Date of Approval: October 18, 2013

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-432

NEXHA

hyaluronate sodium

injectable solution

Horses

Treatment of joint dysfunction of the carpus or fetlock in horses due to non-infectious synovitis associated with equine osteoarthritis.

Sponsored by:

Bioniche Animal Health USA, Inc.

Table of Contents

I. GENERAL INFORMATION:

A. File Number

ANADA 200-432

B. Sponsor

Bioniche Animal Health USA, Inc.
119 Rowe Rd.
Athens, GA 30601

Drug Labeler Code: 064847

C. Proprietary Name

NEXHA

D. Established Name

Hyaluronate sodium

E. Pharmacological Category

Anti-inflammatory

F. Dosage Form:

Injectable solution

G. Amount of Active Ingredient

10 mg/ml

H. How Supplied

2 mL and 4 mL vials

I. Dispensing Status

Rx

J. Dosage Regimen

2 mL (20 mg) by intra-articular injection into the carpus or fetlock or 4 mL (40 mg) by slow intravenous injection into the jugular vein. Treatment may be repeated at weekly intervals for a total of three treatments.

K. Route of Administration

Intra-articular or intravenous injection

L. Species/Class

Horses

M. Indication

Treatment of joint dysfunction of the carpus or fetlock in horses due to non-infectious synovitis associated with equine osteoarthritis.

N. Reference Listed New Animal Drug

LEGEND Injectable Solution; hyaluronate sodium; NADA 140-883; Bayer HealthCare LLC, Animal Health Division

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 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). 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 reference listed new animal drug (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, Bioniche Animal Health USA, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product NEXHA (hyaluronate sodium) injectable solution. The generic product is administered as 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 LEGEND (hyaluronate sodium) Injectable Solution, and was approved for use in horses on September 12, 1991.

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:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in horses, which are not food producing animals.

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 NEXHA:

Do not use in horses intended for human consumption.

HUMAN WARNINGS: Not for use in humans. Keep this and all other drugs out of reach of children.

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