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

20 January 2021

Ms. Silvia Armada
Technical Director
Eurofins BioPharma Product Testing Spain S.L.U.
Calle Josep Argemi 13-15
Esplugues de Llobregat ,Barcelona ,08950, Spain

Dear Ms. Armada:

The U.S. Food and Drug Administration (FDA) reviewed an inspection conducted by the General Sub-Directorate of Planning and Healthcare and Pharmaceutical Quality, Catalonia Ministry of Health, at Eurofins BioPharma Product Testing Spain S.L.U., located at Calle Josep Argemi 13-15 Esplugues de Llobregat, from 5-6 November 2018. 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: 2021.01.20 09:54:24 -05'00'

Ann Marie Montemurro
Director, Division of Pharmaceutical Quality Programs

FEI: 3007914833

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