FREEDOM OF INFORMATION SUMMARY
FOR
COMPONENT® E-H (Progesterone and Estradiol Benzoate)

1. GENERAL INFORMATION

NADA Number: 135-906

Sponsor: Ivy Laboratories
Division of Ivy Animal Health, Inc.
8857 Bond Street
Overland Park, KS 66214

Generic Name: Testosterone Propionate, Estradiol Benzoate, and Tylosin Tartrate

Trade Name: Component® E-H with Tylan®

Marketing Status: Over-the-counter (OTC)

Effect of Supplement: This supplement provides for the addition of a tylosin tartrate pellet as a local antibacterial to Component® E-H.

2. INDICATIONS FOR USE

For growth promotion and improved feed efficiency in heifers weighing 400 lbs or more.

3. DOSAGE FORM(S), ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

Dosage Form: Implantation

Route of Administration: Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.

Recommended Dosage: One implant containing 200 mg testosterone propionate, 20 mg estradiol benzoate, and 29 mg tylosin tartrate.

4. EFFECTIVENESS

The effectiveness requirement for this supplemental new animal drug application, with the indications for use and dosage as given in Sections 2 and 3 above, is met by utilizing the existing database in NADA 135-906 and conducting the additional adequate and well-controlled study included in this supplemental application.

Pivotal Study:

A study was conducted by William Barton, CAVL, Inc, Amarillo,TX, to evaluate the effectiveness of Component® E-H with Tylan® to lower the incidence of ear abscess formation. An implant site abscess induction model was developed to reliably create a high abscess rate in test animals. This model was used to test the ability of a tylosin tartrate pellet to reduce implant site abscess incidence in animals expected to develop an ear abscess. In the study, 40 beef heifers were subjected to the abscess-inducing culture at the same time they were implanted with either Component® E-H with a Tylan® pellet or Component® E-H alone. Implant sites were observed at regular intervals up to 35 days following implantation. Abscess rate at each time point was significantly lower ($P<0.0001$) in heifers treated with Component® E-H with a Tylan® pellet compared to heifers treated with Component® E-H alone, with the maximum incidence of abscesses of 0% and 90%, respectively.

5. TARGET ANIMAL SAFETY

Target animal safety of Component® E-H is established by data in the parent application. The data provided in the effectiveness study described above was sufficient to conclude that the use of the tylosin pellet was safe for use in cattle. No further studies were required.

6. HUMAN SAFETY

Human safety is established for Component® E-H by data in the parent application. No further studies were required for use of the tylosin pellet.

7. AGENCY CONCLUSIONS

Adequate data demonstrates the safe and effective use of a tylosin tartrate pellet added to Component® E-H as a local antibacterial.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change providing for the addition of a tylosin tartrate pellet as a local antibacterial to Component® E-H. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

8. LABELING

Facsimile labeling is attached as follows:

1. Component® E-H with Tylan® Box Label
2. Component® E-H with Tylan® 20 Dose Foil Pouch
3. Component® E-H with Tylan® Package Insert