Date of Approval: April 11, 2012

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-456

Dexamethasone Solution

dexamethasone

Injectable Solution (2 mg/mL)

Cattle and Horses

For intravenous and intramuscular use in the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses.

Sponsored by:

Med-Pharmex Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-456
JINAD 011-289

B. Sponsor

Med-Pharmex, Inc.
2727 Thompson Creek Road.
Pomona, CA 91767-1861

Drug Labeler Code: 054925

C. Proprietary Name

Dexamethasone Solution

D. Product Established Name

Dexamethasone

E. Pharmacological Category

Anti-inflammatory

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

2 mg/ml.

H. How Supplied

100 mL multi vial dose

I. Dispensing Status

Rx

J. Dosage Regimen

Cattle: 5 to 20 mg
Horses: 2.5 to 5 mg

K. Route of Administration

Intravenous or Intramuscular Injection.

L. Species/Class

Cattle and Horses

M. Indication(s)

For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses

N. Reference Listed New Animal Drug

PAZIUM Injectable Solution; dexamethasone; NADA 012-559; 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, *Med-Pharmex, Inc.*, was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Dexamethasone Solution (dexamethasone) Solution. The generic drug product is an injectable solution, containing 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 PAZIUM *(dexamethasone) Injectable Solution*, sponsored by Intervet Inc. under NADA 012-559 and, was approved for use in cattle and horses on March 29, 1961.

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.

The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues:

An acceptable daily intake (ADI) is not cited for total residues of dexamethasone. The tolerances established for the RLNAD apply to the generic product. A tolerance for dexamethasone has not been established.

B. Withdrawal Period(s):

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal periods are those previously assigned to the RLNAD product. No withdrawal period has been established for dexamethasone in cattle.

C. Regulatory Method for Residues:

There is no validated regulatory method for the determination and confirmation of residues of dexamethasone in cattle, 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 does not contain information regarding safety for humans handling, administering, or exposed to Dexamethasone Solution.

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

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