Date of Approval: April 16, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-579

Altrenogest Solution

Altrenogest

Oral Solution

Swine

Altrenogest Solution is indicated for the synchronization of estrus in sexually mature gilts that have had at least one estrus cycle. Treatment with altrenogest solution 0.22% results in estrus (standing heat) 4 to 9 days after completion of the 14-day treatment period.

Sponsored by:

Ceva Sante Animale

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I. GENERAL INFORMATION:

A. File Number

ANADA 200579

B. Sponsor

Ceva Sante Animale
10 Avenue de la Ballastière
33500 Libourne, France

Drug Labeler Code: 013744

US Agent Name and Address:

Alicia Henk
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215

C. Proprietary Name

Altrenogest Solution

D. Product Established Name

altrenogest

E. Pharmacological Category

Steroid hormone

F. Dosage Form

Oral solution

G. Amount of Active Ingredient

2.2 mg/mL

H. How Supplied

1000 mL bottle

I. Dispensing Status

OTC

J. Dosage Regimen

Administer 6.8 mL (15 mg altrenogest) per gilt once daily for 14 consecutive days. Treat gilts on an individual animal basis by top dressing Altrenogest Solution on a portion of each gilt's daily feed allowance.

K. Route of Administration

Oral

L. Species

Swine

M. Indication

For synchronization of estrus in sexually mature gilts that have had at least one estrus cycle. Treatment with altrenogest solution 0.22% results in estrus (standing heat) 4 to 9 days after completion of the 14-day treatment period.

N. Reference Listed New Animal Drug

MATRIX; altrenogest; NADA 141-222; Intervet, Inc.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug (RLNAD)). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, 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. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Ceva Sante Animale, was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Altrenogest Solution (altrenogest) oral solution. The generic drug product is an oral 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 MATRIX (altrenogest) oral solution, sponsored by Intervet, Inc. under NADA 141-222 and, was approved for use in swine on September 30, 2003.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for swine:

A. Tolerances for Residues:

The tolerances established for the RLNAD apply to the generic product. A tolerance of 1 ppb is established for altrenogest residues (the marker residue) in the uncooked edible tissues of the muscle (the target tissue), and 4 ppb for liver, under 21 CFR 556.36. The acceptable daily intake (ADI) for total residues of altrenogest is 0.04 micrograms per kilogram of body weight per day.

B. Withdrawal Period:

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 21 days has been established for altrenogest in swine.

C. Regulatory Method for Residues:

The validated regulatory method for the determination and confirmation of residues of altrenogest is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

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

Keep this and all medication out of the reach of children. Avoid skin contact. Wear protective gloves when handling this product. DO NOT USE LATEX GLOVES. Pregnant women or women who suspect they are pregnant should not handle altrenogest solution 0.22%. Women of childbearing age should exercise extreme caution when handling this product. Accidental exposure could lead to a disruption of the menstrual cycle or prolongation of pregnancy. Wash off accidental spillage on the skin immediately with soap and water.

People who should not handle this product:

1. Women who are or suspect they are pregnant.
2. Anyone with thrombophlebitis or thromboembolic disorders or with a history of these events.
3. Anyone with cerebral-vascular or coronary-artery disease.
4. Women with known or suspected carcinoma of the breast.
5. People with known or suspected estrogen-dependent neoplasia.
6. Women with undiagnosed vaginal bleeding.
7. People with benign or malignant tumors which developed during the use of oral contraceptives or other estrogen-containing products.
8. Anyone with liver dysfunction or disease.

Accidental exposure: Altrenogest is readily absorbed from contact with the skin. In addition, this oil based product can penetrate porous gloves. Altrenogest should not penetrate intact vinyl, neoprene or nitrile protective gloves; however, if there is leakage (i.e., pinhole, spillage, etc.) the contaminated area covered by such occlusive materials may have increased absorption. DO NOT USE LATEX GLOVES.

The following measures are recommended in case of accidental exposure.

Skin Exposure: Wash immediately with soap and water.

Eye Exposure: Immediately flush with plenty of water for 15 minutes. Get medical attention.

If Swallowed: Do not induce vomiting. Altrenogest solution 0.22% contains an oil. Call a physician. Vomiting should be supervised by a physician because of possible pulmonary damage via aspiration of the oil base. If possible, bring the container and labeling to the physician.

Effects of Overexposure: There has been no human use of this specific product. The information contained in this section is extrapolated from data available on other products of the same pharmacological class that have been used in humans. Effects anticipated are due to the progestational activity of altrenogest. Acute effects after a single exposure are possible; however, continued daily exposure has the potential for more untoward effects such as disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy and headaches. The oil base may also cause complications if swallowed. In addition, the list of people who should not handle this product is based upon the known effects of progestins used in humans on a chronic basis.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Altrenogest Solution, when used according to the label, is safe and effective.

Additionally, data demonstrate that residues in food products derived from species treated with Altrenogest Solution will not represent a public health concern when the product is used according to the label.