DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Carolyn Renshaw, Building 71 Rm. 4042 Telephone: (240) 402-7343 Industry Information: www.fda.gov/oc/industry	07/24/2023 to 07/27/2023
	FEI NUMBER 3004536648

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Hans Huber, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Biomay AG	Lazarettgasse 19/1
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Vienna 1090 Austria	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. Procedures for contamination control are not followed. Specifically,
a. Equipment is not in state of good repair. Specifically, visible (b) (4) were observed (b) (4) the Grade (b) (4) during manufacturing operations.
b. Cleaning (b) (4) were found stored (b) (4) and (b) (4) of the room (b) (4). According to SOP-(b) (4)006, room (b) (4) must be kept clear at all times and must not be covered at any time.

2. Equipment is not adequately qualified. Specifically, an air visualization study under in-operation conditions has not been performed to qualify the Grade (b) (4) to adequately demonstrate appropriate air flow is maintained during manufacturing operations.

SEE REVERSE OF THIS PAGE

/s/

DATE ISSUED
07/27/2023

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."