

04/17/2018

Dr. R. Santing, Managing Director **Eurofins MicroSafe Laboratories** Darwinweg 24 Leiden, Zuid-Holland 2333 CR Netherlands

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): 9/5/2017 - 9/7/2017

Location: Eurofins MicroSafe Laboratories

Darwinweg 24

Leiden, Zuid-Holland 2333 CR Netherlands

Dear Dr. R. Santing:

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 there is any question about the released information, feel free to contact me at 518-453-2414 ext. 1014

Juan R. Jiménez, Acting Supervisory Consumer Safety Officer Pharma Division 1, Investigations Branch II

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely.

Digitally signed by Juan R. Jimenez Juan R. Jimenez Garcia S DN: c=US, 0=U.S. Government, 0u=HHS, 0u=FDA, 0u=People, 0.9.2342.19200300.100.1.1=1300176207, cn=Juan R. Jimenez Garcia -S Date: 2018.04.17 13:47:50 -04'00'

FEI: 3004594563

Enclosure: Establishment Inspection Report (EIR)

U.S. Food and Drug Administration

www.fda.gov