



Food and Drug Administration
10903 New Hampshire Avenue
WO66- Room #2624
Silver Spring, MD 20993-0002

Via United Parcel Service

MAY 21 2014

Mario Bernkopf
General Manager (Sterilization) and Owner
BBF Sterilisationservice GmbH
Willy-Rusch-Strasse 10/1
Kernen-Rommelshausen, 71394
Germany

Re: 3006017180

Dear Dr. Bernkopf:


We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at the above referenced address on February 17 - 19, 2014, by Daniel S. Fam, on behalf of the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 C.F.R. 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. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency is working 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 reflects redactions made by the Agency in accordance with the FOIA and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

If there is any question about the released information, feel free to contact Ms. Fleadia Farrah at 301-796-5817 or write to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Field Inspections Support Branch
White Oak Building 66, Rm. 2624
10903 New Hampshire Ave.
Silver Spring, MD 20993

Sincerely yours,

for 

Steven D. Silverman
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: Summary of Inspectional Findings