LabAnalysis
HIGH QUALITY CONTROLS

GDUFA Self-ID Confirmation Statement – FY2024

LabAnalysis srl hereby confirms that the following facilities, sites and organizations have been electronically self-identified with the United States Food and Drug Administration for FY2024

Signature

May 18, 2023
Date

Stefano Maggi
Qualified Person – Casanova Lonati site
LabAnalysis srl
Telephone number +39-0385287128
Fax:+39-038557311
e.mail: l.maggi@labanalysis.it

Facilities/Sites/Organizations Names and Addresses				**Self-Identified Yes or No**
Registrant - LabAnalysis srl (338466205)				Yes
Contact Giuseppe Ceramelli	**Address** Address: Via Domenico Cimarosa 95/105 City, State, Zip: Livorno, 57124 Country: ITA	**Telephone Number** +39-0385-287128	**Email Address** giuseppe.ceramelli@labanalysis.it	
Facility				
Name LabAnalysis srl	**Address** Address: Via Europa 5 City, State, Zip: Casanova, Lonati, 27041 Country: ITA	**ID/FEI** 338466205/3006684386	**Business Operations** api/fdf analytical testing(Manufactures Non-Generics)	
Contact Stefania Rai	**Address** Address: Via Europa 5 City, State, Zip: Casanova, Lonati, 27041 Country: ITA	**Telephone Number** +39-0385-287128 FAX: +39-0385-57311	**Email Address** S.Rai@labanalysis.it	

Revised: 05/2023

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

25 May 2021

Dr. Stefano Maggi
Qualified Person
LabAnalysis S.R.L.
Via Europa 5
Casanova Lonati
27041, Pavia IT

Dear Dr. Maggi:

The U.S. Food and Drug Administration (FDA) reviewed an inspection conducted by the Italian Medicines Agency (AIFA) at LabAnalysis S.R.L., located at Via Europa 5, Casanova Lonati, 27041 Pavia IT, from 13 – 15 November 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: 2021.05.27 09:46:11 -04'00'

Ann Marie Montemurro
Director, Division of Pharmaceutical Quality Programs

FEI: 3006684386

eCC: AIFA

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing Quality
Division of Drug Quality I
10903 New Hampshire Avenue
Building #51, Room 435
Silver Spring, MD 2099

TELEPHONE: (240) 402-734
FAX: (301) 847-874

March 8, 2016

Prof. Luigino Maggi
Owner
LabAnalysis S.R.L.
Via Europa 5
Casanova Lonati (Pavia) 27041
Italy

Reference: FEI 3006684386

Dear Professor Maggi:

We completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your contract testing facility in Casanova Lonati, Italy by Investigator Sandra Hughes during the period of October 12 through 15, 2015. A Form FDA-483, Inspectional Observations was issued at the conclusion of the inspection.

We have also reviewed your company's response dated November 3, 2015, with supportive documentation. Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm.

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

Lynnsey Renn

Lynnsey Renn, Ph.D.
Compliance Officer
Division of Drug Quality II
Global Compliance Branch 3
CDER / OC / OMQ

Enclosure: EIR