



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

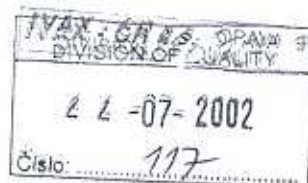
CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
Foreign Inspection Team, HFD-322
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JUL 10 2002

Dr. Ales Berka, Vice President for Quality
IVAX - CR a.s.
Ostravska 29/305
747 70 Opava - Komarov, Czech Republic



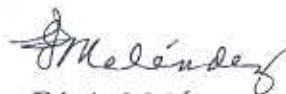
Dear Dr. Berka

We have completed review of the Establishment Inspection Report for the inspection of your non-sterile pharmaceutical manufacturing facility in Opava, by FDA Investigator Charles R. Cote, and Chemist Donald Lech, during March 2002. The inspection found deviations from current good manufacturing practices which were listed on an Inspectional Observations form FDA-483, issued to you at the conclusion of the inspection.

We have reviewed the May 14 & 20, 2002 written response to the FDA-483 submitted by you. The response appears to provide satisfactory corrections and commitments for the deviations listed on the FDA-483. Based on this response, we are currently classifying your facility as acceptable for the manufacturer of Active Pharmaceutical Ingredients and non-sterile pharmaceutical products. The corrections described in the response will be evaluated during the next routine inspection of your facility. It remains your responsibility to assure continued compliance with current good manufacturing practices.

In addition, we enclose a copy of the March 2002 establishment inspection report (EIR) which is provided to you for information purposes. The Agency is working to make its regulatory processes and activities more transparent to the regulated industry. Releasing this EIR to you is part of that effort. The copy provided to you comprises the narrative portion of the report and reflects redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. This, however, does not preclude you from requesting and possibly, obtaining any additional information under FOIA.

You may contact me at the address or telephone numbers given above if you have any questions regarding this letter. Reference Central File Number 9610088 on all correspondence to this office.


Edwin Meléndez
Compliance Officer