysis (CoA) are not from the original manufacturer and your firm has no documented scientific justification to demonstrate this raw material is appropriate for use in an injectable drug product.
- Riboflavin 5' -Phosphate lot #(b) (4) used to make lot #(b) (4) of Riboflavin (B2) Injection 10mg/mL on (b) (4). The Riboflavin is not tested per the USP monograph. For example, the specification for assay (dry basis) listed on the CoA from the manufacturer is (b) (4)% with a result listed as (b) (4)%. USP monograph specification for assay 98.0%-102.0% on the dried basis.
- Vitamin B1 (Thiamine Hydrochloride) Food Grade batch (b) (4) was used to make lot #(b) (4) of Vitamin B-Complex Injection.
- L-Ornithine batch (b) (4) used to make lot #(b) (4) of Tri-Amino Injection. There is no USP/NF monograph for L-Ornithine.
- (b) (4) (supplier lot #(b) (4) used in lot #(b) (4) of Sermorelin Acetate Injection 15mg/Vial. The CoA does not show all tests have been performed per the NF monograph for sucrose specifically, testing for bacterial endotoxin and is not labeled parenteral grade.
- (b) (4) batch #(b) (4) is labeled a "FOOD ADDITIVE". This has been used to make several lots including lot #(b) (4) of Vitamin B-Complex Injection. Your firm has no documentation to show this product is suitable for use in an injectable drug product.

b) CAPA No. 112001 contains an investigation into endotoxin failures that were attributed to L-Citrulline. Testing conducted of L-Citrulline from several suppliers revealed high endotoxin levels for at least (b) (4) of the suppliers. The corrective action stated "as part of the incoming raw materials process, endotoxin testing will be required for new lots of L-Citrulline before they can be released to production. Compendial testing for L-Citrulline has also been added to the incoming raw materials testing schedule". Your firm

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has not been testing lots of L-Citrulline for endotoxin received since this CAPA was approved 08/09/2021.

**OBSERVATION 9**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, media fills for the (b) (4) product Methylcobalamin (B12) Injection do not simulate worst case. For example, your firm compounds solution to fill (b) (4) vials and then uses it to fill (b) (4) sublots of (b) (4) vials. (b) (4) vials are placed in the (b) (4) after each sublot is filled and the entire (b) (4) vials are (b) (4). Your media fill is only simulating the filling of (b) (4) vials, placing the (b) (4) vials in the (b) (4), and then (b) (4) those (b) (4) vials. The media fill does not simulate the filling of the (b) (4) sublots and placing all (b) (4) (b) (4) vials in the (b) (4).

**OBSERVATION 10**

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

Specifically,

a) Your firm uses multiple manufacturers of several active pharmaceutical ingredients (API). Your firm has not performed method suitability for sterility testing on formulations for all API manufacturers. For example,

i. Your firm has used (b) (4) different manufacturers of Taurine (API). Your firm has (b) (4) contract labs who perform sterility testing of Taurine Injection 50mg/mL however, method suitability has only been performed for formulations containing one of the (b) (4) suppliers. Lot (b) (4) of Taurine Injection 50mg/mL was made using the API supplied the manufacturer for which method suitability has not been performed. This lot has been released and distributed.

ii. Your firm has (b) (4) different manufacturers of Thiamine HCl (API). Your firm has (b) (4)

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contract labs who can perform sterility testing of Vitamin B-Complex Injection that contains Thiamine HCl. Your firm has not performed method suitability for sterility testing at each contract lab of Vitamin B-Complex Injection using all manufacturers of this API.

iii. Your firm has at (b) (4) different manufacturers of L-Ornithine Hydrochloride. Your firm has (b) (4) contract labs who perform sterility testing of Tri-Amino Injection. For one of the contract labs, your firm has no documentation of the manufacturers of the APIs for the lot used for method suitability. In addition, your firm has not performed method suitability for sterility testing at each contract lab of Tri-Amino Injection using all manufacturers of this API.

b) Your firm has no documentation show how endotoxin limits were established for injectable drug products. For example, the endotoxin limit your firm has reported to your contract testing labs for certain products such as Sermorelin Acetate Injection 15mg/Vial, Riboflavin (B2) Injection, and Tri-Amino Injection is (b) (4) EU/mL. Your firm has no documentation to show how this limit was determined.

## OBSERVATION 11

Drug product containers and closures were not clean and sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

a) Your firm has not performed a hold time study to show the (b) (4) expiration date you have assigned to (b) (4) after (b) (4) is appropriate. For example, the (b) (4) used for lot (b) (4) of Sermorelin Acetate Injection filled and (b) (4) on 06/06/2022 were (b) (4) on 04/21/2022 (lot (b) (4)).

b) Your firm is not using final rinse water that meets the specifications of WFI, USP for washing of vials to be used for filling sterile injectable drug products.

## OBSERVATION 12

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Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm does not perform testing of non-sterile drug products if the number of units made per lot is (b) (4). For example, from March 2020 until July 2022, your firm has made approximately (b) (4) lots of Ketamine Nasal Spray (2mL, 5mL and 15mL sizes). None of these lots has been tested for potency (assay of active ingredient).

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**OBSERVATION 13**

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically, your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six-month period. Specifically, (b) (4) products of various strengths and formulations were compounded at your outsourcing facility and not identified on your report dated June 2022.

Examples of products include:

- (b) (4) - NIACINAMIDE / SODIUM HYALURONATE / TRETINOIN (30 ML) 4/0.5/0.025% CREAM
- ROSACEA CREAM 3.3.1 (IVERMECTIN / METRONIDAZOLE / NIACINAMIDE) (30 ML)
- (b) (4) - TRI-ROSACEA CREAM - AZELAIC ACID / IVERMECTIN / METRONIDAZOLE / NIACINAMIDE (30 ML) 5/1/1/4% CREAM
- (b) (4) (ESTRIOL) (30 ML) 0.3% CREAM
- PSORIASIS CREAM 1.4.1 (COAL TAR SOLUTION / SALICYLIC ACID / TRIAMCINOLONE ACETONIDE / UREA) (30 ML) 5/5/0.16/10% CREAM
- MELASMA CREAM 4.3.2 (HYDROQUINONE / TRETINOIN / TRIAMCINOLONE ACETONIDE) (30 ML) 4/0.025/0.1% CREAM
- ECZEMA OINTMENT 1.2.2 (NIACINAMIDE / TACROLIMUS) (30 ML) 4/0.1% OINTMENT
- DERMATITIS, SEBORRHEIC SHAMPOO 1.2.1 (CICLOPIROX / CLOBETASOL PROPIONATE)

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(120 ML) 0.77/0.05% SHAMPOO
- CALCIPOTRIENE/ETHOXY DIGLYCOL 5 MG/G (0.5%) SOLUTION
- ALOPECIA SOLUTION 1.4.1 (AZELAIC ACID / FINASTERIDE / KETOCONAZOLE / MINOXIDIL) (60 ML) 12.5/0.1/2/5% SOLUTION

## OBSERVATION 14

Adverse drug experience information has not been reported to FDA.

Specifically, your outsourcing facility has not submitted adverse event reports to FDA in accordance with the content and format requirements established through guidance or regulation under 21 CFR 310.305 as required by section 503B(b)(5). Your firm did not submit the following adverse event reports within 15 calendar days after first receiving information about the adverse event:

- INC-0000015002
- INC-0000023861

## OBSERVATION 15

The labels of your outsourcing facility's drug products are deficient.

1. Specifically, the labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:
   a) The statement "This is a compounded drug";
      - Example: (b) (4) Capsule

   b) The date that the drug was compounded;
      - Example: (b) (4) Capsule

   c) The storage and handling instructions;
      - Example: (b) (4) Capsule

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|---|---|
| 1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214)253-5200 Fax:(214)253-5314<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 7/18/2022-8/5/2022*<br>FEI NUMBER<br>3011887629 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Pejmon Jonathan Abrarpour, Chief Production Officer | |
| FIRM NAME<br>Empower Clinic Services LLC dba Empower Pharmacy | STREET ADDRESS<br>5980 W Sam Houston Pkwy N Ste 300 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Houston, TX 77041-5251 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility |

d) The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only";
- Example: (b) (4) Capsule

e) A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

Examples:
- Ketamine Nasal Spray 100 mg/mL (10 mg/Spray):
- Ketamine Troche 200 mg:
- Estradiol Pellet 6 mg
- Rosacea Cream
- Tri-Rosacea Cream
- (b) (4) Capsule

2. 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 1800FDA1088 <http://www.fda.gov/medwatch and 1800FDA1088>;

Examples of your container labels that do not contain this information:
- (b) (4) Capsule

**OBSERVATION 16**

Written procedures are not established and followed for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

Specifically, your firm did not conduct an annual product review (APR) for any drug products in 2021. The APR conducted in 2020 consisted of a review of three (3) batch records for each product regardless of the number of

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batches made during the year, and did not include a review of all quality information related to the product with the exception of the three lots reviewed. Your firm is not reviewing quality metrics for the entirety of products made over the period of review such as complaints, deviations, and finished product testing.

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**OBSERVATION 17**

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

Specifically, examples of bulk drug substances used by your firm that are from manufacturers that have not registered with FDA include the following. All finished product lots listed have been released and distributed.

i. L-Citrulline batch #(b) (4) (supplier lot #(b) (4) ) used to make lot (b) (4) of Tri-Amino Injection.

ii. Riboflavin 5' -Phosphate lot (b) (4) used to make lot #(b) (4) of Riboflavin (B2) Injection 10mg/mL on 05/23-24/2022.

iii. L-Methionine batch #(b) (4) used to make lot (b) (4) of Lipo-B Injection (30mL).

iv. Inositol batch #(b) (4) used to make lot (b) (4) of Lipo-B Injection (30mL).

v. Choline Chloride lot #(b) (4) used to make lot (b) (4) of Lipo-B Injection (30mL).

vi. Pyridoxine HCl batch #(b) (4) used to make lot #s (b) (4) and (b) (4) of Vitamin B-Complex Injection.

vii. L-Arginine HCl batch #(b) (4) used to make lot (b) (4) of Arginine HCl Injection 200mg/mL.

viii. Ubidecarenone (Co Enzyme Q10) batch #(b) (4) used to make lot (b) (4) of Coenzyme Q-10 (Ubidecarenone) Injection 20mg/mL.

ix. Your firm has (b) (4) manufacturers of Taurine (API) and (b) (4) are registered with FDA. Taurine batch #(b) (4) used to make lot (b) (4) of Taurine Injection 50 mg/mL and batch #(b) (4) used to make lot (b) (4) of Taurine Injection 50 mg/mL.

x. Thiamine HCl batch #(b) (4) used to make lot (b) (4) of Vitamin B-Complex Injection.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Margaret M Annes, CSO<br>Suzanne N Vallez, Investigator | DATE ISSUED<br>8/5/2022 |
|---|---|---|

X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 08-05-2022 07:31: E

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xi. L-Ornithine batch #(b) (4) used to make lot (b) (4) of Tri-Amino Injection.

***DATES OF INSPECTION**

7/18/2022(Mon), 7/19/2022(Tue), 7/20/2022(Wed), 7/21/2022(Thu), 7/22/2022(Fri), 7/25/2022(Mon), 7/26/2022(Tue), 7/27/2022(Wed), 7/29/2022(Fri), 8/01/2022(Mon), 8/02/2022(Tue), 8/05/2022(Fri)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Margaret M Annes, CSO<br>Suzanne N Vallez, Investigator | X Margaret M Annes CSO Signed By: Margaret M. Annes -S Date Signed: 08-05-2022 07:31: E | 8/5/2022 |

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."