Attachment 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Biotechnology Manufacturing 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPFBLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	08/22/2022 - 08/26/2022
	FEI NUMBER 3005987757

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Wolfgang Weikmann, Senior Vice President Quality

FIRM NAME	STREET ADDRESS
Vetter Pharma-Fertigung GmbH & Co. KG	Mooswiesen 2
CITY, STATE AND ZIP CODE Ravensburg, Germany 88214	TYPE OF ESTABLISHMENT INSPECTED Drug Product Manufacture

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:

Observation 1

Written procedures for production and process control designed to assure that the drug products have the identify, strength, quality and purity they purport or are represented to possess is not established or is deficient. Specifically,

a. On 24 August 2022, we observed the setup of the (b) (4) Fill Line (b) (4) for (b) (4) manufacture, Batch (b) (4) in support of (b) (4) drug product manufacture. Observed was RABS (b) (4) into Grade A airflow, Grade B space in assembly of the stopper and (b) (4) bowl to the fill line, with the RABS into Grade A space without sanitization.

b. Deviation 759735, 04 March 2022 and Deviation 630260, 12 March 2020 were raised for non-integral HEPA filters in Grade A/B space and outside the RABS in Grade A airflow (Grade B space), respectively for the (b) (4) Fill Line (b) (4) The initial classification of each HEPA filter failure was minor, without the completion of a detailed and comprehensive deviation investigation for impact on product quality. Your product quality impact assessment failed to include a review of product complaints and an inspection of product reserve samples that may provide additional insight into product quality.

Observation 2

An equipment system in support of drug product manufacture is not adequately maintained. Specifically,

On 22 August 2022, we observed the (b) (4) Fill Line (b) (4) mechanical box cover for the (b) (4) in Grade A space not sealed as designed.

Observation 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Wayne Seifert Zonglin Hu	Wayne Seifert, Consumer Safety Officer Zonglin Hu, Microbiologist	08/26/2022

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Ravensburg, Germany 88214	Drug Product Manufacture

A standard operating procedure in support of drug product manufacture is not followed. Specifically,

a. According to SOP 11093, "Good Documentation Practices", v15, Section 5.3.4, Correction in Records provides instruction for correction of a documentation error, with a single line-out of the error that includes initial and date and the reason for the correction. On 22 August 2022, we observed numerous documentation write overs for the (b)(4) 2 - 8°C walk-in storage logbook without proper correction. The standard operating procedure was not followed.

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		Wayne Seifert, Consumer Safety Officer Zonglin Hu, Microbiologist	08/26/2022