Approval Date: October 28, 2004

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 138-612

FINAPLIX-H
(Trenbolone Acetate)

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:

Intervet, Inc.
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966

FREEDOM OF INFORMATION SUMMARY

FINAPLIX-H
Ear Implant for Heifers Fed in Confinement for Slaughter

1. GENERAL INFORMATION:

a. File Number:	NADA 138-612
b. Sponsor:	Intervet, Inc. 29160 Intervet Lane P.O. Box 318 Millsboro, DE 19966 Drug Labeler Code: 057926
c. Established Names:	Trenbolone Acetate
d. Propriety Names:	FINAPLIX-H
e. Dosage Form:	Implantation (ear implant) as per 21 CFR 522.2476
f. How Supplied:	Each shipping container contains 4 x 1000 dose packages. Each carton contains 10 x 100 dose packages. Each box contains 10 x 10 cartridge implants. Each cartridge contains 1 implant dose. Each dose consists of 200 mg trenbolone acetate.
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	200 mg trenbolone acetate.
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 fed in confinement for slaughter.
k. Recommended Dosage:	One implant containing 200 mg trenbolone acetate.
l. Pharmacological Category:	Steroid hormone

m. Indications:	Increases rate of weight gain and improves feed efficiency in a slow-release delivery system. The product is to be used in feedlot heifers only during approximately the last 63 days prior to slaughter.
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 product's effectiveness has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for FINAPLIX-H (NADA 138612).

3. TARGET ANIMAL SAFETY:

No new target animal safety data are required for the approval of this supplement. The product's target animal safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for FINAPLIX-H (NADA 138612).

4. HUMAN SAFETY:

No new human food safety data are required for the approval of this supplement. The product's human food safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for FINAPLIX-H (NADA 138612).

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 this product, adequate directions for use by the layperson have been provided and the product 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 product status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent its 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 patent information was submitted by the sponsor with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

FINAPLIX-H Package Insert
FINAPLIX-H Box Label
FINAPLIX-H Carton Label
FINAPLIX-H Shipping Container Label