DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Lek Pharmaceutical and Chemical Co.
Attention: Alenka Vukadin-Skulj
1526 Ljubljana
Verovskova 57, Slovenia

Reference Number: 99-415

Dear M. Vukadin-Skulj:

This is in response to your November 9, 1999, letter requesting a meeting with the Agency, the Office of Generic Drugs (OGD) and the Division of Scientific Investigations (DSI) in particular, to keep FDA informed of your voluntary corrective action plan.

Thank you for your continued cooperation with the Agency. We recognize your full commitment to correcting your procedures and documentation systems in relation to the conduct and analysis of bioequivalence studies. Unfortunately, a meeting would not be the appropriate venue for FDA assessment of your changed procedures. We discussed your proposal for a meeting with Dr. Viswanathan, as well, and he concurred that a meeting would likely not be beneficial at this time. The actual assessment of your changed procedures can only occur at the time of a repeat audit by FDA investigators. If you have specific questions that OGD or DSI might answer, please let us know what those questions are.

If you have any additional questions in the mean time, please contact me via facsimile as you have done (301-594-0183) or telephone me at 301-827-5845.

Sincerely,

DZ Sporn

Douglas Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: C.Viswanathan, Ph.D

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