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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May 14, 2014

Mr. David Rose
Quality Manager
Mexichem Fluor UK Ltd
Tech Park The Health Business & Technical
Rocksavage Site
Runcorn Cheshire WA7 4JE GBR
UK
Reference: FEI 3008872103

Dear Mr. Rose:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your medical gas pharmaceutical manufacturing facility in Runcorn, Cheshire, GBR, UK by Investigator Parul Patel during the period of March 3, 4 and 5, 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 March 27, 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 practices (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,

Regina T. Brown

Regina T. Brown
Senior Policy Advisor
Division of International Drug Quality