

## FINAL REPORT

**Trial:** #0893

**Title:** Safety Testing Express 4/HS (Modified Live Infectious Bovine Rhinotracheitis, Bovine Virus Diarrhea, Parainfluenza Virus, Killed Bovine Respiratory Syncytial Virus and Haemophilus somnus bacterin) in cattle.

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**Study Location:** Texas A&M Research Center, Bushland Facility.

**Dates:** On test: 6-23-95  
Off test: 8-3-95

**Sponsor:** Boehringer Ingelheim Animal Health, Inc.  
2621 North Belt Highway  
St. Joseph, Missouri 64506

### Objective

To assess the safety of Express 4/HS when used to immunize cattle.

### Test System

Fifty (50) crossbred steers (avg wt 252 kg) were purchased via the normal commercial cattle order buyer system. All steers were weighed and randomly tagged in the ear with individual identification numbers. Steers randomly allotted in groups of eight and kept in feedlot pens containing bunk feeders. Steers were given a minimum of four days adaptation to environment and diet (Table 1).

## **Experimental Design:**

### **A. Description of experimental design:**

The sections of the study completed under GLP like conditions included:

1. Thermometer calibrations (Appendix II).
2. Recording and Analysis of data.
3. Auditing of the study by quality assurance.
4. On sight inspection where field trials will be conducted.

Animals were treated according to study procedures.

### **B. Exclusion criteria:**

All animals were examined for health and age requirements (Appendix VIII).

### **C. Inclusion criteria:**

All animals were examined found to meet the health and age requirements (Appendix VIII).

### **D. Animal care**

All drugs were used according to labeled directions. All treatments were recorded on Biological and Pharmaceutical Records form at the time of treatment.

### **E. Housing and diet:**

All steers were housed in feedlot pens. The diet fed to all steers is shown in Table 1. Water was available on an *ad libitum* basis.

## **Study Procedure**

Steers were acclimated to facilities and diet before the start of the study.

### **A. Body Temperature:**

Thermometer (Model M216F) was calibrated by GLA Agricultural Electronics, 4120 Horizon Lane #F, San Luis Obispo, CA 93401. The thermometer was checked daily for accuracy before use. Also, daily ambient temperature (Appendix IV) was recorded before and after data collection. Individual animal rectal temperatures were monitored on days -1, 0, +1, +2, +3, and +4 on all animals. Individual rectal temperatures were taken at approximately the same time each day and recorded on Body Temperature Form (Appendix III).

B. Each steer was vaccinated (intramuscularly) on the left side of the neck region with a 2mL dose using aseptic technique. Steers were booster vaccinated (intramuscularly) on the right side of the neck region on day 21 using the complete Express 4/HS vaccine.

C. Ambient air temperature was recorded before and after injection site palpation and body temperature recording (Appendix IV).

D. Injection site was palpated when the body temperatures were recorded. Additional palpations were done on day 6, 10 and 14 post-vaccination 1 and post-vaccination 2. All observations were recorded on Injection Site Palpations Form (Appendix VI).

E. No animals died during the course of this study (Appendix VII).

### **Animal Disposition**

The study was terminated 14 days after second vaccination. However, five of the injection sites were mis-located on the spine of the neck region during the second vaccination. Although the size of the swelling had decreased (< 1cm) significantly, it was concluded that these might not disappear completely. Steers were released from the study 21 days after second vaccination.

### **Summary of Results**

One steer had lameness in the left rear leg and 20 cm swelling on the left side but was not treated. On 6/30/95, two steers exhibited nasal secretions and blood in the feces but they were not treated. On day 3 of the study (7/2/95), three (3) of the steers indicated blood in the feces and were treated with neomycin sulfate (Common name: Neovet; Brand name: Neomycin sulfate; Lot # 884696; Expiration date: September, 1992). Also, on day 4 (7/3/95) of the study, one (1) steer had blood in the feces and was treated with Amprolium (Common name: MSDagvet-Corrid, Brand name: Amprolium; Lot #TRX030; Expiration date: August, 1996). On 7/20/95, one steer injured the left eye and was treated with Neomycin eye powder (Common name: Tylan + Neomycin eye powder; Brand name: Neo eye powder; Lot # DP3031AMB; No Expiration date). None of the observed clinical symptoms could be attributed to the Express 4/HS vaccine. All steers exhibited normal body temperature (< 104 °F) throughout the entire study. Also, all steers appeared to have no decrease in their feed consumption.

Injection site swelling disappeared in 14 days post-vaccination 1 and 2 except in a few cases where the injection site was mis-located on the spine. However, these steers exhibited injection site swelling of < 1 cm. Therefore, in conclusion all steers exhibited normal, healthy behavior at the time of release.

Table 1. Diet Fed to Steers Vaccinated with Express 4/HS.

Ingredient	Percent <sup>a</sup>
Corn	60
Cottonseed hulls	35
Starter supplement	5

<sup>a</sup>As-fed basis.