Approval Date: October 28, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 118-123

COMPUDOSE and ENCORE
(Estradiol with Oxytetracycline)

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.
8857 Bond Street
Overland Park, KS 66214

FREEDOM OF INFORMATION SUMMARY

COMPUDOSE and ENCORE
Ear Implants for Suckling and Pastured Steers, and Steers and Heifers Fed in Confinement for Slaughter

1. GENERAL INFORMATION:

a. File Number:	NADA 118-123
b. Sponsor:	Ivy Laboratories Division of Ivy Animal Health, Inc. 8857 Bond Street Overland Park, KS 66214 Drug Labeler Code: 021641
c. Established Names:	Estradiol, oxytetracycline
d. Propriety Names:	COMPUDOSE ENCORE
e. Dosage Form:	Implantation (ear implant) as per 21 CFR 522.840
f. How Supplied:	COMPUDOSE: Each box contains 100 silicon rubber implants containing 25.7 mg estradiol coated with not less than 0.5 mg oxytetracycline as a local antibacterial. ENCORE: Each box contains 100 silicon rubber implants containing 43.9 mg estradiol coated with not less than 0.5 mg oxytetracycline as a local antibacterial.
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	COMPUDOSE: 25.7 mg estradiol. 0.5 mg oxytetracycline. ENCORE: 43.9 mg estradiol. 0.5 mg oxytetracyline.

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:	Suckling and pastured steers, and steers and heifers fed in confinement for slaughter.
k. Recommended Dosage:	COMPUDOSE: One implant containing 25.7 mg estradiol with 0.5 mg oxytetracycline. ENCORE: One implant containing 43.9 mg estradiol with 0.5 mg oxytetracycline.
l. Pharmacological Category:	Steroid hormones, antibacterial
m. Indications:	COMPUDOSE and ENCORE: For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers.
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 COMPUDOSE and ENCORE (NADA 118123).

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 COMPUDOSE and ENCORE (NADA 118123).

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 COMPUDOSE and ENCORE (NADA 118123).

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.

No patents were submitted by the sponsor with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

COMPUDOSE Carton Label
COMPUDOSE Package Insert
ENCORE Carton Label
ENCORE Package Insert