Date of Approval: June 5, 2009

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-291

VETORYL

Trilostane
Capsules
Dog

The effect of this supplement is the addition of a 10 mg capsule size.

Sponsored by:

Dechra, Ltd.

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I. GENERAL INFORMATION:

A. File Number: NADA 141-291

B. Sponsor:

Dechra, Ltd.
Dechra House
Jamage Industrial Estate
Talke Pits
Stoke-on-Trent
Staffordshire, ST71XW
United Kingdom

Drug labeler Code: 043264

U.S. Agent:

Karen G. Bond
Clinical Trials Manager
Dechra Pharmaceuticals
7015 College Boulevard, Suite 525
Overland Park, KS 66211

C. Proprietary Name(s): VETORYL

D. Established Name(s): Trilostane

E. Pharmacological Category: Adrenocortical suppressant

F. Dosage Form(s): Capsule

G. Amount of Active Ingredient(s): 10, 30 and 60 mg

H. How Supplied: Box of three blister cards with 10 capsules/card

I. How Dispensed: Rx

J. Dosage(s):

The starting dose for the treatment of hyperadrenocorticism in dogs is 1.0-3.0 mg/lb (2.2 – 6.7 mg/kg) once a day based on body weight and capsule size. VETORYL Capsules should be administered with food.

Starting dose

Weight range (pounds)	**Weight range** (kg)	**Starting dose** (mg) **ONCE DAILY**
≥ 3.8 to < 10	≥ 1.7 to < 4.5	10
≥ 10 to < 22	≥ 4.5 to < 10	30
≥ 22 to < 44	≥ 10 to < 20	60
≥ 44 to < 88	≥ 20 to < 40	120 (2 x 60 mg)
≥ 88 to < 132*	≥ 40 to < 60	180 (3 x 60 mg)

*Dogs over 132 pounds (60 kg) should be administered the appropriate combination of capsules.

K. Route(s) of Administration: Oral

L. Species/Class: Dogs

M. Indication(s): VETORYL Capsules are indicated for the treatment of pituitary-dependent hyperadrenocorticism in dogs. VETORYL Capsules are indicated for the treatment of hyperadrenocorticism due to adrenocortical tumor in dogs.

N. Effect(s) of Supplement: This supplement provides for the addition of a 10 mg capsule size.

II. EFFECTIVENESS:

A. Dosage Characterization:

This supplemental approval does not change the previously approved dosage range. The Freedom of Information (FOI) Summary for the original approval of NADA 141-291 dated, December 5, 2008, contains dosage characterization information for dogs.

B. Substantial Evidence:

CVM did not require effectiveness studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-291 dated December 5, 2008, contains a summary of studies that demonstrate effectiveness of the drug for dogs.

III. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this supplemental approval. The FOI Summary for the original approval of NADA 141-291 dated December 5, 2008, contains a summary of target animal safety studies for dogs.

IV. HUMAN FOOD SAFETY:

This drug is intended for use in dogs, which are non-food animals. 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 NADA.

V. USER SAFETY:

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

"Keep out of reach of children. Not for human use.

Wash hands after use. Do not empty capsule contents and do not attempt to divide the capsules. Do not handle the capsules if pregnant or if trying to conceive. Trilostane is associated with teratogenic effects and early pregnancy loss in laboratory animals. In the event of accidental ingestion/overdose, seek medical advice immediately and take the labeled container with you."

The human user warnings are based on scientific articles, safety studies in human subjects, case reports, toxicological studies in laboratory species, and the material safety data sheets.

VI. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 514. The data demonstrate that VETORYL Capsules, when used according to the label, are safe and effective for the treatment of pituitary- and adrenal-dependent hyperadrenocorticism in dogs.

A. Marketing Status:

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status). Adequate directions for lay use cannot be written because professional expertise is required to properly diagnose hyperadrenocorticism and to monitor the safe use of the product, including treatment of any adverse reactions.

B. Exclusivity:

VETORYL, as approved for the treatment of pituitary-dependent hyperadrenocorticism, does not qualify for additional marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

VETORYL, as approved for the treatment of hyperadrenocorticism due to adrenocortical tumor in dogs, continues to qualify for SEVEN years of exclusive marketing rights which began on the date of the original approval. This drug qualifies for exclusive marketing rights under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) because it is a designated new animal drug under section 571(a) of the act. Except as provided in section 573(c)(2) of the act, CVM may not approve or conditionally approve another application submitted for such new animal drug with the same designated intended use as VETORYL.

C. Supplemental Applications:

This supplemental NADA did not require a reevaluation of the safety or effectiveness data in the original NADA (21 CFR 514.106(b)(1)).

D. Patent Information:

The sponsor did not submit any patent information with this application.

VII. ATTACHMENTS:

Facsimile Labeling:
Package insert
Dog owner information about VETORYL (trilostane) Capsules
Blister label (10 mg)
Dispensing container carton label (10 mg)