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 Insp.: Alifiya H. Ghadiali Telephone: 301-796-2064 Industry Information: www.fda.gov/oc/industry	04/01/2024 - 04/05/2024
	FEI NUMBER 3014294024

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Heather Prichard, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Humacyte Global, Inc.	2525 E. Highway NC 54
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Durham, NC 27713	Drug 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 (I) (WE) OBSERVED:

1. There is no microbial quality assurance of the (b) (4) used for the (b) (4) Specifically, there is no microbial testing or (b) (4) formulated using (b) (4) steps.

2. Quality oversight is inadequate for the following issues observed:

a. Investigating Out of Specification Results, SOP-0313-04, does not contain procedures for requesting an extension or opening a deviation if the investigation is not completed within the recommended 60 days. There were 10 out of 31 out-of-specification investigations from (b) (4) that were open for more than 100 days, with the longest being open for 710 days.

b. The contract cleaning crew was not current with their (b) (4) cGMP Refresher Training as required by the Training Program, SOP-0315-04. Additionally, one member of the cleaning crew was not current on the GxP Cleaning Contractor Core Training "Facility Cleaning and Disinfection".

c. A complete record for the role-based training (b) (4) was not available for an operator observed participating in (b) (4) in (b) (4) Room (b) (4)

d. The quality review of the (b) (4) preventative maintenance of the air handling unit was approved without the required documentation in (b) (4) per Use of (b) (4) SOP-0127-01 and Preventative Maintenance, SOP-0169-04.

SEE REVERSE OF THIS PAGE	/S/	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Alifiya H. Ghadiali, Lead Consumer Safety Officer Zainab Mansaray-Storms, Consumer Safety Officer Laura Ricles, Division Director Jin Sung Hong, Biologist	04/05/2024

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 judgement, 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."