

Approval Date: 06/20/2004

**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



## Finaplix®-H

(trenbolone acetate)

### WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

### STORAGE CONDITIONS

Store in a refrigerator (2-8° C; 36-47° F) and protect from sunlight. Use before the expiration date printed on the box and on the cartridge.

### PACKAGE QUANTITIES

Box of 10 x 10 cartridge implants

Made in Austria by:  
Intervet GesmbH

Distributed by:  
Intervet Inc.  
Millsboro, DE 19966

790706-C



NADA # 138-612, Approved by FDA

### FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

### DESCRIPTION

Finaplix®-H is an implant containing 200 mg of trenbolone. Each implant consists of 10 small yellow pellets. Ten implants are provided in a cartridge.

Manufactured by a non-sterilizing process.

### INDICATIONS

Increases rate of weight gain and improves feed efficiency in a slow-release delivery system. This product is to be used in feedlot heifers only during approximately the last 63 days prior to slaughter.

Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

### DOSAGE

#### Dosage Form:

One implant containing 200 mg trenbolone acetate is administered to each animal. The 10 pellets which make up the dosage of Finaplix®-H are contained in one division of the multiple dose cartridge. Ten doses are in each cartridge. The cartridge is designed to be used with a special implant gun.

#### Route of Administration:

The implant is placed under the skin on the posterior aspect of the ear by means of a special implanter available from Intervet Inc.

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With the animal suitably restrained, the skin on the outer surface of the ear should be cleaned. The implant is then administered by the method shown in the diagram below.

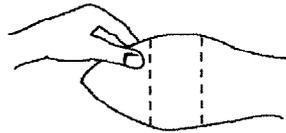


Fig. 1 - Ear of Bovine Ready for Implantation

#### SITE OF IMPLANTATION

After appropriately restraining the animal to allow access to the ear, cleanse the skin at the implant needle puncture site. It is subcutaneous between the skin and cartilage on the back side of the ear and below the midline of the ear. The implant must not be placed closer to the head than the edge of the cartilage ring farthest from the head. The location of insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Care should be taken to avoid injuring the major blood vessels or cartilage of the ear.

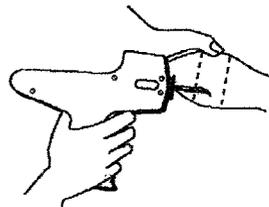
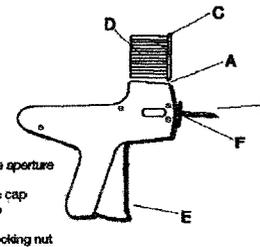


Fig. 2 - Rear View of the Bovine Ear Showing the Site for Insertion of the Implanter Needle.

#### METHOD OF USE

1. Do not remove the cap of the cartridge containing the implants.
2. Place the cartridge (D) with the capped end to the front into slot at the top of the implanter magazine marked (A) on the diagram.
3. Gently push the cartridge into the slot until it clicks into place.
4. The implanter is then ready for use.
5. Take the ear of the animal firmly with the free hand in the manner shown in Fig. 1. Then insert the needle into the subcutaneous tissue at the point indicated in Fig. 2.
6. After inserting the needle to its full extent, squeeze the trigger (E) gradually. Allow the pellets of the implant to be deposited in a single row.
7. Withdraw the implanter. This will advance the cartridge one groove in the magazine and the next implant is now ready for use.
8. When all the implants have been administered, the cartridge will discharge out the bottom of the magazine and may be replaced by a new one.
9. To change the needle, loosen the needle locking nut labeled (F) in Fig. 3 and replace the needle. Tighten the nut finger tight and the implanter is ready for use.



- A - Magazine aperture
- B - Needle
- C - Cartridge cap
- D - Cartridge
- E - Trigger
- F - Needle locking nut

Fig. 3 - Diagram of the Implanter and Cartridge



Manufactured by a non-sterilizing process

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER  
Box of 10 x 10 Cartridge Implants

Finaplix-H  
(trenbolone acetate)

520099 FWH240  
012



00021784807104

Finaplix-H

(trenbolone acetate)

Lot Number  
Expiration Date

**PACKAGE QUANTITIES:**

Box of 10 x 10 implants  
Cartridge 100 doses in ten cartridges with ten implants per cartridge.  
Each dose contains 10 small yellow pellets.  
Each pellet contains 20 mg of trenbolone acetate.

**STORAGE CONDITIONS:**

Store in a refrigerator (2-8°C, 36-47°F) and protect from sunlight.  
Use before the expiration date printed on the box and/or the cartridge.

**INDICATIONS:**

Increases rate of weight gain and improves feed efficiency in growing finishing feeder heifers in a slow-release delivery system. This product is to be used on heifer calves only during approximately the last 60 days prior to slaughter.  
Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**USE DIRECTIONS:**  
See enclosed package insert.

400749-D

FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER  
Box of 10 x 10 Cartridge Implants

Manufactured by a non-sterilizing process



**WARNINGS:**

Not to be used in animals for subsequent breeding or in other animals. For Animal Treatment Only. Not for use in humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted sites for human or animal food.  
A withdrawal period has not been established for this product in pre-ruminant calves. Do not use in calves to be processed for veal.



NADA # 138-612, Approved by FDA

Made in Austria by  
Intervet Geberit  
Distributed by  
Intervet Inc.  
Millsboro, DE 19966

140075075  
136 D  
120  
r=60, y=70

# Finaplix-H

(trenbolone acetate)



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## FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

### NET CONTENTS

Box of 10 x 100 dose packages  
Manufactured by a non-sterilizing process

### STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 38-47° F) and protect from sunlight.  
Use before the expiration date printed below and on the cartridge.

### WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.  
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear only. Any other location is in violation of Federal Law. Do not attempt salvage of implanted site for human or animal food.  
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

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Made in Austria by:  
Intervet GesmbH  
Distributed by:  
Intervet Inc.  
Millsboro, DE 19966

LOT  
EXP



NADA # 138-612, Approved by FDA

# Finaplix-H

(trienbolone acetate)



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## FOR HEIFERS FED IN CONFINEMENT FOR SLAUGHTER

### NET CONTENTS

4 x 1000 dose packages

Manufactured by a non-sterilizing process

### STORAGE CONDITIONS:

Store in a refrigerator (2-8° C; 38-47° F) and protect from sunlight.  
Use before the expiration date printed below and on the cartridge

### WARNING:

Not to be used in animals intended for subsequent breeding, or in dairy animals.  
For Animal Treatment Only. Not for Use in Humans. Implant pellets in the ear  
only. Any other location is in violation of Federal Law. Do not attempt salvage of  
implanted site for human or animal food.  
A withdrawal period has not been established for this product in pre-ruminating  
calves. Do not use in calves to be processed for veal.

780709-C

508995 ZW240 012



Made in Austria by:  
Intervet Geombl  
Distributed by:  
Intervet Inc.  
Millsboro, DE 19966

LOT

EXP



NADA # 138-012, Approved by FDA