DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
ORA OPQO HQ, Room #2032 12420 Parklawn Drive, Rockville, MD 20857 E-mail: ORAPHARMInternational483responses@fda.hhs.gov	03/20/2023-03/24/2023
	FEI NUMBER 3010363503

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Hans-Peter Frueh, Chief Executive Officer

FIRM NAME	STREET ADDRESS
FRUEH VERPACKUNGSTECHNIK AG	Allmendstrasse 47
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fehraltorf, Zurich, 8320 Switzerland	Drug Product Packager, Medical Device Packager

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 WE OBSERVED:

DRUG

OBSERVATION 1

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically, your firm has not performed any cleaning validation studies to assess the effectiveness of your cleaning procedures for equipment and rooms used in the packaging operations for (b)(4) (b)(4) drug products. Additionally, no disinfectant efficacy studies have been conducted to ensure the effectiveness of your disinfectants used during cleaning operations.

OBSERVATION 2

Requirements that must be met by suppliers have not been adequately established.

Specifically, (b)(4) components of (b)(4) drug product are not adequately controlled for bioburden levels. Specifications for (b)(4) (b)(4) do not include a bioburden requirement and incoming certificates of conformity do not certify that components meet a bioburden requirement.

OBSERVATION 3

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in manufacturing, processing, and packing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Arsen Karapetyan	Arsen Karapetyan, Inv-Dedicated Drug Cadre Stephen D. Eich, Investigator	March 24, 2023

Specifically, during packaging operations of [(b)(4)] drug product, we observed [(b)(4)] [(b)(4)] This practice of [(b)(4)] is not detailed in your batch record, nor is it described in a procedure.

OBSERVATION 4

The responsibilities and procedures applicable to the quality unit are not in writing and fully followed.

Specifically

Supervisory oversight over quality/production unit operations and laboratory/production electronic system and data is deficient. For Example

A. The Quality Unit lacks adequate control over the issuance of production batch records purported to be controlled under your batch issuance procedures. During the inspection, it was observed that copies of official batch records for drug products [(b)(4)] [(b)(4)] without adequately controlling each page. For example,

(b)(4)

B. There are no requirements for the Quality Unit oversight of Master Batch Record storage and copying for use in manufacturing to ensure executed record instructions are accurate reproductions of the master records. Your firm does not maintain adequate master batch records for the above-mentioned drug products. During the inspection, we observed at least two recent deviations where incorrect batch record documents were issued and used by the production unit.

C. Your firm does not have adequate Quality Unit oversight of visual inspection qualification test kits and the qualification process for operators performing visual inspection operations during packaging of drug products [(b)(4)]. For example, per your firm's procedure, the [(b)(4)]

(b)(4)

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D. There is no adequate data integrity program in place to include an adequate review of all electronic data by the Quality Assurance Unit for standalone and network systems, to ensure completeness, consistency, and accuracy of all laboratory and production equipment electronic data generated by your firm. Specifically, per your firm's procedure, (b)(4) (b)(4) This review process does not appear to be adequate, in that all potential data generated during that specific review period for that product are not reviewed. There is no adequate reconciliation of all generated electronic test and production data during the review process for standalone and network equipment.

E. Your firm does not have a written procedure, which include, but not limited to, establishing the requirements for quality agreements, the responsibilities of each party, and the review and approval for the agreements.

OBSERVATION 5

Each lot in shipment received was not identified with a distinctive code for each container or grouping of containers for components,

Specifically,

The firm does not assign unique lot number for each lot in each shipment received for all drug components. Currently, the firm uses the (b)(4) (b)(4)

MEDICAL DEVICE

OBSERVATION 6

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated.

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Specifically, the sterilization process (as reported in Document VB 15254) for (b)(4) (b)(4) The validation does not demonstrate that the process can consistently produce dry product.

Annotation
Observation 6 promised to correct by (b)(4)
AK 03/24/2023

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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 judgment, 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."