U.S. FOOD & DRUG ADMINISTRATION

Office of Pharmaceutical Quality Operations
Division 1
10 Waterview Blvd, 3rd Floor
Parsippany, NJ 07054
www.fda.gov

Via UPS
Return Receipt Requested

11/16/2018

Mr. Bjorn Kumer
Head of Operations
A & M StabTest GmbH
Galileo-Galilei-Str. 28
Mainz, 55129 Germany

Dear Mr. Bjorn Kumer:

The U.S. Food and Drug Administration (FDA) conducted an inspection at A & M StabTest GmbH, FEI:3008929709, located at Galileo-Galilei-Str. 28, Mainz, 55129 DE from 10/08/2018 - 10/09/2018. FDA has determined that the inspection classification of this facility is "no action indicated" ('NAI')[1]. Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

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 NAI 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 CDER's Office of Pharmaceutical Quality. 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 CDR Paul C. Mouris via telephone at 914-682-2826 ext. 13 or email at Paul.Mouris@FDA.HHS.GOV.

Sincerely,

Paul C. Mouris -S5

Digitally signed by Paul C. Mouris -S5
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300193100, cn=Paul C. Mouris -S5
Date: 2018.11.16 16:11:31 -05'00'

CDR Paul C. Mouris
Supervisory Consumer Safety Officer
Pharma Division I, Investigations Branch II

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