



06/10/2019

Nikolaos Megkoulas, PhD  
Chief Executive Officer  
QualiMetrix SA  
579 Mesogeion Avenue  
Athens, Agia Paraskevi 15343 Greece

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

Reference: Inspection Date(s): 4/22/2019 - 4/23/2019

Location: QualiMetrix SA  
579 Mesogeion Avenue  
Athens, Agia Paraskevi 15343 Greece  
FEI: 3015131309

Dear Dr. Megkoulas:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency 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 Valerie L. Whipp via telephone at 240-402-2599 or email at Valerie.Whipp@fda.hhs.gov.

For more information on the U.S. FDA, please visit our website at [www.fda.gov](http://www.fda.gov).

Sincerely,  
Valerie L. Whipp -  
S

Digitally signed by Valerie L. Whipp -S  
DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA,  
ou=People, o=S.2342.19200300.100.1.1-1300072724,  
cn=Valerie L. Whipp -S  
Date: 2019.06.10 10:27:39 -0400

Valerie L. Whipp  
Supervisory Consumer Safety Officer  
Investigations Branch II  
Division I, OPQO

Enclosure: Establishment Inspection Report (EIR)

U.S. Food and Drug Administration  
[www.fda.gov](http://www.fda.gov)