

Date of Approval: June 1, 2020

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-134
FERTAGYL®
(gonadorelin)
Injectable Solution
Beef cows

Provides for the addition of a new target animal subclass, beef cows, to the existing estrous synchronization indication.

Sponsored by:
Intervet, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-134

B. Sponsor

Intervet, Inc.
2 Giralda Farms
Madison, NJ 07940

Drug Labeler Code: 000061

C. Proprietary Name

FERTAGYL®

D. Drug Product Established Name

gonadorelin

E. Pharmacological Category

Peptide hormone

F. Dosage Form

Injectable Solution

G. Amount of Active Ingredient

43 mcg gonadorelin/mL as gonadorelin acetate

H. How Supplied

Multi-dose vials containing 20 mL and 100 mL

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Reproductive Synchrony

For beef cows, the intramuscular dosage of FERTAGYL® is 86 mcg gonadorelin (2 mL) per cow, used in reproductive synchrony programs similar to the following:

- Administer the first FERTAGYL® injection (2 mL) on Day 0.
- Administer 500 mcg cloprostenol (as cloprostenol sodium) by intramuscular injection 6 to 8 days after the first FERTAGYL® injection.
- Administer the second FERTAGYL® injection (2 mL) 30 to 72 hours after the cloprostenol sodium injection.
- Perform fixed time artificial insemination (FTAI) 0 to 24 hours after the second FERTAGYL® injection, or inseminate cows on detected estrus using standard herd practices.

K. Route of Administration

Intramuscular injection

L. Species/Class

Beef cows

M. Indications

Reproductive Synchrony

FERTAGYL[®] is indicated for use with cloprostenol sodium to synchronize estrous cycles to allow for FTAI in 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 the addition of a new target animal subclass, beef cows, to the existing estrous synchronization indication.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Intervet, Inc., was granted a biowaiver for the generic product FERTAGYL[®] (gonadorelin). The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is CYSTORELIN[®] (gonadorelin) injectable solution, sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 098-379 and, was approved for use in dairy cattle (for the treatment of cystic ovaries) on March 10, 1978, and in lactating dairy cows and beef cows (for use with cloprostenol sodium to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI)) on June 14, 2018.

III. HUMAN FOOD SAFETY

CVM did not require human food safety studies for this supplemental approval.

IV. USER SAFETY

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

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

V. AGENCY CONCLUSIONS

This information submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that FERTAGYL® when used according to the label, is safe and effective.

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