



3759 14 07 13 2013

(302) 933-4049

12 April 2004

Dr. Lonnie Luther, Staff Chief (HFV-102)
C/O: Dockets Management Branch, HFA-305
Room 1061
5630 Fishers Lane
Food and Drug Administration
Rockville, MD 20852

**RE: SUITABILITY PETITION FOR REVIEW AND ACTION – Intravaginal
Progesterone Insert for Cattle**

Dear Dr. Luther:

Please find enclosed a suitability petition for Agency review and action. Intervet Inc. is requesting permission to file an abbreviated new animal drug application (ANADA) for a generic intravaginal progesterone insert for cattle that differs from the pioneer product (EAZI-BREED™ CIDR®; NADA 141-200) in strength (i.e., concentration) of the active ingredient.

Your timely review of the enclosed petition will be greatly appreciated.

Please feel free to call (302-933-4049) or e-mail (ruth.lacrosse-vernimb@intervet.com) me should you have any questions or if I can be of assistance.

Sincerely,

Ruth LaCrosse-Vernimb
Manager, Regulatory Compliance and QA – Pharmaceuticals
Intervet Inc.

Enclosure

2004P-0175

CPI

Suitability Petition**Intervet Inc.
Intravaginal Progesterone Insert for Cattle
12 April 2004**

The undersigned submits this petition under Section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to permit the filing of an application for a generic intravaginal progesterone insert for cattle that differs from the pioneer product (EAZI-BREED™ CIDR®; NADA 141-200) in strength of the active ingredient in the proposed drug product.

Action Requested

We are requesting that the Commissioner permit the filing of an Abbreviated New Animal Drug Application (ANADA) for an intravaginal progesterone insert for cattle (trade name to be determined). The application will include a bioequivalence study. Our proposed product differs from the pioneer product as follows:

Pioneer Product**Trade name**

EAZI-BREED™ CIDR® Cattle Insert (NADA 141-200)

Active ingredients

Progesterone

Dosage form

Intravaginal Insert.

Strength

Each insert contains 1.38 grams of progesterone in molded silicone (silastic) over a nylon spine.

Sponsor

DEC International, Inc.

Dosage

For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers; administer one EAZI-BREED™ CIDR® Cattle Insert per animal

for 7 days. Inject 5 mL LUTALYSE Sterile Solution (equivalent to 5 mg/mL dinoprost) 1 day prior to EAZI-BREED™ CIDR® Cattle Insert removal, on day 6 of the 7 day administration period. Observe animals for signs of estrus on days 1 to 3 after removal of the EAZI-BREED™ CIDR® Cattle Insert and inseminate animals about 12 hours after onset of estrus.

For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus, administer one EAZI-BREED™ CIDR® Cattle Insert per animal 14 ± 1 days after insemination and remove the EAZI-BREED™ CIDR® Cattle Insert 7 days later. Observe animals for signs of estrus on days 1 to 3 after removal of the EAZI-BREED™ CIDR® Cattle Insert and inseminate animals about 12 hours after onset of estrus.

Proposed Drug Product

Trade name

To be selected

Active ingredients

Progesterone

Dosage form

Intravaginal Insert.

Strength

Each insert contains 1.00 gram of progesterone in molded silicone (silastic) over a nylon spine.

Sponsor

Intervet Inc.

Dosage

For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers; administer one Cattle Insert per animal for 7 days. Inject 5 mL LUTALYSE Sterile Solution (equivalent to 5 mg/mL dinoprost) 1 day prior to Cattle Insert removal, on day 6 of the 7 day administration period. Observe animals for signs of estrus on days 1 to 3 after

removal of the Cattle Insert and inseminate animals about 12 hours after onset of estrus.

For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus, administer one Cattle Insert per animal 14 ± 1 days after insemination and remove the Cattle Insert 7 days later. Observe animals for signs of estrus on days 1 to 3 after removal of the Cattle Insert and inseminate animals about 12 hours after onset of estrus.

Statement of Grounds

The proposed generic product contains the same active ingredient and will be labeled with the same indications, precautions and warnings as the approved pioneer product. The route of administration (intravaginal) and the dosage form (intravaginal insert) are the same for the generic and pioneer products. The strength of the active ingredient, progesterone, in the proposed product will be slightly lower than that in the pioneer product. The bioavailability and subsequent clinical effect of the generic product is expected to be similar to that of the pioneer product due to different active release profiles between the proposed and pioneer products. Because the proposed product has a faster release of progesterone from the silicone than the pioneer product, a lower strength of progesterone can be used to allow for similar dose administration per animal between the proposed and pioneer products.

While the proposed generic product differs in strength of the active ingredient as compared to the pioneer product, the dose of progesterone administered per animal will be similar to that of the pioneer product, as demonstrated in a bioequivalence study.

Environmental Impact

In accordance with 21 CFR 25.33(a)(1), Intervet Inc. requests a categorical exclusion from the requirement to file an environmental impact assessment for this action, as the generic drug will be marketed under the same conditions of approval as a previously approved animal drug.

Economic Impact

Information pertaining to the economic impact of this petition will be submitted if requested by the commissioner.

Differences Between Pioneer and Proposed Generic Product Labeling

The changes in the labeling noted below may not be placed in the same areas as they are located on the pioneer product. The changes noted will be reflected in

the proposed drug product's labeling in an appropriate manner so that it is clear and readily understood by the end-user. Please see the attached proposed labeling.

References to "EAZI-BREED™ CIDR® Cattle Insert" will be changed to "progesterone" or to the new trade name as appropriate throughout the labeling.

The EAZI-BREED™ CIDR® Cattle Insert name and logo will be removed and replaced with the new brand name and logo throughout the labeling.

The product number will be changed.

The NADA number will be changed.

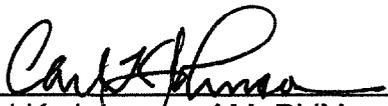
The sponsor information will be changed.

Under Net Contents and Active Ingredient:

Levels of progesterone per device of "1.38" will be changed to "1.00" grams.

Certification

Intervet Inc. certifies that this suitability petition contains all information known to them that is unfavorable to the petition.



Carl K. Johnson, AM, DVM
Director, Product Development And
Regulatory Affairs - Pharmaceuticals

12 April 04
Date

00000b

Pioneer Labeling

EAZI-BREEDTM CIDR[®]

Cattle Insert

NDC 0009-5207-01

NET CONTENTS

10 EAZI-BREED CIDR Cattle Inserts per bag.

Each EAZI-BREED CIDR Cattle Insert contains 1.38 grams of progesterone in molded silicone over a flexible nylon spine. Attached to each EAZI-BREED CIDR Cattle Insert is a polyester tail.

Caution: Federal law prohibits extra-label use of this drug to enhance food and/or fiber production in animals.

DRUG FACTS

Active Ingredient: Progesterone, 1.38 grams per EAZI-BREED CIDR Cattle Insert.

Uses:

- Synchronization of estrus in suckled beef cows, and replacement beef and dairy heifers
- Advancement of first postpartum estrus in suckled beef cows
- Advancement of first pubertal estrus in replacement beef heifers
- Synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus

The EAZI-BREED CIDR Cattle Insert provides an exogenous source of the hormone progesterone during the 7-day administration period. Removal of the EAZI-BREED CIDR Cattle Insert on treatment day 7 results in a rapid fall in plasma progesterone levels, which results in synchronization of estrus in those animals responding to treatment.

WARNINGS:

Human Warning: Avoid contact with skin by wearing latex gloves when handling the inserts. Keep this and all medications out of the reach of children.

Environmental Warning: Store removed EAZI-BREED CIDR Cattle Inserts in a plastic bag or other sealable container until they can be properly disposed in accordance with applicable local, state and Federal regulations.

Residue Warning: Neither a pre-slaughter withdrawal interval nor a milk discard time is required when this product is used according to label directions.

Do Not Use:

- in beef or dairy heifers of insufficient size or age for breeding or in cattle with abnormal, immature or infected genital tracts.
- in beef cows that are less than 20 days postpartum or in lactating dairy cows less than 40 days postpartum. The sponsor has not provided effectiveness and animal safety data for the use of this product in beef cows that are less than 20 days postpartum or in lactating dairy cows that are less than 40 days postpartum.
- the EAZI-BREED CIDR Cattle Insert in lactating dairy cows concurrently with LUTALYSE[®] Sterile Solution or other prostaglandin products for synchronization of the return to estrus. The concurrent use with prostaglandin products is not approved in lactating dairy cows.
- an insert more than once. To prevent the potential transmission of venereal and blood-borne diseases the EAZI-BREED CIDR Cattle Insert should be disposed after a single use.

When Using This Product:

- For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers, you must use the EAZI-BREED CIDR Cattle Insert concurrently with an injection of 5 mL of LUTALYSE Sterile Solution (equivalent to 5 mg/mL dinoprost) administered on day 6 of the 7 day administration period to assure maximum effectiveness.
- For synchronizing the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus, **do not administer LUTALYSE Sterile Solution** or other prostaglandin products as they will interrupt pregnancy that may have occurred.
- In animals that respond to treatment the onset of estrus generally occurs within 1 to 3 days after removal of the EAZI-BREED CIDR Cattle Insert.
- Intravaginal administration of EAZI-BREED CIDR Cattle Insert for periods greater than 7 days may result in reduced fertility.

You May Notice:

- Increased loss of EAZI-BREED CIDR Cattle Inserts in animals housed under crowded conditions, especially in heifers. Avoid crowded conditions during treatment as other cattle, particularly heifers, may remove EAZI-BREED CIDR Cattle Inserts by pulling on the tail of the EAZI-BREED CIDR Cattle Insert. If loss rates are high re-evaluate insertion technique and cattle handling facilities.
- Clear, cloudy, yellow or bloody mucus on the outside of EAZI-BREED CIDR Cattle Insert when removed from animals. The mucus may have an offensive odor. This is a result of mild irritation to the vaginal lining by the presence of the EAZI-BREED CIDR Cattle Insert, and generally clears between the time of removal and insemination. Such irritation does not affect fertility at inseminations following treatment.
- Reduced pregnancy rates to inseminations conducted immediately prior to administration of EAZI-BREED CIDR Cattle Inserts used for synchronizing the return to estrus in lactating dairy cows.

Directions:

Suckled Beef Cows, Replacement Beef and Dairy Heifers: For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers:

- Administer one EAZI-BREED CIDR Cattle Insert per animal for 7 days (for example, if administered on a Monday remove on the following Monday).
- Inject 5 mL LUTALYSE Sterile Solution (equivalent to 5 mg/mL dinoprost) 1 day prior to EAZI-BREED CIDR Cattle Insert removal, on day 6 of the 7 day administration period.
- Observe animals for signs of estrus on days 1 to 3 after removal of the EAZI-BREED CIDR Cattle Insert and inseminate animals about 12 hours after onset of estrus.

(Directions continued)

Lactating Dairy Cows: For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

- Administer one EAZI-BREED CIDR Cattle Insert, per animal, 14±1 days after insemination and remove the EAZI-BREED CIDR Cattle Insert 7 days later (for example, if administered on a Monday remove on the following Monday)
- Observe animals for signs of estrus on days 1 to 3 after removal of the EAZI-BREED CIDR Cattle Insert and inseminate animals about 12 hours after onset of estrus.
- **Reminder:** do not administer LUTALYSE Sterile Solution or other prostaglandin products to cows, as this will interrupt pregnancy that may have occurred at the immediately previous insemination.

Insertion:

1. Avoid contact with skin by wearing latex gloves when handling inserts.
2. Only use the specially designed EAZI-BREED CIDR Cattle Insert Applicator for administration.
3. Restrain cattle appropriately (head catch, squeeze chute, gate, etc.) prior to administration.
4. Wash the EAZI-BREED CIDR Cattle Insert Applicator in a non-irritating antiseptic solution, and then lubricate the front portion of the EAZI-BREED CIDR Cattle Insert Applicator with a veterinary obstetrical lubricant.
5. Push the flexible tail end of the EAZI-BREED CIDR Cattle Insert into the EAZI-BREED CIDR Cattle Insert Applicator taking care to assure the tail is extending upward through the slot of the EAZI-BREED CIDR Cattle Insert Applicator and is pointed toward the handle.
6. Fold the wings of the EAZI-BREED CIDR Cattle Insert to make it longer and continue to advance the EAZI-BREED CIDR Cattle Insert into the applicator until it is fully seated. When fully seated only the tips of the wings should protrude (one half-inch) from the end of the EAZI-BREED CIDR Cattle Insert Applicator (see Figure 1 below).
7. Lubricate the protruding tips of the wings of the EAZI-BREED CIDR Cattle Insert with veterinary obstetrical lubricant.
8. Lift the tail of the animal and clean the exterior of the vulva.
9. Open the lips of the vulva and gently place the loaded EAZI-BREED CIDR Cattle Insert Applicator through the vulva. The slot in the EAZI-BREED CIDR Cattle Insert Applicator should face upwards (see Figure 2 below).
10. Once the loaded EAZI-BREED CIDR Cattle Insert Applicator is past the vulva slope the EAZI-BREED CIDR Cattle Insert Applicator slightly upwards (35-45° angle) by lowering the handle, and then forward, without forcing, until the EAZI-BREED CIDR Cattle Insert Applicator is fully inserted or resistance is felt (see Figure 3 below).
11. Squeeze the finger grips within the handle of the EAZI-BREED CIDR Cattle Insert Applicator to deposit the EAZI-BREED CIDR Cattle Insert in the anterior vagina (see Figure 4 below) and then pull the EAZI-BREED CIDR Cattle Insert Applicator backwards to remove it from the vagina.
12. With the EAZI-BREED CIDR Cattle Insert correctly placed, with the wings open in the anterior portion of the vagina, the tail of the EAZI-BREED CIDR Cattle Insert should be visible, pointing downward from the vulva of the animal. Tails of EAZI-BREED CIDR Cattle Inserts that protrude more than 2.5 inches from the vulva may be clipped to minimize removal by other animals.

Removal:

1. Remove EAZI-BREED CIDR Cattle Inserts by pulling, gently but firmly, on the protruding polyester tail.
2. EAZI-BREED CIDR Cattle Inserts have been reported to reverse direction within the vagina; therefore, if the polyester tail of the insert is not visible on the day of removal, check the vagina to determine if an insert is present.

Figure 1

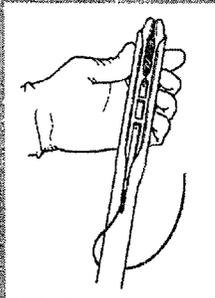


Figure 2

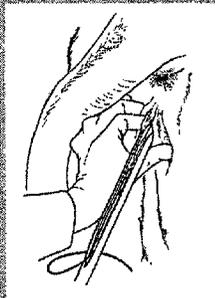


Figure 3

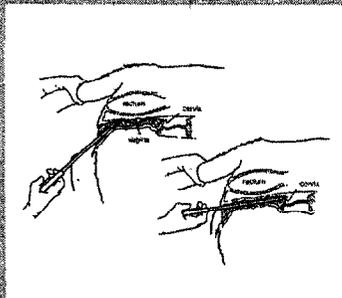
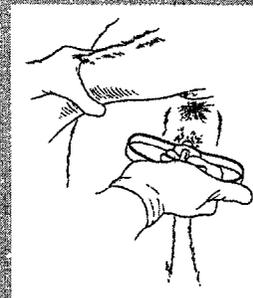


Figure 4

**Other information:**

Store below 86°F (30°C)

Made in New Zealand for
Pharmacia & Upjohn Company
Kalamazoo, Michigan 49001, USA
By: DEC International, NZ, Ltd.
Hamilton, New Zealand
819 241 002E



Lot Number:

Expiration Date:

Inactive Ingredients: silicone rubber, nylon and polyester.

Questions/Comments: 1-866-493-1954

NADA #141-200, Approved by FDA

EAZI-BREED is a trademark and CIDR is a registered trademark of DEC International, NZ, Ltd.
LUTALYSE is a registered trademark of Pharmacia & Upjohn Company

39006604-08/03

Proposed Generic Labeling

"TRADENAME TO BE SELECTED" Cattle Insert**NET CONTENTS**

10 "TRADENAME TO BE SELECTED" Cattle Inserts per bag
Each "TRADENAME TO BE SELECTED" Cattle Insert contains 1.00 grams of progesterone in molded silicone over a flexible nylon spine. Attached to each "TRADENAME TO BE SELECTED" Cattle Insert is a polyester tail.

Caution: Federal law prohibits extra-label use of this drug to enhance food and/or fiber production in animals.

DRUG FACTS

Active Ingredient: Progesterone, 1.00 grams per "TRADENAME TO BE SELECTED" Cattle Insert

Uses:

- Synchronization of estrus in suckled beef cows, and replacement beef and dairy heifers
- Advancement of first postpartum estrus in suckled beef cows
- Advancement of first pubertal estrus in replacement beef heifers
- Synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus

The "TRADENAME TO BE SELECTED" Cattle Insert provides an exogenous source of the hormone progesterone during the 7-day administration period. Removal of the "TRADENAME TO BE SELECTED" Cattle Insert on treatment day 7 results in a rapid fall in plasma progesterone levels, which results in synchronization of estrus in those animals responding to treatment.

WARNINGS:

Human Warning: Avoid contact with skin by wearing latex gloves when handling the inserts. Keep this and all medications out of the reach of children.

Environmental Warning: Store removed "TRADENAME TO BE SELECTED" Cattle Inserts in a plastic bag or other sealable container until they can be properly disposed in accordance with applicable local, state and Federal regulations.

Residue Warning: Neither a pre-slaughter withdrawal interval nor a milk discard time is required when this product is used according to label directions.

Do Not Use:

- in beef or dairy heifers of insufficient size or age for breeding or in cattle with abnormal, immature or infected genital tracts.
- in beef cows that are less than 20 days postpartum or in lactating dairy cows less than 40 days postpartum. The sponsor has not provided effectiveness and animal safety data for the use of this product in beef cows that are less than 20 days postpartum or in lactating dairy cows that are less than 40 days postpartum.

- the "TRADENAME TO BE SELECTED" Cattle Insert in lactating dairy cows concurrently with LUTALYSE® Sterile Solution or other prostaglandin products for synchronization of the return to estrus. The concurrent use with prostaglandin products is not approved in lactating dairy cows.
- an insert more than once. To prevent the potential transmission of venereal and blood borne diseases the "TRADENAME TO BE SELECTED" Cattle Insert should be disposed after a single use.

When Using This Product:

- For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers, you must use the "TRADENAME TO BE SELECTED" Cattle Insert concurrently with an injection of 5 mL of LUTALYSE Sterile Solution (equivalent to 5 mg/mL dinoprost) administered on day 6 of the 7 day administration period to assure maximum effectiveness.
- For synchronizing the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus, **do not administer LUTALYSE Sterile Solution** or other prostaglandin products as they will interrupt pregnancy that may have occurred.
- In animals that respond to treatment the onset of estrus generally occurs within 1 to 3 days after removal of the "TRADENAME TO BE SELECTED" Cattle Insert.
- Intravaginal administration of "TRADENAME TO BE SELECTED" Cattle Insert for periods greater than 7 days may result in reduced fertility.

You May Notice:

- Increased loss of "TRADENAME TO BE SELECTED" Cattle Inserts in animals housed under crowded conditions, especially in heifers. Avoid crowded conditions during treatment as other cattle, particularly heifers, may remove "TRADENAME TO BE SELECTED" Cattle Inserts by pulling on the tail of the "TRADENAME TO BE SELECTED" Cattle Insert. If loss rates are high re-evaluate insertion technique and cattle handling facilities.
- Clear, cloudy, yellow or bloody mucus on the outside of "TRADENAME TO BE SELECTED" Cattle Insert when removed from animals. The mucus may have an offensive odor. This is a result of mild irritation to the vaginal lining by the presence of the "TRADENAME TO BE SELECTED" Cattle Insert, and generally clears between the time of removal and insemination. Such irritation does not affect fertility at inseminations following treatment.
- Reduced pregnancy rates to inseminations conducted immediately prior to administration of "TRADENAME TO BE SELECTED" Cattle Inserts used for synchronizing the return to estrus in lactating dairy cows.

Directions:

Suckled Beef Cows, Replacement Beef and Dairy Heifers: For synchronization of estrus in suckled beef cows and replacement beef and dairy

heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers:

- Administer one "TRADENAME TO BE SELECTED" Cattle Insert per animal for 7 days (for example, if administered on a Monday remove on the following Monday).
- Inject 5 mL LUTALYSE Sterile Solution (equivalent to 5 mg/mL dinoprost) 1 day prior to "TRADENAME TO BE SELECTED" Cattle Insert removal, on day 6 of the 7 day administration period.
- Observe animals for signs of estrus on days 1 to 3 after removal of the "TRADENAME TO BE SELECTED" Cattle Insert and inseminate animals about 12 hours after onset of estrus.

Lactating Dairy Cows: For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus:

- Administer one "TRADENAME TO BE SELECTED" Cattle Insert per animal 14+1 days after insemination and remove the "TRADENAME TO BE SELECTED" Cattle Insert 7 days later (for example, if administered on a Monday remove on the following Monday).
- Observe animals for signs of estrus on days 1 to 3 after removal of the "TRADENAME TO BE SELECTED" Cattle Insert and inseminate animals about 12 hours after onset of estrus.
- Reminder: do not administer LUTALYSE Sterile Solution or other prostaglandin products to cows, as this will interrupt pregnancy that may have occurred at the immediately previous insemination.

Insertion:

1. Avoid contact with skin by wearing latex gloves when handling inserts.
2. Only use the specially designed "TRADENAME TO BE SELECTED" Cattle Insert Applicator for administration.
3. Restrain cattle appropriately (head catch, squeeze chute, gate, etc.) prior to administration.
4. Wash the "TRADENAME TO BE SELECTED" Cattle Insert Applicator in a non-irritating antiseptic solution, and then lubricate the front portion of the "TRADENAME TO BE SELECTED" Cattle Insert Applicator with a veterinary obstetrical lubricant.
5. Push the flexible tail end of the "TRADENAME TO BE SELECTED" Cattle Insert into the "TRADENAME TO BE SELECTED" Cattle Insert Applicator taking care to assure the tail is extending upward through the slot of the "TRADENAME TO BE SELECTED" Cattle Insert Applicator and is pointed toward the handle.
6. Fold the wings of the "TRADENAME TO BE SELECTED" Cattle Insert to make it longer and continue to advance the "TRADENAME TO BE SELECTED" Cattle Insert into the applicator until it is fully seated. When fully seated only the tips of the wings should protrude (one half inch) from the end of the "TRADENAME TO BE SELECTED" Cattle Insert Applicator (see Figure 1 below).

7. Lubricate the protruding tips of the wings of the "TRADENAME TO BE SELECTED" Cattle Insert with veterinary obstetrical lubricant.
8. Lift the tail of the animal and clean the exterior of the vulva.
9. Open the lips of the vulva and gently place the loaded "TRADENAME TO BE SELECTED" Cattle Insert Applicator through the vulva. The slot in the "TRADENAME TO BE SELECTED" Cattle Insert Applicator should face upwards (see Figure 2 below).
10. Once the loaded "TRADENAME TO BE SELECTED" Cattle Insert Applicator is past the vulva slope the "TRADENAME TO BE SELECTED" Cattle Insert Applicator slightly upwards (35-45° angle) by lowering the handle, and then forward, without forcing, until the "TRADENAME TO BE SELECTED" Cattle Insert Applicator is fully inserted or resistance is felt (see Figure 3 below).
11. Squeeze the finger grips within the handle of the "TRADENAME TO BE SELECTED" Cattle Insert Applicator to deposit the "TRADENAME TO BE SELECTED" Cattle Insert in the anterior vagina (see Figure 4 below) and then pull the "TRADENAME TO BE SELECTED" Cattle Insert Applicator backwards to remove it from the vagina.
12. With the "TRADENAME TO BE SELECTED" Cattle Insert correctly placed, with the wings open in the anterior portion of the vagina, the tail of the "TRADENAME TO BE SELECTED" Cattle Insert should be visible, pointing downward from the vulva of the animal. Tails of "TRADENAME TO BE SELECTED" Cattle Inserts that protrude more than 2.5 inches from the vulva may be clipped to minimize removal by other animals.

Removal:

1. Remove "TRADENAME TO BE SELECTED" Cattle Inserts by pulling, gently but firmly, on the protruding polyester tail.
2. "TRADENAME TO BE SELECTED" Cattle Inserts have been reported to reverse direction within the vagina; therefore, if the polyester tail of the insert is not visible on the day of removal, check the vagina to determine if an insert is present.

Figure 1

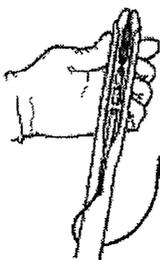


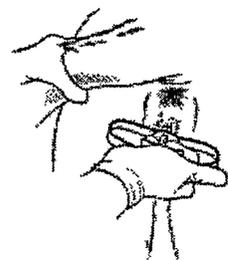
Figure 2



Figure 3



Figure 4



Other Information:

Store below 86°F (30°C)



Manufactured for:
INTERVET INC.
Millsboro, DE 19966
Made in "XXX"

Lot Number:

Expiration Date:

Inactive Ingredients: silicone rubber, nylon and polyester.

Questions/Comments: 1-800-441-8272

NADA #TBD, Approved by FDA

LUTALYSE is a registered trademark of Pfizer Animal Health, Inc.