



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  
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April 30, 2015

Dr. S.D. Sawant, PhD  
Director  
Centaur Pharmaceuticals Private Limited  
Plot No. 75/76, 76/1  
Chikloli MIDC, Ambernath (West)  
Thane, India 421 501

Reference: FEI 3003973520

Dear Dr. Sawant:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your non-sterile Active Pharmaceutical Ingredient (API) by chemical synthesis manufacturing facility in Thane, India by Investigator Angela E. Glenn during the period of February 2, 2015 to February 5, 2015.

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 practices (CGMPs).

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](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,

Concepcion Cruz  
Branch Chief (Acting)  
Division of Quality Surveillance Assessment

Enclosure: EIR

Cc: