



**FDA** **U.S. FOOD & DRUG**  
ADMINISTRATION

07/23/2019

Dr. Markus Limberger, CEO  
Quasaar GmbH Comotorstr. 2  
Uberherrn, Saarland, 66802  
Germany

U.S. Food & Drug Administration  
Attn: Diana Amador Toro  
Pharma Division 1 Director  
10 Waterview Blvd. 3rd Floor  
Parsippany, NJ 07054

Reference: Inspection Date(s):05/27/2019 - 05/29/2019

Location: Quasaar GmbH  
Comotorstr. 2  
Uberherrn, 66802  
DE

Dear Dr. Markus Limberger:

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 Paul C Mouris via telephone at 914-682-2826 ext. 13 or email at [Paul.Mouris@FDA.HHS.GOV](mailto:Paul.Mouris@FDA.HHS.GOV).

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

Sincerely,  
Paul C. Mouris -  
S5

Digitally signed by Paul C. Mouris -S5  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,  
ou=People, o.9.2342.19200300.100.1.1=1300193100,  
cn=Paul C. Mouris -S5  
Date: 2019.07.23 09:56:35 -0400

FEI:3014297892  
Enclosure: Establishment Inspection Report (EIR)

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

CDR Paul C Mouris  
Supervisory Investigator  
Division of Pharmaceutical Quality  
Operations I  
Investigations Branch