Date of Approval: December 18, 2025

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-576

CosACTHen®

(cosyntropin injection)

Solution

Dogs

For the evaluation of adrenal function in dogs.

Sponsored by:

Dechra, Ltd.

Executive Summary

CosACTHen® (cosyntropin injection) is approved for the evaluation of adrenal function in dogs. The drug is administered by intravenous (IV) or intramuscular (IM) injection with the purpose of performing the adrenocorticotropic hormone (ACTH) stimulation test.

Safety and Effectiveness

The sponsor conducted a well-controlled laboratory study in sixteen healthy, female beagle dogs intramuscularly administered CosACTHen® (8 dogs) or saline (8 dogs). Plasma cortisol concentrations were determined 30 minutes prior to dosing and at 30, 60, and 90 minutes after CosACTHen® or saline administration. All dogs in the CosACTHen® group had a positive response (defined as a serum cortisol concentration greater than 6.5 µg/dL after dosing) at 30, 60, and 90 minutes. No dogs in the control group had a positive response. There were statistically significant differences in positive response rates between the two groups at 30, 60, and 90 minutes post-dosing, in favor of the CosACTHen® group. There were no adverse reactions reported during the study. In a separate well-controlled study using a non-final formulation of cosyntropin injection administered IM or IV, all dogs in the cosyntropin injection groups had a positive response at 30, 60, and 90 minutes, regardless of the route of administration.

The sponsor conducted a field study in client-owned dogs suspected of having hypoadrenocorticism or hyperadrenocorticism. The study included male and female mixed breed dogs, with a range of ages and weights. All dogs were randomized to receive a non-final formulation of cosyntropin injection by either IV or IM injection. A dog was considered to have a response indicative of hypoadrenocorticism if the serum cortisol concentration after cosyntropin injection administration was less than 2 µg/dL. The results were confirmed using baseline cortisol concentrations less than 2 µg/dL. A dog was considered to have a response indicative of hyperadrenocorticism if the serum cortisol concentration after cosyntropin injection administration was greater than 20 µg/dL. The results were confirmed using results of a low-dose dexamethasone suppression test on Day 7. Diagnostic performance (accuracy, negative predictive value, positive predictive value, sensitivity, and specificity) was calculated for each population and route of administration based on serum cortisol concentrations. The study demonstrated that a non-final formulation of cosyntropin injection was effective for the evaluation of adrenal function in dogs. Adverse reactions included vomiting and the development of a hematoma following IV administration.

The sponsor conducted a laboratory margin of safety study in young, healthy, male and female beagle dogs. The dogs were administered a non-final formulation of cosyntropin injection as three weekly IV or IM injections. The IV-dosed dogs were administered multiples of 0X, 1X, 3X, or 5X the maximum exposure dose of 0.056 mg/kg and the IM-dosed dogs were administered multiples of 0X, 1X, or 2X the maximum exposure dose. Control dogs were administered saline. Clinical signs related to cosyntropin injection administration included transient salivation, vomiting within an hour of dosing, and a hypersensitivity reaction in one 5X IV-dosed dog, which included injected mucous membranes, inguinal erythema, facial edema, and tachycardia. After 1 hour, the facial edema had improved, and the other signs persisted for approximately 150 minutes. The dog recovered without medical intervention.

The following adverse events were reported voluntarily during post-approval use of CosACTHen® in dogs in foreign markets: lethargy, anxiety, muscle tremor/weakness, abdominal pain, anorexia, diarrhea, injection site pain/bruising, lameness, and hypersensitivity reactions.

Table of Contents

I. GENERAL INFORMATION

A. File Number

NADA 141-576

B. Sponsor

Dechra, Ltd.
Snaygill Industrial Estate
Keighley Rd.
Skipton, North Yorkshire
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Drug Labeler Code: 043264

U.S. Agent Name and Address:

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Dechra Ltd
7015 College Blvd
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Overland Park, KS 66211

C. Proprietary Name

CosACTHen®

D. Drug Product Established Name

cosyntropin injection

E. Pharmacological Category

Synthetic adrenocorticotropic hormone (ACTH) analog for diagnostic use

F. Dosage Form

Solution

G. Amount of Active Ingredient

0.25 mg/mL

H. How Supplied

CosACTHen® (cosyntropin injection) is supplied in a clear glass vial with 1 mL cosyntropin (0.25 mg/mL).

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The dose is 0.25 mg (1 mL) per dog weighing 10-110 lbs (4.5-50 kg), administered by intravenous or intramuscular injection, with the purpose of performing the adrenocorticotropic hormone ACTH stimulation test.

K. Route of Administration

Intravenous or intramuscular

L. Species

Dogs

M. Indication

For the evaluation of adrenal function in dogs.

II. EFFECTIVENESS

The effectiveness of CosACTHen® (cosyntropin injection) was evaluated in two well-controlled laboratory studies and one field study. Following significant changes in the product manufacturing process after an initial well-controlled laboratory study and field study, the sponsor conducted a second well-controlled laboratory study. That study was conducted in only female dogs because the previous non-final formulation studies demonstrated no sex-related differences in response to cosyntropin injection. The second study was conducted using only the IM route of administration because the previous non-final formulation studies demonstrated the effect of cosyntropin injection on cortisol concentrations was comparable for both IV and IM routes.

A. Dosage Characterization

A dose of 0.25 mg (1 mL) CosACTHen® per dog weighing between 10 - 110 lbs (4.5 - 50 kg), administered by IV or IM injection, was selected based on published literature.[1,2,3,4,5] The studies demonstrated that a minimum effective dose of 0.005 mg/kg adequately stimulates cortisol production based on serum or plasma cortisol concentration results measured one hour after cosyntropin injection administration.

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[1] Feldman, EC, et al. Comparison of aqueous porcine ACTH with synthetic ACTH in adrenal stimulation tests of the female dog. *Am J Vet Res*, 43:522-524. 1982.

[2] Kemppainen, RJ, et al. Use of a low dose synthetic ACTH challenge test in normal and prednisone-treated dogs. *Res Vet Sci*, 35:240-242. 1983.

[3] Hansen, BL, et al. Synthetic ACTH (cosyntropin) stimulation tests in normal dogs: Comparison of intravenous and intramuscular administration. *J Am Anim Hosp Assoc*, 30:38-41. 1994

[4] Watson, ADJ, et al. Plasma cortisol responses to three corticotrophic preparations in normal dogs. *Aust Vet J*, 76:255-257. 1998.

[5] Frank, LA, et al. Serum concentrations of cortisol, sex hormones of adrenal origin, and adrenocortical steroid intermediates in healthy dogs following stimulation with two doses of cosyntropin. *Am J Vet Res*, 65:1631-1633. 2004.

B. Substantial Evidence

1. Laboratory Effectiveness Study

Title: Pivotal Pharmacodynamic Study of the Effect of CosACTHen® (Cosyntropin Injection) 0.25 mg/mL on Cortisol Concentrations After Intramuscular Administration to Healthy Beagle Dogs. (Study No. D24006)

Study Dates: September 19, 2024 to December 10, 2024

Study Location: Ballina, Ireland

Study Design:

Objective: To evaluate the effect of CosACTHen® (cosyntropin injection) on cortisol concentrations in dogs at 30, 60, and 90 minutes after a single IM administration at the minimum effective dose of 0.005 mg/kg body weight compared to the effect of saline administration.

Study Animals: Sixteen healthy, female beagle dogs, 9 to 56 months of age, and weighing 7.7 to 14.2 kg.

Experimental design: The study was a masked, randomized, controlled, parallel-designed laboratory study. Dogs were acclimated and pair housed from Day -10 until the day of dosing. Dogs were randomized to one of two treatment groups on Day -3. The study was conducted in accordance with Good Laboratory Practice (GLP) regulations.

Table II.1. Study D24006; Treatment Groups

Treatment Group	Number of Dogs
CosACTHen®	8
Control	8

Drug Administration: The CosACTHen® group was administered a dose of 0.005 mg/kg (0.02 mL/kg) IM once on Day 0. The control group was administered saline IM at an equivalent dose volume (0.02 mL/kg) as the CosACTHen® group.

Measurements and Observations: Physical examinations were conducted at the start of acclimatization and Days -3 and 1. Dogs were weighed at the start of acclimatization and on Days -1 and 1. General health observations were conducted twice daily from the start of acclimatization until Day 1. Blood samples were collected for serum chemistry and hematology on Day -6. Urinalysis was conducted on Day -7. Clinical observations were conducted on Day 0 prior to dosing and at 0.25 hour (h) (± 3 minutes (mins)), 1 h (± 5 mins), 6 h (± 10 mins), and 24 h (± 10 mins) after dosing. Injection site observations were conducted prior to dosing, 1 h (± 5 mins), 6 h (± 10 mins), and 24 h (± 10 mins) after dosing. Blood samples to analyze serum cortisol concentrations were collected immediately prior to dosing and 30, 60, and 90 minutes after dosing.

Statistical methods: Dogs were included in the effectiveness evaluation if their pre-dose serum cortisol concentration was 0.5 - 6.5 µg/dL. A positive response was defined as a serum cortisol concentration greater than 6.5 µg/dL after dosing. The positive response rates were compared between the CosACTHen® group and the control group at 30, 60, and 90 minutes using Fisher's Exact test. CosACTHen® was considered effective if there were statistically significant differences in positive response rates between the CosACTHen® and control groups, in favor of the CosACTHen® group, at all 3 timepoints (2-sided tests, $p \leq 0.05$).

Results: All dogs had a pre-dose serum cortisol concentration of 0.5 - 6.5 µg/dL. All dogs in the CosACTHen® group had a positive response at 30, 60, and 90 minutes. No dogs in the control group had a positive response. There were statistically significant differences in positive response rates between the two groups at 30, 60, and 90 minutes post-dosing, in favor of the CosACTHen® group ($p = 0.0002$ at each time point).

Table II.2. Study D24006; Mean and Range Serum Cortisol Concentrations (µg/dL) by Treatment Group

Timepoint	CosACTHen® Mean	CosACTHen® Range	Saline Mean	Saline Range
Pre-dose	1.9	1.2 - 2.6	2.6	1.6 - 5.2
30 minutes	9.2	7.6 - 10.1	1.9	1.3 - 2.9
60 minutes	12.9	10.6 - 14.6	2.3	0.8 - 3.4
90 minutes	11.8	8.8 - 14.7	1.8	1.2 - 2.9

Adverse Reactions: No adverse reactions were reported during the study.

Conclusions: CosACTHen® administered IM at the minimum labeled dose of 0.005 mg/kg body weight to healthy beagle dogs is effective at stimulating a positive serum cortisol response, defined as a change from a pre-dose serum cortisol concentration of 0.5 - 6.5 µg/dL to a post-dose serum cortisol concentration greater than 6.5 µg/dL, at 30, 60, and 90 minutes after administration.

2. Laboratory Effectiveness Study

Title: Pivotal Laboratory Efficacy Study of Synthetic ACTH In Dogs. (Study No. NAH-07-0036)

A laboratory effectiveness study using a non-final formulation of cosyntropin injection was conducted in 2008 with 32 healthy, 7- to 9-month-old beagle dogs. Cosyntropin injection was administered IM (8 dogs) or IV (8 dogs). Sixteen control dogs received saline. Plasma cortisol concentrations were determined 30 minutes prior to dosing and at 30, 60, and 90 minutes after cosyntropin injection or saline administration. Compared to the control group, the number of positive responses (defined as a change from a pre-dose serum cortisol concentration of 0.5 - 6 µg/dL to a post-dose serum cortisol concentration greater than 6 µg/dL) was greater at 30, 60, and 90 minutes after cosyntropin injection administration,

regardless of the route of administration There were no adverse reactions attributed to cosyntropin injection administration.

3. Field Study

Title: Field Efficacy and Safety of Synthetic ACTH for the Evaluation of Adrenal Function in Dogs. (Study No. NAH-08-0003)

Study Dates: October 8, 2008 to May 5, 2009

Study Locations:

Atlanta, GA
East Lansing, MI
Houston, TX
Irving, TX
Quakertown, PA
San Diego, CA
San Francisco, CA
Springfield, MO

Study Design:

Objective: To demonstrate the effectiveness, diagnostic performance, and safety of a non-final formulation of cosyntropin injection at a dose of 0.25 mg/dog for the evaluation of adrenal function in dogs.

Study Animals: One hundred nineteen (72 females and 47 males) dogs of various breeds, between 20 months and 16 years of age, weighing between 10 to 110 lbs, and suspected of having hypoadrenocorticism or hyperadrenocorticism were enrolled in the study.

Experimental Design: The study was a randomized, unmasked, multi-site study. The dogs were randomized into two treatment groups to receive cosyntropin injection by either IM or IV administration. All dogs were treated with a non-final formulation of cosyntropin injection. The study was conducted in accordance with Good Clinical Practice (GCP) guidelines.

Table II.3. Study NAH-08-0003; Treatment Groups - Number of Dogs by Condition

Treatment Group	Hypoadrenocorticism (Enrolled / Evaluable)	Hyperadrenocorticism (Enrolled / Evaluable)
IM	10 / 10	49 / 43
IV	11 / 10	49 / 44

Drug Administration: Dogs were administered cosyntropin injection at a dose of 0.25 mg (1 mL) per dog (dose range 0.005 - 0.056 mg/kg) either IM or IV once on Day 0 as part of the ACTH stimulation test.

Measurements and Observations: Physical examinations and body weight measurements were conducted once between Day -14 and Day 0 and again on Day 7. Blood and urine samples were collected for serum chemistry, hematology, and urinalysis between Day -14 and Day 0 and again on Day 7. Blood samples were collected for serum cortisol concentrations on Day 0 prior to dosing and again 60 minutes after cosyntropin injection dosing. Clinical observations and injection site evaluations were performed on Day 0 prior to dosing, then at 1, 4, and 8 hours after dosing and again on Day 7.

For dogs suspected of having hyperadrenocorticism, a low-dose dexamethasone suppression (LDDS) test was conducted on Day 7. Blood was collected for a baseline serum cortisol concentration. Dexamethasone sodium phosphate (DexSP) was then administered IV. Eight hours after DexSP administration, blood was collected for serum cortisol concentration.

Statistical Methods: A dog was considered to have a response indicative of hypoadrenocorticism if the serum cortisol concentration after cosyntropin injection administration was less than 2 µg/dL. The results were confirmed using baseline cortisol concentrations less than 2 µg/dL.

A dog was considered to have a response indicative of hyperadrenocorticism if the serum cortisol concentration after cosyntropin injection administration was greater than 20 µg/dL. The results were confirmed using results of the LDDS test on Day 7.

Diagnostic performance (accuracy, negative predictive value, positive predictive value, sensitivity, and specificity) was calculated (Table II.4) for each population and route of administration based on serum cortisol concentrations (Table II.5 and Table II.6).

Table II.4. Study NAH-08-0003; Diagnostic Performance Calculation Method

Diagnostic Performance	Calculation
Accuracy	(TP + TN) / (TP + FP + FN + TN)
Negative Predictive Value	TN / (TN + FN)
Positive Predictive Value	TP / (TP + FP)
Sensitivity	TP / (TP + FN)
Specificity	TN / (TN + FP)

Table II.5. Study NAH-08-0003; Effectiveness Evaluation for the Dogs with Suspected Hypoadrenocorticism

Baseline Cortisol Concentration	Cortisol Concentration Greater than or equal to 2 µg/dL After Cosyntropin Injection Administration	Cortisol Concentration Less than 2 µg/dL After Cosyntropin Injection Administration
Greater than or equal to 2 µg/dL	True Negative (TN)	False Positive (FP)
Less than 2 µg/dL	False Negative (FN)	True Positive (TP)

Table II.6. Study NAH-08-0003; Effectiveness Evaluation for the Dogs with Suspected Hyperadrenocorticism

Cortisol Concentration After LDDS Test (Day 7)	Cortisol Concentration Less than or equal to 20 µg/dL After Cosyntropin Injection Administration	Cortisol Concentration Greater than 20 µg/dL After Cosyntropin Injection Administration
Less than 1.4 µg/dL	True Negative (TN)	False Positive (FP)
Greater than or equal to 1.4 µg/dL	False Negative (FN)	True Positive (TP)

Results: Diagnostic performance was evaluated in 107 dogs and safety was evaluated in 119 dogs. The true and false negative and positive results are summarized in Table II.7. The accuracy, negative and positive predictive value, and sensitivity and specificity results are summarized in Table II.8.

Table II.7. True and False Negative and Positive Results for Non-Final Formulation Cosyntropin Injection

Diagnostic Performance	Dogs with Suspected Hypoadrenocorticism IM or IV Administration (n = 20)	Dogs with Suspected Hyperadrenocorticism IM Administration (n = 43)	Dogs with Suspected Hyperadrenocorticism IV Administration (n = 44)
True Negative	100% (10)	9.3% (4)	9.1% (4)
True Positive	100% (10)	60.5% (26)	61.4% (27)
False Negative	0	11.6% (5)	9.1% (4)
False Positive	0	18.6% (8)	20.5% (9)

Table II.8. Accuracy, Negative and Positive Predictive Value, Sensitivity, and Specificity of Non-Final Formulation Cosyntropin Injection

Diagnostic Performance	Dogs with Suspected Hypoadrenocorticism IM or IV Administration	Dogs with Suspected Hyperadrenocorticism IM Administration	Dogs with Suspected Hyperadrenocorticism IV Administration
Accuracy	100%	69.8%	70.5%
Negative Predictive Value	100%	44.4%	50.0%
Positive Predictive Value	100%	76.5%	75.0%
Sensitivity	100%	83.9%	87.1%
Specificity	100%	33.3%	30.8%

Adverse Reactions: Two dogs vomited within 8 hours after cosyntropin injection administration. One dog developed a hematoma following IV administration of cosyntropin injection.

Conclusion: A non-final formulation of cosyntropin injection, administered at a dose of 0.25 mg/dog, was safe and effective for the evaluation of adrenal function in dogs.

III. TARGET ANIMAL SAFETY

A. Margin of Safety Study

Title: Pivotal Target Animal Safety Toxicity Study of Synthetic ACTH in Dogs. (Study No. NAH-07-0035)

Study Dates: October 7, 2008 to April 27, 2010

Study Location: Ontario, Canada

Study Design:

Objective: To evaluate the safety, including injection site tolerance, of a non-final formulation of cosyntropin injection, when administered as three weekly IV or IM injections to healthy Beagle dogs.

Study Animals: Thirty-two healthy Beagle dogs (16 males and 16 females), 5 to 6 months of age, and weighing 7.0 to 9.5 kg on the day of the first injection.

Experimental Design: The study was a masked, randomized, controlled, parallel-designed laboratory study. Dogs were randomized to one of seven groups and administered saline or cosyntropin injection by IV or IM route of administration. Dogs dosed IV were administered multiples of 0X, 1X, 3X, or 5X the maximum exposure dose of 0.056 mg/kg; and IM-dosed dogs were administered multiples of 0X, 1X, or 2X the maximum exposure dose. Control dogs (0X) were administered saline. The

study was conducted in accordance with Good Laboratory Practices (GLP) regulations.

Table III.1: Study NAH-07-0035; **Treatment Groups**

Group*	Dose Multiple (Route of Administration)†	Dose (Dose Volume)	Number And Sex of Animals
1	0X (IV)	0 mg/kg (1.12 mL/kg)	4 (2 M, 2 F)
2	1X (IV)	0.056 mg/kg (0.224 mL/kg)	4 (2 M, 2 F)
3	3X (IV)	0.168 mg/kg (0.672 mL/kg)	4 (2 M, 2 F)
4	5X (IV)	0.280 mg/kg (1.12 mL/kg)	8 (4 M, 4 F)
5	0X (IM)	0 mg/kg (0.448 mL/kg)	4 (2 M, 2 F)
6	1X (IM)	0.056 mg/kg (0.224 mL/kg)	4 (2 M, 2 F)
7	2X (IM)	0.112 mg/kg (0.448 mL/kg)	4 (2 M, 2 F)

***** Groups 1 and 5 were administered saline
† IV: intravenous; IM: intramuscular

Drug Administration: Dogs received three weekly injections of saline or cosyntropin injection either by IV (via butterfly catheter inserted in the cephalic vein) or IM injection (into the lumbar musculature). The weekly injections were administered using alternating sides.

Measurements and Observations: Detailed clinical observations (at least twice daily); injection site observations (prior to dosing and 1, 8, 24, and 30 hours after dosing); physical and neurologic examinations (Days 1, 8, and 15); and ophthalmic and electrocardiographic examinations (once during acclimation, again within 5 days of euthanasia) were conducted. Body weight (3 times during acclimation, Days 4 and 11, and prior to dosing on Days 0, 7, and 14), and food consumption were measured. Samples for hematology, coagulation, serum chemistry, and urinalysis assessment were collected twice during acclimation and on Days 1 and 15. Additional samples for hematology and serum chemistry were collected on Day 4. Samples for serum cortisol assessment were collected after dosing on Days 0 and 14. A complete necropsy with organ weights and histopathologic examination were performed on all dogs on Day 16.

Statistical Method: No statistical analysis was conducted. Summary statistics were presented for all variables.

Results: All dogs completed the study.

Clinical signs related to cosyntropin injection administration included transient salivation observed during and/or immediately after dosing in six of eight dogs in the 5X IV-dosed group during the third dose. Of these six dogs, one male and one female were observed salivating during both the second and third doses of cosyntropin injection. One of the 5X IV-dosed dogs had a hypersensitivity reaction to its third injection. The reaction started within three minutes of dosing and included: transient salivation, injected mucous membranes, inguinal erythema, facial edema, and tachycardia. After 1 hour, the facial edema had improved, and the other signs persisted for approximately 150 minutes. The dog recovered without medical intervention.

One of four 1X IV-dosed dogs and three of eight 5X IV-dosed dogs vomited once within an hour of dosing. Dogs in all groups had loose stool sporadically throughout the study. The observations of loose stool were not directly related to cosyntropin injection administration.

On histopathology examination, there was minimal to mild microfocal mineralized deposits in the fundic glands and/or lamina propria of the stomach fundus in 14 of 32 dogs; one of which was a control dog. Three of 16 males had non-suppurative interstitial inflammation of the prostate; no control dogs had this change. The relationship of the microscopic findings to administration of cosyntropin injection is unknown.

Conclusions: The study supports the safe use of cosyntropin injection in dogs when used at the labeled dose. Cosyntropin injection demonstrated an adequate margin of safety when administered as three weekly IV injections at 1X, 3X, or 5X the maximum exposure dose of 0.056 mg/kg or by IM injections at 1X or 2X the maximum exposure dose. Salivation, hypersensitivity reaction, and vomiting are considered possible drug-related adverse reactions.

B. Foreign Experience

The following adverse events were reported voluntarily during post-approval use of CosACTHen® in dogs in foreign markets: lethargy, anxiety, muscle tremor/weakness, abdominal pain, anorexia, diarrhea, injection site pain/bruising, lameness, and hypersensitivity reactions.

IV. HUMAN FOOD SAFETY

This drug is intended for use in dogs. 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 CosACTHen®:

Not for use in humans. Keep this and all drugs out of reach of children.
People with known hypersensitivity to cosyntropin or ACTH should avoid contact with the product.

Pregnant women and breastfeeding women should take care to avoid accidental self-injection.

If any anaphylactic or allergic symptoms (skin reactions, dizziness, nausea, vomiting, urticaria, pruritus, flushing, malaise, dyspnea, angioneurotic edema) develop following exposure to CosACTHen®, medical advice must be sought immediately. In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

If skin contact occurs, wash affected area with soap and water.

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 (FD&C Act) and 21 CFR part 514. The data demonstrate that CosACTHen®, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.

A. Marketing Status

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

B. Exclusivity

CosACTHen®, as approved in our approval letter, qualifies for FIVE years of marketing exclusivity beginning as of the date of our approval letter. This drug qualifies for exclusivity under section 512(c)(2)(F)(i) of the FD&C Act because this is the first time we are approving this active moiety in a new animal drug application submitted under section 512(b)(1) of the FD&C Act.

C. Patent Information

For current information on patents, see the Green Book Reports in the Animal Drugs @ FDA database.