U.S. FOOD & DRUG ADMINISTRATION

Pharmaceutical Quality Investigation Branch
19701 Fairchild Rd.
Irvine, CA 92612
www.fda.gov

Via UPS
Return Receipt Requested

09/17/2019

Mr. Jure Kapetan
Managing Director
Eurofins Biopharma Product Testing Munich GmbH
Behringstr. 6/8
Planegg, Bavaria, 82152 Germany

Dear Mr. Kapetan:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Eurofins Biopharma Product Testing Munich GmbH, FEI:3003706029, located at Behringstr. 6/8, Planegg, Bavaria, 82152 Germany from 07/08/2019 - 07/12/2019. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI").[1] Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product-and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact me at (949) 608-3519 or email at Katherine.Jacobitz@fda.hhs.gov.

Sincerely,

Katherine E. Jacobitz -S

Digitally signed by Katherine E. Jacobitz -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300153047, cn=Katherine E. Jacobitz -S
Date: 2019.09.17 08:51:53 -07'00'

CAPT Katherine E. Jacobitz
Investigations Branch Director, Division IV
Office of Pharmaceutical Quality Operations

[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.