DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality
Office of Surveillance
Division of Quality Surveillance Assessment
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Silver Spring, MD 20993
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08/24/2016

Heppeler GmbH
Marie Curie Strasse 7
Lorrach, Baden-w¿rttemberg , DE

Reference: Inspection Date(s): 05/02/2016 - 05/04/2016

Location: Heppeler GmbH
Marie Curie Strasse 7
Lorrach, 79539 , DE

Dear Mr. Felix Heppeler,

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 240-402-6594.

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

Sincerely,

Jeneen Huff
for
Coki Cruz

FEI: 3007933377

Enclosure: Establishment Inspection Report (EIR)

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SUMMARY

This was a pre-announced inspection of a registered control testing laboratory. This inspection was conducted in accordance with CP 7356.002, Drug Process Inspections. This was a routine GMP inspection covering the Quality and Laboratory systems. This inspection includes profile class CTL and was conducted under eNSpect Operation ID# 18968.

The previous GMP inspection conducted in January 2014 and was classified as NAI.

No FDA-483 was issued, no samples were collected, and there were no refusals. Management was informed of their responsibility to adhere to the FD&C Act.

ADMINISTRATIVE DATA

Inspected firm:	Heppeler GmbH
Location:	Marie Curie Strasse 7 Lorrach, Baden-wrttemberg, 79539 Germany
Phone:	49-07621-9345-0
FAX:	07621-9345-67