Date of Approval: November 4, 2014

# FREEDOM OF INFORMATION SUMMARY

## ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-573

Dexmedetomidine HCl

dexmedetomidine hydrochloride

Sterile Injectable Solution

Dogs and cats

For use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. Dexmedetomidine HCl is also indicated for use as a preanesthetic to general anesthesia in dogs and cats

Sponsored by:

Putney, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-573

B. Sponsor

Putney, Inc.
One Monument Sq.
Suite 400
Portland, ME 04101

Drug Labeler Code: 026637

C. Proprietary Name

Dexmedetomidine HCl

D. Established Name

Dexmedetomidine hydrochloride

E. Pharmacological Category

alpha$_2$-adrenoceptor agonist

F. Dosage Form:

Sterile injectable solution

G. Amount of Active Ingredient

0.5 mg/mL

H. How Supplied

10 mL, glass, sterile, multi-dose vial

I. Dispensing Status

Rx

J. Dosage Regimen

Dogs: for sedative and analgesic administer 375 mcg/m$^2$ by intravenous (IV) injection or 500 mcg/m$^2$ by intramuscular (IM) injection; for preanesthesia administer 125 or 375 mcg/m$^2$ by IM injection.

Cats: for sedation, analgesia, or preanesthesia administer 40 mcg/kg IM.

K. Route of Administration

Dogs: IV or IM; Cats: IM

L. Species / Class

Dogs and cats

M. Indication

For use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. Dexmedetomidine HCl is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

N. Reference Listed New Animal Drug

DEXDOMITOR; dexmedetomidine hydrochloride; NADA 141-267; Orion Corp.

## 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, Putney, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Dexmedetomidine HCl (dexmedetomidine hydrochloride) 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 DEXDOMITOR (dexmedetomidine hydrochloride) sterile injectable solution, sponsored by Orion Corp. under NADA 141-267, and was approved for use in dogs and cats on December 1, 2006.

## 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 dogs and cats, which are not food producing animals.

## VI. USER SAFETY:

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

Not for human use. Keep out of reach of children. Dexmedetomidine hydrochloride can be absorbed following direct exposure to skin, eyes, or mouth, and may cause irritation. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. Appropriate precautions should be taken while handling and using filled syringes. Accidental topical (including ocular) exposure, oral exposure, or exposure by injection could cause adverse reactions, including sedation, hypotension, and bradycardia. Seek medical attention immediately. Users with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid any exposure to this product. Caution should be exercised when handling sedated animals. Handling or any other sudden stimuli, including noise, may cause a defense reaction in an animal that appears to be heavily sedated. The material safety data sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users or to obtain a copy of the MSDS for this product call 1-866-683-0660.

## 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 Dexmedetomidine HCl, when used according to the label, is safe and effective.