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 4223
Silver Spring, MD 20993

TELEPHONE: (240) 402-4131
FAX: (301) 847-8742

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

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

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

TELEPHONE: (215) 717-3008
FAX: (301) 847-8742

July 7, 2016

Mr. Eric Petat
Owner
ACM Pharma
34, Avenue du 21 aout 1944
45270 Bellegarde
France

Reference FEI 3004177283
Reference inspection date (s): April 14-15, 2016
Establishment Locale: Bellegarde, France

Dear Mr. Petat:

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,

Vlada Matusovsky -A

Digitally signed by Vlada Matusovsky -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300119207, cn=Vlada Matusovsky -A
Date: 2016.07.07 10:23:28 -04'00'

Vlada Matusovsky
Consumer Safety Officer
Inspection Assessment Branch

Enclosure: EIR

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Office of Regulatory Affairs
12420 Parklawn Dr.
Rockville, MD 20852
www.fda.gov

Via UPS Worldwide Saver (Express)
Return Receipt Requested

19 January 2021

Mr. Eric Petat
Responsible Pharmacist
ACM Pharma
30 avenue du 21 Aout 1944
Bellegarde, Loiret, France 45270

Dear Mr. Petat,

The U.S. Food and Drug Administration (FDA) reviewed an inspection conducted by the Agence Nationale de Sécurité (ANSM) at ACM Pharma at 30 avenue du 21 Aout 1944, Bellegarde, Loiret, France 45270, dated 29-30 September 2020. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI").[1] Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although documented objectionable conditions were found during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any deviations noted during the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3). If you have any questions regarding this letter, please contact: ORAMRAInspectionReview@fda.hhs.gov.

Sincerely,

Ann M. Montemurro -S

Digitally signed by Ann M. Montemurro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000095112, cn=Ann M. Montemurro -S
Date: 2021.01.19 15:32:13 -05'00'

Ann Marie Montemurro
Director, Division of Pharmaceutical Quality Programs

FEI: 3004177283
CC: Linda Gallais, ANSM, international.inspection@ansm.sante.fr

[1] See Inspection Classification Definitions at http://www.fda.gov/ICECI/Inspections/ucm223231.htm