U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Office of Regulatory Affairs
12420 Parklawn Dr.
Rockville, MD 20852
www.fda.gov

Via UPS Worldwide Saver (Express)
Return Receipt Requested

1 June 2021

Mr. Adriaan Broer
Business Unit Manager
Eurofins PROXY Laboratories B.V
Archimedesweg 25 2333 CM
Leiden Netherlands

Dear Mr. Broer

The U.S. Food and Drug Administration (FDA) reviewed an inspection conducted by the Ministry of Health Welfare and Support at Eurofins PROXY Laboratories, located at Archimedesweg 25 2333 CM Leiden NE, from April 3 to May 1, 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 documented objectionable conditions were found 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 deviations noted during 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). If you have any questions regarding this letter, please contact: ORAMRAInspectionReview@fda.hhs.gov.

Sincerely,

Ann M. Montemurro -S

Digitally signed by Ann M. Montemurro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000095112, cn=Ann M. Montemurro -S
Date: 2021.06.02 16:41:55 -04'00'

Ann Marie Montemurro
Director, Division of Pharmaceutical Quality Programs

FEI:3004939239

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