



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

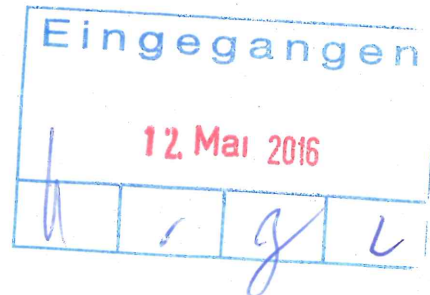
Division of Quality Surveillance Assessment
Inspection Assessment Branch
10903 New Hampshire Avenue
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Silver Spring, MD 20993

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5/10/2016

Dr. Jürgen Branke
Technical Managing Director
Daimlerstrasse 5b
Karlsruhe,
Germany

Reference FEI 3004058183
Reference inspection date (s): January 18-19, 2016
Establishment Locale: Karlsruhe, Germany



Dear Dr. Branke:

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 the above address or number.

Sincerely,

Merideth Rose
Consumer Safety Officer
Inspection Assessment Branch

Enclosure: EIR