U.S. FOOD & DRUG ADMINISTRATION

Office of Human and Animal Food Operations -East
Division Foreign Human and Animal Food Operations - East
12420 Parklawn Drive
Element Building, Room 1025
Rockville, MD 20857

9/13/2018

Mr. Lucky S. Thakur, Asst. General Manager QA
Fermenta Biotech Ltd.
District Mandi, Village Takoli, P O Nagwain
Nagwain, Himachal Pradesh, 175121, India

Reference: Inspection Date(s): 8/6/2018-8/7/2018

Location: Village Takoli, P O Nagwain, District Mandi
Nagwain, Himachal Pradesh, 175121
India

Dear Mr. Lucky S. Thakur,

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 Guy.Cartwright@fda.hhs.gov

Information on FDA's foreign facility inspection program can be accessed at:
http://www.fda.gov/Food/ComplianceEnforcement/Inspections/ucm196386.htm.

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

Sincerely,

Guy W. Cartwright -S

Digitally signed by Guy W. Cartwright -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300040871, cn=Guy W. Cartwright -S
Date: 2018.08.06 09:12:05 -04'00'

FEI: 3007278757

Enclosure: Establishment Inspection Report (EIR)