



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
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July 11, 2014

Eric Petat, Owner
ACM Pharma
30 Avenue du 21 Aout 1944
Bellegarde, France

Reference: FEI 3004177283

Dear Mr. Eric Petat:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your control testing laboratory facility in Bellegarde, France by Investigator Nicole E. Knowlton and Microbiologist Almaris N. Alonso from April 3 to 4, 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 April 23, 2014 with supportive documentation. The proposed commitments and corrective actions described in your responses will be verified during the next inspection. 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,

Thuy T. Nguyen
Compliance Officer
Division of International Drug Quality

Enclosure: EIR
CC: Mr Pierre Devaux, Director of Quality