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

15 September 2018

Mr. Luigino Maggi, Owner
LabAnalysis Srl
Via Europa 5
Casanova Lonati
Pavia IT 27041

Dear Mr. Maggi:

The U.S. Food and Drug Administration (FDA) reviewed an inspection conducted by Agenzia Italiana Del Farmaco (AIFA) at LabAnalysis Srl located at Via Europa 5, Casanova Lonati, Pavia IT 27041, from 15 – 17 February 2017. 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 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.

If you have any questions regarding this letter, please contact us at: ORAMRAInspectionReview@fda.hhs.gov.

Sincerely,

Julianne C. Mccullough -S

Digitally signed by Julianne C. Mccullough -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13001253961, cn=Julianne C. Mccullough -S
Date: 2018.09.15 13:45:56 -04'00'

Consumer Safety Officer
Mutual Reliance Inspection Review Team

FEI: 3006684386

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