DRUG NATIONAL AUTHORITY

Plot 46-48 Lumumba Avenue
P.O. Box 23096
Fax: 041 4 255758
Tel: 0414 255665 / 347391 / 347392
Kampala, Uganda (E.A)
Email: ndaug@nda.or.ug
Website:www.nda.or.ug

Date: 1st August 2012

Your Ref: .....

Our Ref: 088/INS/NDA-08/12

Veterinarski Zavod Subotica
Beogradski put 123, Subotica,
Republic of Serbia

Attn: Aleksandar Dimitric

REPORT OF cGMP/QUALITY ASSURANCE AUDIT

The manufacturing facility of Veterinarski Zavod Subotica, located on Srpska Crnja,Partzanska bb, Srpska Crnja Republic of Serbia, audited on 23rd – 24th May, 2012, **complied** with the cGMP requirements as per National Drug Authority guidelines at the time of inspection for the following **dosage production lines:**

- **Powders for oral, veterinary use (non beta lactam)**

Attached please find the inspection report. Attention should be given to the noted deficiencies and corrective action taken on the critical, major and minor deficiencies observed in due course. Please send the corrective action schedule and documentation of what has been done. In the event that the company is interested in supplying products from the above failed line in Uganda, corrective action report and a new application must be submitted to NDA for re-inspection.

Please note;

1. That each product must be registered with NDA before export to Uganda.
2. NDA can inspect your facility at any time as long as your product is on the Ugandan market.
3. Approval for GMP compliance is valid for three years from the date of inspection. The company has to apply for re-inspection six months prior to the expiry date if interested in maintaining products on the National Drug Register.

Gordon K. Sematiko
EXECUTIVE SECRETARY/REGISTRAR

Copy: Inspectorate Department
Drug Assessment and Registration Department