



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration

College Park, MD

October 23, 2012

Ms. Lily
Fermenta Biotech LTD.
Village Takoli, P.O. Nagwain
Distt. Mandi, Himachal Pradesh
Mandi, India 175121

To whom it may concern:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at Fermenta Biotech LTD, Village Takoli, P.O. Nagwain, Distt. Mandi, Himachal Pradesh, Mandi, India, on May 24-25, 2012, by the U.S. Food and Drug Administration (FDA). 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. 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 may reflect redactions made by the Agency in accordance with the FOIA and 21 CFR 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 me at (240) 402-2271 or write to:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Food Adulteration Assessment Branch (HFS-607)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Sincerely,

Maria Lau
Compliance Officer
Food Adulteration Assessment Branch
Division of Enforcement
Office of Compliance
Center for Food Safety and Applied Nutrition

Enclosure – Fermenta Biotech LTD-EIR
FEI: 3007278757