Approval Date: October 18, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 135-906

COMPONENT E-H
(Testosterone Propionate and Estradiol Benzoate)

COMPONENT E-H with TYLAN
(Testosterone Propionate and Estradiol Benzoate with Tylosin)

This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications.

Sponsored by:

Ivy Laboratories
Division of Ivy Animal Health, Inc.
8557 Bond Street
Overland Park, KS 66214

FREEDOM OF INFORMATION SUMMARY

COMPONENT E-H and COMPONENT E-H with TYLAN
Ear Implant for Heifers Weighing 400 Lbs or More

1. GENERAL INFORMATION:

a. File Number:	NADA 135-906
b. Sponsor:	Ivy Laboratories Division of Ivy Animal Health, Inc. 8557 Bond Street Overland Park, KS 66214 Drug Labeler Code: 021641
c. Established Names:	Testosterone Propionate and Estradiol Benzoate Testosterone Propionate and Estradiol Benzoate with Tylosin
d. Propriety Names:	COMPONENT E-H COMPONENT E-H with TYLAN
e. Dosage Form:	Implantation (ear implant) as per 21 CFR 522.842
f. How Supplied:	COMPONENT E-H: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of testosterone propionate USP 200 mg and estradiol benzoate 20 mg. COMPONENT E-H with TYLAN: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of testosterone propionate USP 200 mg and estradiol benzoate 20 mg with 29 mg tylosin tartrate as a local antibacterial.
g. How Dispensed:	OTC

h. Amount of Active Ingredients:	COMPONENT E-H: 200 mg testosterone propionate. 20 mg estradiol benzoate. COMPONENT E-H with TYLAN: 200 mg testosterone propionate. 20 mg estradiol benzoate. 29 mg tylosin tartrate.
i. Route of Administration:	Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.
j. Species/Class:	Heifers weighing 400 lbs or more
k. Recommended Dosage:	COMPONENT E-H: One implant containing 200 mg testosterone propionate and 20 mg estradiol benzoate. COMPONENT E-H with TYLAN: One implant containing 200 mg progesterone and 20 mg estradiol benzoate with 29 mg tylosin tartrate.
l. Pharmacological Category:	Steroid hormones, antibacterial
m. Indications:	COMPONENT E-H and COMPONENT E-H with TYLAN: For growth promotion and improved feed efficiency.
n. Effect of Supplement:	This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the label indications.

2. DRUG EFFECTIVENESS:

No new effectiveness data are required for the approval of this supplement. The products' effectiveness has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for COMPONENT E-H and COMPONENT E-H with TYLAN (NADA 135906).

3. TARGET ANIMAL SAFETY:

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for COMPONENT E-H and COMPONENT E-H with TYLAN (NADA 135906).

4. HUMAN SAFETY:

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug applications for COMPONENT E-H and COMPONENT E-H with TYLAN (NADA 135906).

5. AGENCY CONCLUSIONS:

The information submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the products will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The products' status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. 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.

COMPONENT E-H with TYLAN is under the following U.S. patent number:

U.S. Patent Number	Date of Expiration
5,874,098	May 28, 2017

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

COMPONENT E-H Carton Label
COMPONENT E-H Foil Pouch (Front)
COMPONENT E-H Foil Pouch (Back)
COMPONENT E-H Package Insert
COMPONENT E-H with TYLAN Carton Label
COMPONENT E-H with TYLAN Foil Pouch (Front)
COMPONENT E-H with TYLAN Foil Pouch (Back)
COMPONENT E-H with TYLAN Package Insert