



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 17, 2012

Mehrdad Barghian, Ph.D
President
Quality Compliance Laboratories
11-145 Konrad Cres.
Markham, Ontario CA L3R9T9

Reference: FEI 3005630028

Dear Dr. Barghian:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your drug manufacturing facility in Markham, Canada by Investigator Charisse Green from January 18 - 20, 2012.

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/drfs/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.

Please send any questions regarding the enclosed EIR to Temeka.Moore@fda.hhs.gov.

Sincerely,

Francis Godwin
Supervisory Consumer Safety Officer
Division of International Drug Quality

Enclosure: EIR