DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality
Division International Drug Quality
International Compliance Branch
10903 New Hampshire Avenue
Building #51, Room 4235
Silver Spring, MD 20993

TELEPHONE: (301) 796-4839
FAX: (301) 847-8742

April 24, 2014

Mr. Navin (NMI) Karnani
Site Director
DECCAN NUTRACEUTICALS PVT LTD
Gat NO1065 Markal
Tal Khed, Pune
Maharashtra, India

Reference: FEI 3007607026

Dear Mr. Karnani:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical ingredient (API) manufacturing facility in Maharashtra, India by Investigator Sandra A. Hughes and Chemist Ralph H. Vocque during the period of January 27-30, 2014. An FDA-483, Notice of Inspectional Observations was issued at the conclusion of the inspection.

We have also reviewed your company's response dated February 13, 2014 with supportive documentation. Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practice (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

Rafael Arroyo
Compliance Officer
Division of International Drug Quality

Enclosure: EIR