DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Inspector: Jie He Telephone: 240-402-9584 Industry Information: www.fda.gov/oc/industry	Feburary 12 to 16, 2024
	FEI NUMBER 3015451326

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tori Arens, Site General Manager, VP, Resilience USA, Inc.

FIRM NAME	STREET ADDRESS
Resilience US, Inc	1733 TW Alexander Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Durham, NC 27703	Cell and Gene Therapy Contract 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 (I) (WE) OBSERVED:

1. Inadequate procedures to classify events as deviations. Appendix 1 of D-00694, Global Deviation Management, contains a list of situations in which neither a deviation nor an explanation is required. Specifically, the procedure allows the following events to occur without initiating a deviation or providing an explanation:
a. Corrections with no explanation, including changes to recorded data.
b. Initials/signatures missing, or incorrect initial used.
c. Transcription error or transcription without explanation.
2. Defined procedures for retesting for Out of Specifications are not established. Specifically, when retesting is permitted, how many retests are allowed, and how final result is calculated.
3. Inadequate procedures to trend similar deviations. Specifically, deviation trending was not identified for the following:
a. Missing product (b) (4) observed (QE-005126, QE-005088, QE-001463)
b. Inappropriate material used in manufacturing (QE-004860, QE-00858)
c. Use of incorrect reference standards (QE-001133, QE-000538)
4. The disinfectant efficacy study is deficient. Specifically, no (b) (4) were used in the study to demonstrate the effectiveness of the selected disinfectants.
5. There are deficiencies in testing for the incoming components. Specifically,
a. There have not been any (b) (4) tests performed by Resilience RTP for (b) (4) (container closure for (b) (4). The Firm has not established the reliability of the supplier's certificate of analysis through verification at appropriate intervals.
b. The (b) (4) of each incoming batch of the (b) (4) used in the production of (b) (4) (b) (4) is not adequately tested to confirm (b) (4)

SEE REVERSE OF THIS PAGE	/S/	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Jie He, Lead Consumer Safety Officer Sharmila Shrestha, Biological Reviewer Anna Kwilas, Supervisory Biologist Laura DeMaster, Biological Reviewer	Feb. 16, 2024