Date of Approval: March 10, 2020

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-670

SENERGY™

(selamectin)

Topical Solution

Dogs and Cats

SENERGY™ is recommended for use in dogs six weeks of age or older and cats eight weeks of age and older for the following parasites and indications:

Dogs:

SENERGY™ kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. SENERGY™ also is indicated for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) and for the control of tick infestations due to *Dermacentor variabilis*.

Cats:

SENERGY™ kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. SENERGY™ is also indicated for the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections in cats.

Sponsored by:

Chanelle Pharmaceuticals Manufacturing Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-670

B. Sponsor

Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road
Loughrea, County Galway, H62 FH90
Ireland

Drug Labeler Code: 061651

U.S. Agent Name and Address:
James H. Schafer, DVM
Schafer Veterinary Consultants, LLC
800 Helena Court
Fort Collins, CO 80524

C. Proprietary Name

SENERGY™

D. Drug Product Established Name

selamectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Topical solution

G. Amount of Active Ingredient

60 mg/mL and 120 mg/mL

H. How Supplied

Available in three-dose cartons for each of the following strengths and sizes for dogs and cats of different weights: 60 mg/mL in 0.25, 0.75 and 1.0 mL tubes and 120 mg/mL in 0.25, 0.5, 1.0, 2.0 and 3.0 mL tubes.

I. Dispensing Status

Rx

J. Dosage Regimen

The recommended minimum dose is 2.7 mg selamectin per pound (6 mg/kg) of body weight. Administer the entire contents of a single dose tube (or two tubes

used in combination for dogs weighing over 130 pounds) of SENERGY™ topically in accordance with the following tables:

Cats (lb)	Package color	mg per applicator	Potency (mg/mL)	Administered volume (mL)
Up to 5	Mauve	15 mg	60	0.25
5.1 – 15	Blue	45 mg	60	0.75
15.1 - 22	Taupe	60 mg	60	1.0

For cats over 22 lbs use the appropriate combination of tubes.

Dogs (lb)	Package color	mg per applicator	Potency (mg/mL)	Administered volume (mL)
Up to 5	Mauve	15 mg	60	0.25
5.1 – 10	Lavender	30 mg	120	0.25
10.1 – 20	Brown	60 mg	120	0.5
20.1 – 40	Red	120 mg	120	1.0
40.1 - 85	Teal	240 mg	120	2.0
85.1 - 130	Plum	360 mg	120	3.0

For dogs over 130 lbs use the appropriate combination of tubes. Recommended for use in dogs 6 weeks of age and older and in cats 8 weeks of age and older.

K. Route of Administration

Topical

L. Species/Class

Dogs and cats

M. Indications

SENERGY™ is recommended for use in dogs six weeks of age or older and cats eight weeks of age and older for the following parasites and indications:

Dogs:
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SENERGY™ kills adult fleas and prevents flea eggs from hatching for one month and is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. SENERGY™ is also indicated for the treatment and control of

roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections in cats.

N. Reference Listed New Animal Drug (RLNAD)

Revolution®; selamectin; NADA 141-152; Zoetis Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic 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. 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, Chanelle Pharmaceuticals Manufacturing Ltd., was granted a biowaiver for the generic product SENERGY™ (selamectin) topical solution. The generic drug product is a topical 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 Revolution® (selamectin) topical solution, sponsored by Zoetis Inc., under NADA 141-152, and was approved for use in dogs and cats on May 26, 1999.

III. HUMAN FOOD SAFETY

This drug is intended for use in dogs and cats. Because this new animal drug is not intended for use in food producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

IV. USER SAFETY

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

Not for human use. Keep out of the reach of children. In humans, SENERGY™ may be irritating to skin and eyes. Reactions such as hives, itching and skin redness have been reported in humans in rare instances. Individuals with known hypersensitivity to SENERGY™ should use the product with caution or consult a health care professional. SENERGY™ contains isopropyl alcohol and the preservative butylated hydroxytoluene (BHT). Wash hands after use and wash off any product in contact with the skin immediately with soap and water. If contact with eyes occurs, then flush eyes copiously with water. In case of ingestion by a human, contact a physician immediately. The safety data sheet (SDS) provides more detailed occupational safety information. To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Virbac AH, Inc. at 1-800-338-3659 or us.virbac.com.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

Flammable - Keep away from heat, sparks, open flames or other sources of ignition.

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 SENERGY™ when used according to the label, is safe and effective.