DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	12/9/2024-12/19/2024* FEI NUMBER 1000117860

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Claudia C. Briell, President/Owner

FIRM NAME	STREET ADDRESS
Quality Bioresources, Inc	1015 N Austin St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seguin, TX 78155-4517	Medical Device and Manufactuer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing, processing, packing and (b) (4)

Specifically, you stated your customer for manufacturing (b) (4), a product derived from (b) (4) (b) (4) (b) (4) or (b) (4) batches manufactured, processed, packed, and (b) (4) at your facility. You stated the customer reviews all finished batch records and approves labeling before the products can be labeled.

There is no document showing approval for (b) (4) to (b) (4) by your customer in the batch records. The (b) (4) batch records for (b) (4), (b) (4), and (b) (4) do not contain documentation, other than your customer approving labeling, that the product is (b) (4).

Your manufacturing agreement, signed (b) (4) and Quality Plan to manufacture (b) (4) does not detail your customers authority to (b) (4) manufactured batches of (b) (4) nor does it remove your quality unit from making such (b) (4) of (b) (4) that has been manufactured, processed, and packed by your employees in your facility and is (b) (4) at your facility.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Richard T Riggie, Investigator	X Richard T Riggie Investigator Signed By: Richard T. Riggie -S Date Signed: 12-19-2024 11:15:53	12/19/2024

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You have not stated the concentration of (b) (4) that (b) (4) is purported to possess. You have not identified in your Quality Plan or demonstrated in batch records for (b) (4) where appropriate during manufacturing, theoretical yields of the (b) (4) and actual yields of (b) (4) were determined.

You currently have batches (b) (4) ((b) (4) lyophilized (b) (4) vials), (b) (4) ((b) (4) vials), (b) (4) ((b) (4) vials), and (b) (4) ((b) (4) vials) in your (b) (4) awaiting (b) (4) to (b) (4).

For batches (b) (4) (manufactured on 11/2/2018) and (b) (4) (manufactured on 1/9/2019), your customer requested new labeling extending the expiration from (b) (4) to (b) (4) after date of manufacturing. For lot (b) (4) (b) (4) labels were requested and the expiration date was increased to November 2026. For lot (b) (4) (b) (4) labels were requested and the expiration date was increased to January 2027.

OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the (b) (4) have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, you have not provided a written validation for the production and process controls for (b) (4) tissue. You do not have a written procedure for processing (b) (4) tissue for employees to refer too.

You do not have a written procedure that allows for your customers to process (b) (4) tissue in your facility while performing on the job training to your employees.

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Your Quality Plan for (b) (4) and batch records do not state or represent what the concentration of the (b) (4) may possess.

Since you began manufacturing and/or lyophilizing (b) (4) in (b) (4), you have manufactured (b) (4) batches for a total of (b) (4) vials (b) (4) and (b) (4) to your customer. You currently have batches (b) (4) ((b) (4) lyophilized (b) (4) vials), (b) (4) ((b) (4) vials), (b) (4) ((b) (4) vials), and (b) (4) ((b) (4) vials) in your (b) (4) awaiting (b) (4) to (b) (4).

Lots (b) (4) and (b) (4) have available vials that have been shipped to the customer on 2/13/2019. Your customer requested new increased the expiration date from (b) (4) to (b) (4), thus making (b) (4) vials of lot (b) (4) available unit November 2026 and (b) (4) vials of lot (b) (4) available until January 2027.

OBSERVATION 3

Employees engaged in the manufacture and processing of a (b) (4) lack the training and experience required to perform their assigned functions.

Specifically, you stated that your employees who are engaged in the manufacturing of (b) (4), a (b) (4) tissue derived product, are not fully trained and that your customer's Vice President of Operations is currently training them when manufacturing (b) (4)

Since you began manufacturing and processing (b) (4), you stated your customer's Vice President of Operations has been present and participates in the manufacturing of all (b) (4) batches, up until the point of filling.

Per your (b) (4)", since (b) (4), you have manufactured (b) batches of

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(b) (4) a total of (b) (4) vials filled, and a total of (b) (4) vials of (b) (4) shipped to your customer.

You do not have a written procedure for processing (b) (4) tissue.

OBSERVATION 4

Strict control is not exercised over labeling issued for use in (b) (4) labeling operations.

Specifically, you shipped manufactured and labeled (b) (4) product lot (b) (4) (manufactured on 11/2/2018) and lot (b) (4) (manufactured on 1/9/2019) on 2/13/2019 to the (b) (4) From (b) (4) the finished lots ((b) (4) and (b) (4) were shipped to your customer. On 7/20/2023, your customer contacted you requesting (b) (4) additional labels for lot (b) (4) and (b) (4) additional labels for lot (b) (4)

These new labels will extend the (b) (4) expiration to an (b) (4) expiration.

You do not have documentation accounting for the use of these labels or a final reconciliation of these labels. The batch records reflect that originally (b) (4) units were produced, labeled, and shipped to your customer.

***DATES OF INSPECTION**

12/09/2024(Mon), 12/10/2024(Tue), 12/11/2024(Wed), 12/12/2024(Thu), 12/13/2024(Fri), 12/16/2024(Mon), 12/17/2024(Tue), 12/19/2024(Thu)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

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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."