Division of Quality Surveillance Assessment
Inspection Assessment Branch
10903 New Hampshire Avenue
Building #51, Room 4316
Silver Spring, MD 20993

TELEPHONE: (301) 796-3254
FAX: (301) 847-8742

January 12th, 2017

Mr. Sadanand Nagaraja Rao
Owner and Managing Director
Supreem Pharmaceuticals Mysore Pvt. Ltd.
Plot No. 73, 74, & 48-P1, K.I.A.D.B. Industrial Area
Nanjangud, Mysore Dist., Karnataka, India 571302

Reference FEI 3006895996
Reference inspection date (s): 08/29/2016 – 09/02/2016
Establishment Locale: India

Dear Mr. Rao:

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,

**Binh T.
Nguyen -A**

Digitally signed by Binh T. Nguyen -A
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Binh T. Nguyen -
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Date: 2017.01.12 14:50:57 -05'00'

Binh T. Nguyen, Pharm.D., M.S. Reg Sci
Consumer Safety Officer
Inspection Assessment Branch

Enclosure: Establishment Inspection Report (EIR)