Date of Approval: September 28, 2020

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-069

OvaCyst®

(gonadorelin)

Injectable Solution

Lactating dairy cows and beef cows

Provides for a new estrous reproductive synchronization indication - "OvaCyst® is indicated for use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows and beef cows."

Sponsored by:

Bimeda Animal Health Ltd.

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I. General Information

A. File Number

ANADA 200-069

B. Sponsor

Bimeda Animal Health Ltd.
1B The Herbert Building,
The Park, Carrickmines
Dublin, 18, Ireland

Drug Labeler Code: 061133

U.S. Agent Name and Address:
Stephanie Batliner
Bimeda Inc.
One Tower Lane
Suite 2250
Oakbrook Terrace, IL 60181

C. Proprietary Name

OvaCyst®

D. Drug Product Established Name

gonadorelin

E. Pharmacological Category

Peptide hormone

F. Dosage Form

Injectable Solution

G. Amount of Active Ingredient

50 mcg/mL gonadorelin diacetate tetrahydrate (43 mcg/mL gonadorelin)

H. How Supplied

Multi-dose vials containing 36 mL of sterile solution in a 50 mL vial

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Reproductive Synchrony
The intramuscular dosage of OvaCyst® is 100 mcg gonadorelin diacetate tetraydrate (2 mL) per cow, used in reproductive synchrony programs similar to the following:

1. Administer the first OvaCyst® injection (2 mL) at Time 0.
2. Administer the 500 mcg cloprostenol (as cloprestenol sodium) by intramuscular injection 6 to 8 days after the first OvaCyst® injection.
3. Administer the second OvaCyst® injection (2 mL) 30 to 72 hours after the cloprostenol sodium injection.
4. Perform FTAI 0 to 24 hours after the second OvaCyst® injection, or inseminate cows on detected estrus using standard herd practices.

K. Route of Administration

Intramuscular injection

L. Species/Class

Lactating dairy cows and beef cows

M. Indication

Reproductive Synchrony
OvaCyst® is indicated for use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows and beef cows.

N. Reference Listed New Animal Drug (RLNAD)

CYSTORELIN®; gonadorelin; NADA 098-379; Boehringer Ingelheim Animal Health USA, Inc.

O. Effect of Supplement

This supplement provides for a new estrous reproductive synchronization indication "OvaCyst® is indicated for use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows and beef cows."

II. BIOEQUIVALENCE

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-069, dated August 26, 2002, contains a summary of data that demonstrates bioequivalence of the drug for use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in lactating dairy cows and beef cows.

III. HUMAN FOOD SAFETY

The tolerance for residues and withdrawal period established for the RLNAD apply to the generic product. The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) is not established for total residues of gonadorelin. The tolerances established for the RLNAD apply to the generic product. A tolerance is not required for residues of gonadorelin in cattle tissues or milk.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. Neither a withdrawal period or milk discard time is required for gonadorelin injectable solution in cattle.

C. Analytical Method for Residues

Because a tolerance is not required for residues of gonadorelin in cattle tissues or milk, a validated analytical method for gonadorelin is not necessary.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to OvaCyst®:

Not for use in humans. Keep out of reach of children.

V. AGENCY CONCLUSIONS

The information submitted in support of this supplemental ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that OvaCyst®, when used according to the label, is safe and effective for the indications listed in Section I.M. above.

Additionally, data demonstrate that residues in food products derived from lactating dairy cows and beef cows treated with OvaCyst® will not represent a public health concern when the product is used according to the label.