

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product 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:

OBSERVATION 1

There is no quality control unit.

Specifically, your firm does not have a quality unit with the responsibility and authority to oversee the labeling, storage, and distribution of your umbilical cord tissue product, (b) (4).
(b) (4).

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots ((b) (4) units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots ((b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot ((b) (4) units) of product marketed as growth factor ((b) (4)).

OBSERVATION 2

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

Specifically,

- a) Your firm did not perform an aseptic process validation for biological products derived from human umbilical cord tissue.
- b) Your firm has not validated the use the (b) (4) (equipment ID (b) (4)) that is used to sterilize finished product (b) (4), and processing tools that come into contact with umbilical cord tissue.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

c)Your firm did not validate the cleaning process of your ISO ^(b)₍₄₎ biological safety cabinet used to process and fill finished products derived from human umbilical cord.

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately ^(b)₍₄₎ lots (^(b)₍₄₎ units) of product marketed as Wharton's Jelly (^(b)₍₄₎), ^(b)₍₄₎ lots (^(b)₍₄₎ units) of product marketed as exosomes (^(b)₍₄₎), and ^(b)₍₄₎ lot (^(b)₍₄₎ units) of product marketed as growth factor (^(b)₍₄₎).

OBSERVATION 3

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, your firm has not designed production controls that ensure the human umbilical cord tissue products, ^(b)₍₄₎, have the identity, strength, quality and purity they purport to possess. The lack of process controls include, but are not limited to, the following:

- a)You have not validated the manufacturing process for the products listed above.
- b)You do not have SOPs stating how processing for each product is performed.
- c)You have not validated the time in which you ^(b)₍₄₎ human umbilical cord tissue in ^(b)₍₄₎. You ^(b)₍₄₎ human umbilical cord tissue for anywhere from ^(b)₍₄₎ with no indication that the process does not affect the product quality or remain as a residual in final finished product.

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately ^(b)₍₄₎ lots (^(b)₍₄₎ units) of product marketed as Wharton's Jelly (^(b)₍₄₎), ^(b)₍₄₎ lots (^(b)₍₄₎ units) of product marketed as exosomes ^(b)₍₄₎, and ^(b)₍₄₎ lot (^(b)₍₄₎ units) of product marketed as growth factor (^(b)₍₄₎).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

OBSERVATION 4

There is a failure to thoroughly review 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 did not investigate sterility failures in biological products manufactured from human umbilical cord tissue.

From September 2023 - December 2025, your firm failed to investigate (b) (4) sterility test failures out of (b) (4) manufactured batches of human umbilical cord tissue. Sterility samples are collected (b) (4) from the finished lot, with an average of (b) (4) vials submitted to a (b) (4) laboratory for sterility testing per batch. (b) (4) of the 11 failed lots were released for distribution.

Date of Processing	Product Type	Volume	Lot#	Donor ID	Bioburden testing	Number of vials	Sterility results
(b) (4)	WJY	1mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	Growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	2mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	No growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	2mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	Growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	2mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	Growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	1mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	No growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	1mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	No growth	(b) (4)	Failed (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed by: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

							(b) (4)
(b) (4)	WJY	1mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	No growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	2mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	Growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	2mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	Growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	1mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	Growth	(b) (4)	Failed (b) (4)
(b) (4)	WJY	1mL	(b) (4)	(b) (4), (b) (6), (b) (7)(C)	No growth	(b) (4)	Failed (b) (4)

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots (b) (4) units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots (b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot ((b) (4) units) of product marketed as growth factor ((b) (4)).

OBSERVATION 5

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed by: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

Specifically, there is no routine environmental monitoring of ISO ^{(b) (4)} clean rooms conducted during manufacturing of biological products to include human umbilical cord tissue products, ^{(b) (4)} ^{(b) (4)}

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately ^{(b) (4)} lots ^{(b) (4)} units) of product marketed as Wharton's Jelly ^{(b) (4)}), ^{(b) (4)} lots ^{(b) (4)} units) of product marketed as exosomes ^{(b) (4)}), and ^{(b) (4)} lot ^{(b) (4)} units) of product marketed as growth factor ^{(b) (4)}).

OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm has not conducted a stability study to determine the expiration dating of ^{(b) (4)} ^{(b) (4)} from time of processing used for human umbilical cord tissue to include ^{(b) (4)} ^{(b) (4)}.

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately ^{(b) (4)} lots ^{(b) (4)} units) of product marketed as Wharton's Jelly ^{(b) (4)}), ^{(b) (4)} lots ^{(b) (4)} units) of product marketed as exosomes ^{(b) (4)}), and ^{(b) (4)} lot ^{(b) (4)} units) of product marketed as growth factor ^{(b) (4)}).

OBSERVATION 7

Procedures describing the handling of all written and oral complaints regarding a drug product are not established.

Specifically, your firm does not have written procedures for the receipt of complaints associated with

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	X Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21	DATE ISSUED 12/16/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

(b) (4)

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots (b) (4) units) of product marketed as Wharton's Jelly (b) (4), (b) (4) lots (b) (4) units) of product marketed as exosomes (b) (4), and (b) (4) lot (b) (4) units) of product marketed as growth factor (b) (4).

OBSERVATION 8

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

Specifically,

- a) You have not validated or established written procedures for the process of manufacturing sterile antibiotic solutions used in the processing of human umbilical cord product. You reconstitute (b) (4) to create what you call an (b) (4) which is made up of (b) (4) (b) (4) designed to be added to a (b) (4) (b) (4). The (b) (4) includes (b) (4) to create an (b) (4) for incoming human umbilical cord tissue. You have not validated this process.
- b) You failed to establish a sampling plan that assesses the sterility assurance of your product.
- c) You failed to validate in house sterility sampling used to determine the sterility assurance of your products. The final sample used to determine the batch release is obtained (b) (4) the product is (b) (4).

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots (b) (4) units) of product

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

marketed as Wharton's Jelly ((b) (4)), (b) (4) lots (b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot ((b) (4) units) of product marketed as growth factor ((b) (4)).

OBSERVATION 9

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, your firm has no written procedures for the cleaning and maintenance of equipment used in the processing, packing and holding of (b) (4).

Equipment used in the processing, packaging and holding of drug product human umbilical cord tissue product includes:

- (b) (4)
- Freezers
- (b) (4)
- Centrifuge
- Biologic Safety Cabinet (BSC)
- Pipetman
- Incubator

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots (b) (4) units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots (b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot ((b) (4) units) of product marketed as growth factor ((b) (4)).

OBSERVATION 10

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Samantha J. Brechner, CEO			
FIRM NAME Bello Bio LLC		STREET ADDRESS 10045 E Dynamite Blvd Ste 260	
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752		TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer	
Batch production and control records do not include complete information relating to the production and control of each batch. Specifically, you did not document each significant step in the manufacture, processing, packing, or holding of each batch of product of human umbilical cord tissue. The batch processing record does not include the following: - who conducted the processing step - labeling of finished product - who performed placing product into quarantine, release from quarantine, and placing into available inventory. - The firm's records do not document final disposition for failed/rejected or otherwise unacceptable vials. From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots ((b) (4) units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots ((b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot ((b) (4) units) of product marketed as growth factor ((b) (4)).			
OBSERVATION 11 Written procedures are lacking which describe in sufficient detail the receipt, identification, storage, handling, sampling, testing, approval and rejection of components and drug product containers. Specifically, your firm has not established written procedures specifying incoming acceptance criteria for receipt, identification, storage, handling, sampling, testing, approval and rejection of human umbilical cord tissue and processing components and final product containers. From September 2023 to December 2025, your firm has manufactured approximately (b) (4) lots ((b) (4)).			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	
		DATE ISSUED 12/16/2025	

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots (b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot (b) (4) units) of product marketed as growth factor (b) (4)).

OBSERVATION 12

The eligibility of an HCT/P donor was not documented by a responsible person, based on results of donor screening and donor testing.

Specifically, your firm does not document the donor eligibility determination for HCT/P donors whose tissues are used to manufacture (b) (4) .

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots (b) (4) units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots (b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot (b) (4) units) of product marketed as growth factor ((b) (4)).

OBSERVATION 13

Procedures designed to assure that correct labels and labeling are used for drug products are not written.

Specifically, you have no written procedures ensuring the proper labels and labeling is applied to human umbilical cord tissue products to include (b) (4) .

- You do not conduct an examination of labels and labeling at any point during the processing of (b) (4) .
- You do not examine each batch of labels prior to labeling (b) (4) (b) (4) vials for injection. There is no control over labeling that is issued.

From September 2023 to December 2025, your firm manufactured and distributed

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

human umbilical cord-derived products including but not limited to approximately (b) (4) lots ((b) (4) units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots ((b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot ((b) (4) units) of product marketed as growth factor ((b) (4)).

OBSERVATION 14

Drug products are not quarantined before being released by the quality control unit.

Specifically, on 11/19/2025, we observed umbilical cord tissue product, (b) (4) , Lot (b) (4) (b) (4) , being stored in Bello Bio's (b) (4) freezer. Lot (b) (4) , has not been released for distribution but was not marked as quarantined. Your firm does not have written procedures on how to handle product held in quarantine.

OBSERVATION 15

After the completion of the donor-eligibility determination, HCT/Ps were not accompanied with a statement whether the donor has been determined to be eligible or ineligible, based on the results of screening and testing.

Specifically, your firm distributes (b) (4) directly to Regen Suppliers LLC. Your firm provides a Certificate of Analysis (COA) for communicable disease testing to Regen Suppliers LLC. This COA is signed by your Medical Director, however, the certificate lacks:

- A statement of whether the donor is eligible or ineligible
- A statement of donor eligibility based of donor screening results
- A statement that the communicable disease testing was performed by a laboratory certified to

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 11/17/2025-12/16/2025* FEI NUMBER 3028583081
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Samantha J. Brechner, CEO

FIRM NAME Bello Bio LLC	STREET ADDRESS 10045 E Dynamite Blvd Ste 260
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85262-3752	TYPE ESTABLISHMENT INSPECTED Biological Product Manufacturer

perform such testing on human specimens under the Clinical Laboratory Improvement Act of 1988 or has met equivalent requirements determined by the Centers for Medicare and Medicaid Service.

- The address of the establishment reviewing the donor records documents to make a donor eligibility determination.

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots ((b) (4) units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots ((b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot ((b) (4) units) of product marketed as growth factor ((b) (4)).

OBSERVATION 16

Procedures were not designed to ensure compliance with the donor eligibility requirements.

Specifically, your firm lacks written procedures for donor eligibility determination.

From September 2023 to December 2025, your firm manufactured and distributed human umbilical cord-derived products including but not limited to approximately (b) (4) lots ((b) (4) units) of product marketed as Wharton's Jelly ((b) (4)), (b) (4) lots ((b) (4) units) of product marketed as exosomes ((b) (4)), and (b) (4) lot ((b) (4) units) of product marketed as growth factor ((b) (4)).

***DATES OF INSPECTION**

11/17/2025(Mon), 11/18/2025(Tue), 11/19/2025(Wed), 11/20/2025(Thu), 11/21/2025(Fri), 11/24/2025(Mon), 12/01/2025(Mon), 12/08/2025(Mon), 12/11/2025(Thu), 12/16/2025(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Garrad R Poole, Investigator Emily S McGann, Investigator Laurissa S Flowers, Investigator	Garrad R Poole Investigator Signed By: GARRAD R. POOLE - Date Signed: 12-16-2025 08:56:21 X	DATE ISSUED 12/16/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

19701 Fairchild
Irvine, CA 92612-2445
(949) 608-2900 Fax: (949) 608-4417

DATE(S) OF INSPECTION

11/17/2025-12/16/2025*

FEI NUMBER

3028583081

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Samantha J. Brechner, CEO

FIRM NAME

Bello Bio LLC

STREET ADDRESS

10045 E Dynamite Blvd Ste 260

CITY, STATE, ZIP CODE, COUNTRY

Scottsdale, AZ 85262-3752

TYPE ESTABLISHMENT INSPECTED

Biological Product Manufacturer

X
Emily S. McGann
Investigator
Signed By: Emily S. McGann -S
Date Signed: 12-16-2025 08:56:54

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Garrad R Poole, Investigator
Emily S McGann, Investigator
Laurissa S Flowers, Investigator

X
Garrad R Poole
Investigator
Signed By: GARRAD R. POOLE -
S
Date Signed: 12-16-2025
08:56:21

DATE ISSUED

12/16/2025

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."