DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71-5128 Silver Spring, MD 20993-0002 240-402-8906 orabioinspectionalcorrespondence@fda.hhs.gov	2/25/2020-3/5/2020* FEI NUMBER 3008640339

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Vladimir Melnikov, Senior Operation Director & Omrix General Manager

FIRM NAME	STREET ADDRESS
Omrix Biopharmaceuticals Ltd.	14 Einstein Street, Weizmann Science Park
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Nes-Ziona, 7403618 Israel	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 WE OBSERVED:

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Per Procedure-96247 / 05 "Procedure for Cutting 2"x4" Fibrin Pad", EVARREST Patch samples (b) (4) testing are cut into (b) (4) . Per Form-02596 / 01, "Logbook for EVARREST Visual Assessment and Cutting" (b) (4) cut from (b) (4) are designated for specific tests; e.g. thrombin activity, clottable protein, calcium, and total protein. There is no written justification for assigning these (b) (4) of the patch to specific tests.

OBSERVATION 2

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Mihaly S Ligmond, Investigator - Team Biologics Steven E Bowen, Investigator - Team Biologics Chava Kimchi Sarfaty, FDA Center Employee or Employee of Other Federal Agencies	X Mihaly S Ligmond Investigator - Team Biologics Signed By: Mihaly S. Ligmond -S Date Signed: 03-05-2020 02:09:54	3/5/2020

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A. Forms used to record data for the analytical method "Procedure for the Bacterial Endotoxin Test Using the (b) (4) Method, by (b) (4) (Procedure (b) (4)) are not controlled. For this method data are collected using the (b) (4) . Results are (b) (4) by the (b) (4) onto Form (b) (4): "Form for (b) (4) r Test Results-Endotoxin Testing". Blank forms are accessible for (b) (4) to (b) (4), and (b) (4) of the form are not tracked or reconciled.

B.Documentation associated with sample testing is not always controlled. For example, as documented in FORM-01687 / Rev: A, "Logbook for Determination of Clottable Proteins", the (b) (4) of sample (b) (4) was lower than the acceptable (b) (4) . A "verification" of this sample is also documented in this logbook as having been performed. The actual steps performed as part of the "verification" were not completely documented. Additionally, a (b) (4) that was taken as part of the "verification" process was stored in an uncontrolled manner.

OBSERVATION 3

Established laboratory control mechanisms are not documented at the time of performance.

Specifically,

Laboratory procedures do not ensure the control and accountability of samples received by the QC laboratory. For example:

A. Final drug product samples are logged into the (b) (4) system. Entries are not made in this system when samples are removed.

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B. (b) (4) samples are logged into the "QC logbook – QC Laboratory Samples", (b) (4) . Entries are not made in this logbook when samples are removed.

C. (b) (4) samples are logged into the "QC logbook – QC Laboratory Samples", (b) (4) . Entries are not made in this logbook when samples are removed.

D. Samples that were designated as "(b) (4) " in the "QC logbook – QC Laboratory Samples", (b) (4) , were used during an OOS investigation regarding Batch # (b) (4) .

OBSERVATION 4

Batch production and control records do not include complete labeling control records, including specimens or copies of all labeling used for each batch of drug product produced.

Specifically,

A specimen of the Instructions for (b) (4) is not routinely included in the EVARREST batch record.

***DATES OF INSPECTION**

2/25/2020(Tue), 2/26/2020(Wed), 2/27/2020(Thu), 3/01/2020(Sun), 3/03/2020(Tue), 3/04/2020(Wed), 3/05/2020(Thu)

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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."