Temporary Compliance Waiver Notice

At the time of initial posting on 7/25/2017 the attached PDF document may not be fully accessible to readers using assistive technology. A fully accessible version of the document is in preparation and will be posted as soon as it is ready. We regret any inconvenience that this may cause our readers.

In the event you are unable to read this document or portions thereof, please contact Melissa Pickworth in Division of Information Disclosure Policy,Office of Strategic Planning and Operational Policy, U.S. Food and Drug Administration, Office of Regulatory Affairs (ORA) at oraospopfoiadisclosurepolicy@fda.hhs.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
USFDA/ORA/CHI-DO 550 W. Jackson Blvd. 15th floor Chicago, IL 60661 312-353-5863	06/10, 06/13, 06/14, 06/15, 06/19, 06/22, and 07/18/17. FEI NUMBER 3013442632

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael B. Younan, Owner

FIRM NAME	STREET ADDRESS
Bella Pharmaceuticals, Inc.	3101 W Devon Ave.
CITY, STATE AND ZIP CODE Chicago, IL 60659	TYPE OF 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 WE OBSERVED:

Observation 1

Procedures designed to prevent objectionable microorganisms in drug products required to be sterile are not established, written, or followed. Specifically,

A. The aseptic filling operations have not been validated through the use of any media fill simulations.

B. The firm does not keep a record of any (b) (4) cycles used to sterilize container closures such as vials and stoppers used in compounding injectable and ophthalmic drugs purporting to be sterile. In addition the firm does not have a record of any validation for the (b) (4) cycle, does not have any documentation of calibration or maintenance of the (b) (4).

C. The firm is using non-pharmaceutical grade sterilizing (b) (4) labeled in part (b) (4) (b) (4) (b) (4) for drug product (b) (4). The firm has not performed (b) (4) integrity testing with each (b) (4) or production run.

D. On 06/22/17 the Chief Pharmacist compounded (b) (4) @ 0.1 mL fill prefilled syringes of Ceftazidime in (b) (4) brand syringes with 30 g needles 2.5 mg/mL for intravitreal injection using (b) (4) labeled Not for Injection.

E. On 06/22/17 the Chief Pharmacist compounded (b) (4) @ 0.1 mL fill prefilled syringes of Vancomycin Hydrochloride in (b) (4) brand syringes with 30 g needles 1 mg/mL for intravitreal injection and (b) (4) @ 0.1 mL fill prefilled syringes of Ceftazidime in (b) (4) brand syringes with 30 g needles 2.5 mg/mL for intravitreal injection. During this process she did not sanitize the exterior of any of the components before bringing them into the classified area nor were they sanitized prior to putting them in the (b) (4) She placed the (b) (4) (b) (4) directly over the unstoppered vials on several occasions during compounding. In addition an unstoppered vial was used to hold the (b) (4) sterilized solution during filling of the (b) (4) 1 ml syringes.

Observation 2

Your firm did not maintain documented production worksheets for any of the compounded sterile drug products shipped to customers including those listed in the below table:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Brian D Nicholson	Brian D. Nicholson, C.S.O.	18 July 2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
USFDA/ORA/CHI-DO 550 W. Jackson Blvd. 15th floor Chicago, IL 60661 312-353-5863	06/10, 06/13, 06/14, 06/15, 06/19, 06/22, and 07/18/17. FEI NUMBER 3013442632

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael B. Younan, Owner

FIRM NAME	STREET ADDRESS
Bella Pharmaceuticals, Inc.	3101 W Devon Ave.
CITY, STATE AND ZIP CODE Chicago, IL 60659	TYPE OF 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 WE OBSERVED:

Order Date	Count	Drug Product Name	Clinic Name	Address
4/17/2017	(b) (4)	Fluorescein Sodium	(b) (4)	(b) (4)
4/17/2017	(b) (4)	Fluorescein Sodium	(b) (4)	(b) (4)
4/20/2017	(b) (4)	Fluorescein Sodium	(b) (4)	(b) (4)
4/20/2017	(b) (4)	Lidocaine Jelly	(b) (4)	(b) (4)
5/2/2017	(b) (4)	Phenylephrine	(b) (4)	(b) (4)
5/5/2017	(b) (4)	Brilliant Blue 0.5mg/ml	(b) (4)	(b) (4)
5/9/2017	(b) (4)	Fluorescein Sodium	(b) (4)	(b) (4)
5/22/2017	(b) (4)	Lidocaine Jelly	(b) (4)	(b) (4)
5/16/2017	(b) (4)	Lidocaine Jelly	(b) (4)	(b) (4)
5/22/2017	(b) (4)	Lidocaine Jelly	(b) (4)	(b) (4)
5/22/2017	(b) (4)	Lidocaine Jelly PF	(b) (4)	(b) (4)
5/24/2017	(b) (4)	Lidocaine Jelly 3.75%	(b) (4)	(b) (4)
5/24/2017	(b) (4)	Phenylephrine/Tropicamide	(b) (4)	(b) (4)
5/24/2017	(b) (4)	Sodium Bicarbonate 8.4%	(b) (4)	(b) (4)
5/31/2017	(b) (4)	Lidocaine Jelly	(b) (4)	(b) (4)

Observation 3

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

A. The firm uses (b) (4) a broad-spectrum hard surface disinfectant that is not labeled as sporicidal or sterile as (b) (4) sanitizing agent for the ISO-5 area.

B. The firm does not use lint free towels when cleaning and sanitizing the ISO-5 area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	BDN	Brian D. Nicholson, C.S.O.	18 July 2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
USFDA/ORA/CHI-DO 550 W. Jackson Blvd. 15th floor Chicago, IL 60661 312-353-5863	06/10, 06/13, 06/14, 06/15, 06/19, 06/22, and 07/18/17. FEI NUMBER 3013442632

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael B. Younan, Owner

FIRM NAME	STREET ADDRESS
Bella Pharmaceuticals, Inc.	3101 W Devon Ave.
CITY, STATE AND ZIP CODE Chicago, IL 60659	TYPE OF 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 WE OBSERVED:

C. The firm does not document sanitization of the ISO-5 areas.

D. The firm has not demonstrated the effectiveness of the sanitization procedure, for example by taking surface samples before or after cleaning and disinfection.

Observation 4

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

A. The firm does not perform environmental monitoring of the compounding areas for microbiological organisms during compounding.

B. The firm does not perform particle counting for non-viable particulates during compounding.

C. The firm does not monitor any of personnel directly involved in compounding operations for microbiological organisms at any time before, during, or after operations.

Observation 5

The finished product testing for product release does not include:

A. Potency testing on any lots of compounded drug products shipped to date.

B. Endotoxin testing on any lots of compounded drug products shipped to date.

C. Appropriate suitability testing for sterility testing is not documented. The firm does not have any records of sterility test method suitability for any of its distributed products.

D. No preservative effectiveness testing has been performed for any products that may contain preservatives.

Observation 6

Buildings used in the manufacture, processing, packing, or holding of a drug products purporting to be sterile do not have the suitable size, construction, location to facilitate cleaning, maintenance, and proper operations. Specifically,

A. There is a (b) (4) (b) (4) that is visibly dusty just outside the (b) (4) of the (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	BDN	Brian D. Nicholson, C.S.O.	18 July 2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
USFDA/ORA/CHI-DO 550 W. Jackson Blvd. 15th floor Chicago, IL 60661 312-353-5863	06/10, 06/13, 06/14, 06/15, 06/19, 06/22, and 07/18/17.
	FEI NUMBER 3013442632

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael B. Younan, Owner

FIRM NAME	STREET ADDRESS
Bella Pharmaceuticals, Inc.	3101 W Devon Ave.
CITY, STATE AND ZIP CODE Chicago, IL 60659	TYPE OF 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 WE OBSERVED:

Room. The (b) (4) (b) (4) of the (b) (4) Room is cut to allow the (b) (4) to (b) (4) Room. Transparent packing type tape was used to cover the (b) (4) the (b) (4) (b) (4) and the (b) (4) Room. Visible staining can be observed on the transparent packing type tape.

B. The floor in the IV Room which the firm considers an ISO-5 area is a laminate floating floor that shows visible chipping.

C. The firm does not measure differential pressures in the antechamber or the IV Room where compounding takes place.

Observation 7

Procedures designed to prevent mix-ups of drug products have not been established or implemented. Specifically,

A. On 06/13/2017 I observed in the refrigerator 5 amber bags containing unlabeled compounded drug products. Each of the amber bags contained a label on the outside however the contents of each amber bag were unlabeled units of drug product. Two amber bags were labeled "Proparacaine". Inside one of the bags were 12 opaque unlabeled ophthalmic dropper bottles. Inside the other bag were 7 opaque unlabeled ophthalmic dropper bottles. One amber bag labeled "Arginine HCl #12" contained 4 unlabeled vials containing clear colorless solution. One amber bag labeled Lidocaine contained 4 unlabeled ophthalmic dropper bottles. One amber bag labeled "Phenylephrine: contained 20 unlabeled vials containing a clear colorless solution.

B. On 06/22/17 I observed the Chief Pharmacist compound (b) (4) @ 0.1 mL fill prefilled syringes of Vancomycin Hydrochloride in (b) (4) brand syringes with 30 g needles 1 mg/mL for intravitreal injection, placed these in an amber bag, and placed the amber bag on the table in the IV Room. She then compounded (b) (4) @ 0.1 mL fill prefilled syringes of Ceftazidime in (b) (4) brand syringes with 30 g needles 2.5 mg/mL for intravitreal injection and placed these in an identical unlabeled amber bag and placed the amber bag on the table next to the similar amber bag filled with Vancomycin Hydrochloride. There was no way to distinguish the two amber bags and they were not labeled. There was no way to distinguish the contents of each amber bag as each amber bag contained (b) (4) unlabeled 1 mL (b) (4) syringes filled to 0.1 mL fill with clear solution. The Chief Pharmacist did not document any steps on any batch sheets during the compounding of these products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Brian D. Nicholson, C.S.O.	18 July 2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
USFDA/ORA/CHI-DO 550 W. Jackson Blvd. 15th floor Chicago, IL 60661 312-353-5863	06/10, 06/13, 06/14, 06/15, 06/19, 06/22, and 07/18/17. FEI NUMBER 3013442632

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael B. Younan, Owner

FIRM NAME	STREET ADDRESS
Bella Pharmaceuticals, Inc.	3101 W Devon Ave.
CITY, STATE AND ZIP CODE Chicago, IL 60659	TYPE OF 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 WE OBSERVED:

Observation 8

The firm does not have procedures or processes that provide sufficient control over bulk drug substances and components, for example:

A. The firm compounds sterile drug products from non-sterile bulk drug substances. The firm stores and handles these powder drug substances on a table in the IV Room which the firm contends is ISO-5 certified. On this table I observed the following:

I. A container where the name of the previous contents was crossed out in marker and the drug substance name (b) (4) written on the front of the container in marker. On the side of the container the NDC number and the CAS numbers were crossed out however the lot number (b) (4) and the Exp. 09/19 were not crossed out.

II. The following two components were observed to be expired yet still available for use on this shelf. Tobramycin Sulfate, USP 1g assay 726 ug/mg lot (b) (4) exp. 09/16 and Boric Acid, NF (powder) Lot (b) (4) exp 12/16.

III. An open vial with white crust-like material on the interior of the vial and white and tan crust-like material on the exterior of the lip of the vial.

B. The weighing of the bulk drug substances is performed on a balance on the table in the IV Room (ISO-5) outside the (b) (4) and there is no HEPA filter above this area.

Observation 9

The firm does not have procedures or processes that provide sufficient control and storage over non-sterile glass vials prior to their use in compounding. The firm purchases non-sterile glass vials. Throughout the inspection I observed these glass vials being stored uncovered in unclassified areas with the opening up. The firm does not document the reported sterilization of these containers by (b) (4) . The firm does not depyrogenate these containers before use.

Observation 10

Clothing of personnel engaged in the compounding, processing, packing, and holding of drug products purporting

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Brian	Brian D. Nicholson, C.S.O.	18 July 2017

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
USFDA/ORA/CHI-DO 550 W. Jackson Blvd. 15th floor Chicago, IL 60661 312-353-5863	06/10, 06/13, 06/14, 06/15, 06/19, 06/22, and 07/18/17. FEI NUMBER 3013442632

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael B. Younan, Owner

FIRM NAME	STREET ADDRESS
Bella Pharmaceuticals, Inc.	3101 W Devon Ave.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Chicago, IL 60659	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:

to be sterile is not appropriate for the duties they perform. Specifically,

A. Personnel wear garb not labeled as sterile when compounding sterile drug products by aseptic processing.

B. Gowning procedures result in exposed skin around the forehead, brow, eyes, and wrist. On 06/22/17 I observed the Chief Pharmacist compound(b) (4) @ 0.1 mL fill prefilled syringes of Vancomycin Hydrochloride and(b) (4) @ 0.1 mL fill prefilled syringes of Ceftazidime 2.5 mg/mL for intravitreal injection in(b) (4) brand syringes with 30 g needles following her usual gowning procedures for donning overshoes, pants, a smock, cap, dust mask, and gloves result in exposed skin at the brow, around the eyes, and neck during compounding. Also frequently during compounding exposed skin at the wrist occurred due to separation of the smock sleeves and gloves.

Observation 11

The labels of your outsourcing facility's drug products do not include information required by sections 503B(a)(10)(A) and (B).
Specifically, the following information is not found on the product labels for some of the drug products that you produce:

- The statements "This is a compounded drug", "Not for resale", and, "Office Use Only".
- The phone number of the applicable outsourcing facility.
- The dosage form.
- The date the drug was compounded.
- A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

Examples of product labels that do not contain this information:

- o Sodium Bicarbonate 8.4% 5mL Sterile Vial
- o Brilliant Blue 0.5mg/mL Sterile 5mL Vial
- o Fluorescein Sodium 5mL Sterile Injectable Dye
- o Lidocaine Gel PF 3.75% 15mL Sterile Ophthalmic Jelly

Additionally, the following information is not found on the container labels for some or all of the drug products you produce:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Brian D. Nicholson, C.S.O.	18 July 2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
USFDA/ORA/CHI-DO 550 W. Jackson Blvd. 15th floor Chicago, IL 60661 312-353-5863	06/10, 06/13, 06/14, 06/15, 06/19, 06/22, and 07/18/17. FEI NUMBER 3013442632

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael B. Younan, Owner

FIRM NAME	STREET ADDRESS
Bella Pharmaceuticals, Inc.	3101 W Devon Ave.
CITY, STATE AND ZIP CODE Chicago, IL 60659	TYPE OF 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 WE OBSERVED:

- Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.
- Route of administration.

Examples of container labels that do not contain this information:

o Sodium Bicarbonate 8.4% 5mL Sterile Vial
o Brilliant Blue 0.5mg/mL Sterile 5mL Vial
o Fluorescein Sodium 5mL Sterile Injectable Dye

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Brian D Nicholson	Brian D. Nicholson, C.S.O.	18 July 2017