Date of Approval: December 2, 2022

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-377

LinxMed-SP®

(lincomycin hydrochloride)

Soluble Powder

Honey bees

The effect of this supplement provides for labeling changes to include the addition of a new indication for the control of American foulbrood (*Paenibacillus larvae*) in honey bees.

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-377

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:

Deb Ann Voss
Bimeda Inc.
291 Forest Prairie Road
Le Sueur, MN 56058

C. Proprietary Name

LinxMed-SP®

D. Drug Product Established Name

lincomycin hydrochloride

E. Pharmacological Category

Antimicrobial

F. Dosage Form

soluble powder

G. Amount of Active Ingredient

Each gram of soluble powder contains lincomycin hydrochloride equivalent to 0.4 grams of lincomycin.

H. How Supplied

40 g (1.41 oz) pouch
25 x 40 g shipping label
80 g (2.82 oz) pouch
25 x 80 g shipping label
160 g (5.64 oz) pouch
6 x 160 g shipping label
480 g (1 lb. 0.93 oz) pouch
6 x 480 g shipping label
2 lb. (907.2 g) pail

6 x 907.2 g shipping label

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

Administer 100 mg lincomycin per hive. The drug should be administered to the hive weekly for 3 weeks.

Mix 100 milligrams lincomycin with 20 grams confectioners'/powdered sugar and dust over the top bars of the brood chamber once weekly for 3 weeks.

K. Route of Administration

Oral

L. Species/Class

Honey bees

M. Indication

For the control of American foulbrood (*Paenibacillus larvae*) in honey bees.

N. Reference Listed New Animal Drug

LINCOMIX®; lincomycin hydrochloride; NADA 111-636; Zoetis Inc.

O. Effect of Supplement

This supplement provides for labeling changes to include the addition of a new indication for the control of American foulbrood (*Paenibacillus larvae*) in honey bees.

II. BIOEQUIVALENCE

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-377, dated December 6, 2004, contains a summary of data that demonstrates bioequivalence of the drug for honey bees.

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 LinxMed-SP®:

WARNING: Not for human use.

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 Cosmetics Act. The data demonstrate that LinxMed-SP®, 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 honey bees treated with LinxMed-SP® will not represent a public health concern when the product is used according to the label.