DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/6/2023-11/10/2023
	FEI NUMBER 3007503037

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sankalp Vashishtha, VP, GMP & Site Head RBI

FIRM NAME	STREET ADDRESS
Resilience Biotechnologies, Inc.	2585 Meadowpine Blvd
CITY, STATE, ZIP CODE, COUNTRY Mississauga, L5N 8H9	TYPE ESTABLISHMENT INSPECTED Sterile Drug 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 OBSERVED:

OBSERVATION 1

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.

Your investigations failed to evaluate all aspects and provide supporting evidence that could identify the origin of the mold species detected in the in-process samples of the (b) (4) *batches* (b) (4) *solution* (b) (4) *Suspension). Those include Purpureocillium lilacinum, Penicillium rubens, Penicillium chrysogenum/flavigenum, Aspergillus shendaweii and Aspergillus terreus.*

Specifically,

Your investigations pointed that active ingredient batches (b) (4) *as the primary contributor to this contamination. However, the many active ingredients batches received onsite have not been analyzed for microbial load before being used in the formulation process. Although these investigations began since 02/2021, no microbial testing on active ingredients batches has been required to confirm whether these batches are indeed the source of contamination.*

Furthermore, your investigations do not include an overall assessment of the multiple mold species detected in different production and support areas since 2021. Nor have any trend reports been evaluated during as part of these investigations.

OBSERVATION 2

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	Libia M Lugo, Investigator X Libia M Lugo Investigator Signed By: Libia M. Lugo Leon -S Date Signed: 11-10-2023 20: 8: 5	11/10/2023

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

Your current environmental monitoring program and trended data have reported multiple deviations to the established microbial level for air and surfaces in different classified areas throughout your site operations.

Specifically,

Since 02/2022, environmental monitoring samples from formulation and supporting classified rooms (grade C) (i.e., (b) (4) *reported microbial limit excursions and presence of microorganisms that may be objectionable. For example,*

- *On 02/2022, active air samples from rooms* (b) (4) *reported the isolates Cladosporium halotolerans, Aspergillus cristatus/montevidensis, Penicillium chrysogenum I flavigenum, Paraphaeosphaeria neglecta.*
- *On 04/13/2022, surface samples from formulation room* (b) (4) *isolated Alternaria alternata*
- *On 06/20/2022, active air samples from formulation room* (b) (4) *reported Cladosporium sphaerospermum.*
- *On 10/14/2022, surface samples from room* (b) (4) *reported the presence of Penicillium spinulosum.*

Although your firm has cleaning and disinfection procedures for equipment units and areas, among other controls in place, similar excursions were recurring during 2022. And even after implementing several corrective actions, your gown monitoring program has reported several excursions during this year 2023.

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Mississauga, L5N 8H9	Sterile Drug Manufacturer

-Your gowning monitoring also reported events of microbial counts and potentially objectionable organisms detected on gowns and gloves of personnel assigned to classified areas (Garde A and B) since the beginning of 2022.

For example, during media fill activities, samples from operator's glove reported out of limit counts while supporting activities from a grade B area. On 03/29/2022, Peribacillus simplex, identified as an objectionable organism, was isolated from an operator's gown-zipper. On 11/2022, your staff reported out-of-limit counts and isolated Aspergillus cristatus/ montevidensis from a gown-closure.

-In addition, your gowning monitoring has reported at least 16 events of microbial counts on gowns and gloves of staff assigned to classified areas (Grade A and B) during the period April to June 2023. Investigations so far have identified possible Inadequate aseptic techniques during the gowning process may have contributed to these excursions. In this regard, in samples collected on 05/2023, Arthopyrenia salicis ssp. was isolated from an operator's gown.

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Libia M Lugo, Investigator

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