Date of Approval: July 14, 2017

# FREEDOM OF INFORMATION SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-621

SwineMate®

altrenogest

Solution

Swine (gilts)

For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle.

Sponsored by:

Aurora Pharmaceutical, LLC

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## I. GENERAL INFORMATION:

### A. File Number

ANADA 200-621

### B. Sponsor

Aurora Pharmaceutical, LLC
1196 Highway 3 South
Northfield, MN 55057-3009

Drug Labeler Code: 051072

### C. Proprietary Name

SwineMate®

### D. Product Established Name

Altrenogest

### E. Pharmacological Category

Steroid hormone

### F. Dosage Form

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 SwineMate® on a portion of each gilt's daily feed allowance. To produce the desired synchronization of estrus in a group of gilts, treat all of the gilts daily for the same 14-day period.

### K. Route of Administration

Oral

### L. Species/Class

Swine (gilts)

### M. Indication

For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle.

### 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 period 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, Aurora Pharmaceutical, LLC, was granted a waiver from the requirement to demonstrate bioequivalence for the generic product SwineMate® (altrenogest) solution. The generic drug product is a 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) 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 supplemental 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. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) for total residues of altrenogest is 0.04 micrograms *per* kilogram of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 4 parts *per* billion

(ppb) is established for altrenogest (the marker residue) in liver (the target tissue), and 1 ppb in muscle, under 21 §CFR 556.36.

**B. Withdrawal Period:**

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal period is that previously assigned to the RLNAD product. A withdrawal period of 21 days has been established for altrenogest in sexually mature gilts that have had at least one estrous cycle.

**C. Analytical Method for Residues:**

A validated HPLC method for altrenogest in edible tissues 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 SwineMate®:

**WARNINGS:**
**User/Handler Safety:** Keep this and all medication out of the reach of children.

Avoid skin contact. Wear vinyl, neoprene, or nitrile protective gloves when handling this product. DO NOT USE LATEX GLOVES. Pregnant women or women who suspect they are pregnant should not handle SwineMate® (altrenogest) Solution 0.22%. Women of childbearing age should exercise extreme caution when handling this product. Accidental absorption 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 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. SwineMate® (altrenogest) Oral 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 SwineMate®, when used according to the label, is safe and effective.

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