

# NATIONAL

# DRUG



# 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

1<sup>st</sup> August 2012

Your Ref: .....

Date: .....

Our Ref: 087/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 Beogradski put 123, Subotica, Republic of Serbia, audited on 21<sup>st</sup> and 22<sup>nd</sup> May, 2012, **complied** with the cGMP requirements as per National Drug Authority guidelines at the time of inspection for the following **dosage production lines**:

- **Liquid Injectables (SVP and LVP), non  $\beta$ -lactam.**
- **Oral Liquids, non  $\beta$ -lactam**

Attached please find the inspection report. Attention should be given to the noted deficiencies and corrective action taken on the major and minor deficiencies observed in due course. Please send the corrective action schedule and documentation of what has been done.

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