Date of Approval: June 9, 2023

CORRECTED FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-555

apoquel® chewable

(oclacitinib chewable tablet)

Dogs

Control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

Sponsored by:

Zoetis Inc.

Executive Summary

apoquel® chewable (oclacitinib chewable tablet) is approved for the control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age. The drug is administered orally, twice daily for up to 14 days, and then administered once daily for maintenance therapy.

Safety and Effectiveness

The sponsor conducted an *in vivo* bioequivalence study in young, healthy, male Beagles comparing apoquel® chewable to apoquel® (oclacitinib tablet). apoquel® is already approved under a different new animal drug application (NADA 141-345) for the control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age and is available as film coated tablets. The objective of the bioequivalence study was to provide a pharmacokinetic (PK) bridge for safety and effectiveness from apoquel® chewable to apoquel®.

All dogs received a single oral tablet of either apoquel® chewable or apoquel® on Day 0. After a 14-day washout period, all dogs received a single oral tablet of the opposite drug from Day 0. Blood samples were collected at multiple timepoints after each dose, and oclacitinib plasma concentrations were analyzed for several PK parameters. No adverse reactions were reported.

The overall drug exposure and half-lives were similar for apoquel® chewable and apoquel®. apoquel® chewable met the criteria for bioequivalence for one PK parameter, $AUC_{0\text{-}t(last)}$, which is the area under the curve from time zero to the last sampling timepoint, but not for C_{max}, which is the maximum concentration. Therefore, the study did not demonstrate that apoquel® chewable is bioequivalent to apoquel®. However, because the upper bound of the 90% confidence interval (CI) for C_{max} was within the acceptable range and AUC met the criteria for bioequivalence, the study did provide a bridge for safety to apoquel®, and FDA did not require additional safety studies for apoquel® chewable. The Freedom of Information (FOI) Summary for the original approval of apoquel® (NADA 141-345), dated May 14, 2013, contains a summary of target animal safety studies for dogs.

When considering all the evidence, the data provide a bridge for effectiveness to apoquel®. Based on the above bioequivalence study, apoquel® chewable and apoquel® are bioequivalent for AUC, and most dogs are expected to have comparable maximum exposure to oclacitinib after the first dose of apoquel® chewable or apoquel®. Additionally, the PK data from the bioequivalence study were collected after a single dose, but under actual conditions of use, apoquel® chewable and apoquel® are intended to be given more than once. Using PK levels based on the labeled dosage regimen of repeated daily doses, after the first dose, both drugs are expected to have similar C_{max} at steady state. This information, combined with other clinical data regarding use of oclacitinib in dogs with allergic dermatitis or atopy, establishes the effectiveness of apoquel® chewable.

apoquel® chewable is available in 3.6, 5.4, and 16 mg strengths. The sponsor conducted comparative *in vitro* dissolution studies comparing the dissolution profiles of the 3.6 and 16 mg tablets to the dissolution profile of the 5.4 mg tablet. The 5.4 mg tablet was used as the comparator because it was evaluated in the *in vivo* bioequivalence study. The

dissolution profiles for the 3.6 and 5.4 mg tablets were similar in all dissolution media. The dissolution profiles for the 16 and 5.4 mg tablets were similar in all dissolution media, except the 16 mg tablet had a slower release in the pH 7.5 medium. Therefore, the results for the 5.4 mg tablet in the *in vivo* bioequivalence study can be inferred for the 3.6 and 16 mg tablets.

The sponsor also conducted a palatability study in client-owned dogs to evaluate how willingly the dogs consumed apoquel® chewable. Enrolled dogs had been diagnosed with allergic dermatitis or atopic dermatitis. The dogs consumed over 90% of their doses of apoquel® chewable within five minutes of the owner offering the tablet to the dog either from an empty bowl or by hand. Mild, drug-related gastrointestinal signs were reported in some dogs, but the signs resolved without treatment.

Conclusion
Based on the data submitted by the sponsor for the approval of apoquel® chewable, FDA determined that the drug is safe and effective when used according to the labeling.

Table of Contents

I. GENERAL INFORMATION

A. File Number

NADA 141-555

B. Sponsor

Zoetis Inc.
333 Portage St.
Kalamazoo, MI 49007

Drug Labeler Code: 054771

C. Proprietary Name

apoquel® chewable

D. Drug Product Established Name

oclacitinib chewable tablet

E. Pharmacological Category

Immunosuppressant

F. Dosage Form

Chewable tablet

G. Amount of Active Ingredient

3.6, 5.4, or 16 mg of oclacitinib as oclacitinib maleate per tablet.

H. How Supplied

apoquel® chewable tablets contain 3.6 mg, 5.4 mg, or 16 mg of oclacitinib as oclacitinib maleate per tablet. Each strength chewable tablets are packaged in 100 and 250 count bottles. Each chewable tablet is pentagon shaped, scored on both sides and has a dose descriptor (S S, M M or L L) debossed on one face across the score line. The S (small), M (medium) and L (large) markings correspond to the tablet strengths of 3.6 mg, 5.4 mg and 16 mg respectively.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The dose of apoquel® chewable (oclacitinib chewable tablet) is 0.18 to 0.27 mg oclacitinib/lb (0.4 to 0.6 mg oclacitinib/kg) body weight, administered orally, twice daily for up to 14 days, and then administered once daily for maintenance therapy.

K. Route of Administration

Oral

L. Species

Dogs

M. Indication

Control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

II. EFFECTIVENESS

A. Dosage Characterization

This approval does not change the previously approved dosage, as presented in the FOI Summary for the original approval of apoquel® (oclacitinib tablet); NADA 141-345, dated May 14, 2013.

B. Substantial Evidence

1. Bioequivalence Study

Title: Two-Way Cross-Over Bioequivalence Study Comparing apoquel® Tablets with Oclacitinib Chewable Tablets in Dogs. (Study No. A461N-US-21-B66)

Study Dates: May 17, 2021 to November 3, 2022

Study Location:
Concord, OH

Study Design:

Objective: To evaluate the bioequivalence of the approved apoquel® (oclacitinib tablet) film coated tablet (FCT; NADA 141-345) and apoquel® chewable in dogs following oral administration.

Study Animals: 42 male Beagle dogs were enrolled. The dogs ranged from 13 to 35 months of age and weighed 7.1 to 12.0 kg body weight.

Experimental Design: This study was conducted in accordance with Good Laboratory Practice (GLP) regulations. This study was a two-sequence, two-treatment, two-period crossover study with a 14-day washout between treatments.

The 42 dogs were randomized to two sequences in a ratio of 1:1 (21 dogs per sequence/group). All animals were assigned to pens completely at random.

After fasting overnight, each group of 21 dogs received a single oral 5.4 mg tablet of either oclacitinib FCT or apoquel® chewable on Study Day 0. Following a

14-day washout period, each group received a single oral 5.4 mg tablet of the opposite test article (oclacitinib FCT or apoquel® chewable) administered on Study Day 0.

Drug Administration: All tablets were administered followed by oral administration of water. For each dosing, the dogs received one oclacitinib FCT or apoquel® chewable tablet containing 5.4 mg of oclacitinib maleate.

Measurements and Observations: Clinical observations (cage-side) were made at least once in the morning and once in the afternoon, at least 4 hours apart, throughout the study. Body weights were measured on each day of dosing (Study Days 0 and 14). Blood samples were collected within 4 hours prior to dosing and at 0.33, 0.67, 1.0, 1.33, 1.67, 2, 2.5, 3, 6, 10, 24, and 32 hours post dose.

Pharmacokinetic (PK) Analysis: The oclacitinib plasma concentration data were analyzed using noncompartmental PK techniques in Watson LIMS (v 7.4.1 for windows, Thermo Fisher Scientific, Inc.) using nominal sampling times. Estimates of the PK variables maximum concentration (C_{max}), time to maximum concentration (t_{max}), area under the curve from zero to the last sampling time point [$AUC_{0\text{-}t(last)}$], area under the plasma concentration-time curve starting from time zero and extrapolated to infinity ($AUC_{0\text{-}\infty}$), and terminal elimination half-life ($t_{1/2}$) were made for each animal, individually, in each period. The AUC was determined via trapezoidal summation. The $AUC_{0\text{-}\infty}$ and $t_{1/2}$ were estimated using the slope (estimated using linear regression) of the terminal log-linear phase. The percent AUC extrapolation determined as $1\text{-}AUC_{0\text{-}t(last)}/AUC_{0\text{-}\infty} \times 100$ was calculated for each animal in each period.

Values below the lower limit of quantitation (LLOQ) were assumed to be zero when they occurred before the first observed value above the LLOQ. Values below the LLOQ were set to missing when they occurred between the first observed value above the LLOQ and before C_{max}. The first value below the LLOQ that occurred after C_{max}, and all subsequent values, irrespective of whether they were below the LLOQ or not, were set to missing.

Statistical Methods: To determine the means and confidence intervals (CIs) for the PK parameters $AUC_{0\text{-}t(last)}$, $AUC_{0\text{-}\infty}$, C_{max}, $t_{1/2}$, and t_{max}, a general linear mixed model was used. The AUC and C_{max} values were naturally log-transformed prior to analysis. The model included sequence, period, and treatment as fixed effects. The random effects included animal within sequence. Least squares (LS)/geometric means, minimums and maximums were reported for each PK parameter by treatment group. The geometric means and the associated CIs for AUCs and C_{max} were obtained by back-transforming the LS means and the associated CIs obtained from the analysis.

Using the $AUC_{0\text{-}t(last)}$ and C_{max} values, a comparison was made between apoquel® chewable and oclacitinib FCT. Each parameter was reported separately. The geometric mean ratio between treatment groups was determined as the back-transformed difference of the LS means.

Results: Summarized PK data are provided in Table II.1. Overall exposure was similar between the groups with mean $AUC_{0\text{-}t(last)}$ of 2420 and 2500 ng*h/mL for oclacitinib FCT and apoquel® chewable, respectively. The mean $t_{1/2}$ was also similar across groups with mean values of 5.28 and 5.70 hours for oclacitinib FCT and apoquel® chewable, respectively.

Table II.1. Summary of the Oclacitinib PK Parameters Estimates

Parameter	Treatment	No. dogs	Means*	Minimum	Maximum
$AUC_{0\text{-}t(last)}$ (ng*h/mL)	Oclacitinib FCT	42	2420	1050	4410
	apoquel® chewable	42	2500	1170	4560
$AUC_{0\text{-}\infty}$ (ng*h/mL)	Oclacitinib FCT	42	2470	1060	4760
	apoquel® chewable	42	2570	1180	5470
C_{max} (ng/mL)	Oclacitinib FCT	42	339	166	571
	apoquel® chewable	42	292	89.9	565
$t_{1/2}$ (h)	Oclacitinib FCT	42	5.28	2.90	9.34
	apoquel® chewable	42	5.70	3.05	15.0
t_{max} (h)	Oclacitinib FCT	42	1.2	0.33	2.5
	apoquel® chewable	42	1.5	0.67	2.5

*For AUCs and C_{max}, the geometric means are presented; for $t_{1/2}$ and t_{max}, the non- transformed LS means are presented.

Bioequivalence for oclacitinib was demonstrated if the 90% CI for the ratio of the apoquel® chewable and oclacitinib FCT for the $AUC_{0\text{-}t(last)}$ and C_{max} fell between 0.80 to 1.25. The $AUC_{0\text{-}t(last)}$ met the criteria for bioequivalence (90% CI for the geometric mean ratios being contained within 0.80 to 1.25). The lower bound of the 90% CI for C_{max} (0.78) was not contained within the 0.80 to 1.25 bioequivalence limits (Table II.2).

Table II.2. Assessment of Bioequivalence Between Single Oral 5.4 mg Doses of Oclacitinib FCT and apoquel® chewable

Parameter	Geometric Mean Ratio (apoquel® chewable/ Oclacitinib FCT)	90% CI	Passed Bioequivalence*
$AUC_{0\text{-}t(last)}$	1.03	0.98, 1.08	Yes
C_{max}	0.86	0.78, 0.95	No

*90% CI must be contained within 0.80 to 1.25 to pass bioequivalence.

Adverse Reactions: No adverse reactions were reported in this study.

Conclusions: Bioequivalence was demonstrated for the extent of exposure between oclacitinib FCT and apoquel® chewable with the geometric mean ratio for the $AUC_{0\text{-}t(last)}$ of 1.03 and the 90% CI within the acceptance range of 0.80 to 1.25. However, bioequivalence was not demonstrated for C_{max} between oclacitinib

FCT and apoquel® chewable because the lower bound of the 90% CI for C_{max} (0.78) was not within the acceptance range of 0.80 to 1.25. Because the extent of exposure and the upper bound of the 90% CI for C_{max} met the criteria for bioequivalence, the study provides a bridge to the safety studies conducted with oclacitinib FCT. Therefore, no additional safety studies were conducted.

2. Weight of Evidence to Support Effectiveness

Study No. A461N-US-21-B66 demonstrated bioequivalence for the extent of exposure between the apoquel® FCT formulation (NADA 141-345) and apoquel® chewable. However, the study did not demonstrate bioequivalence between the formulations for maximum exposure (C_{max}). When considering the results of study A461N-US-21-B66, simulations regarding repeated dosing in dogs, and the studies to support dosage characterization for the apoquel® FCT formulation, the combined information provides a bridge to the effectiveness studies conducted with the apoquel® FCT formulation and supports substantial evidence of effectiveness for apoquel® chewable.

In study A461N-US-21-B66, the exposure parameter that is typically considered the most relevant regarding drug effect (AUC) was found to be bioequivalent (BE) for the two formulations. However, C_{max} was not found to be BE, and the clinical relevance of AUC versus C_{max} for predicting clinical effect for oclacitinib in dogs with allergic dermatitis or atopic dermatitis, especially following the first dose, is unknown.

apoquel® chewable is not intended as a single dose product, and based on PK evidence, most dogs are expected to have comparable oclacitinib maximum exposure after the first dose following administration of apoquel® chewable or apoquel® (geometric mean ratio between the formulations was 0.86, but the lower bound of the 90% confidence interval missed the criterion for BE by a small margin). Based on simulations in accordance with the dosage regimen, administration twice daily for up to 14 days, and then once daily for maintenance therapy, the lack of BE for the lower bound of the 90% CI of C_{max} would impact only the first dose. No substantial differences in the C_{max} of apoquel® chewable and oclacitinib FCT are predicted at steady state. Therefore, starting with the second dose, exposure to oclacitinib following administration of apoquel® chewable is predicted to be comparable to the approved FCT formulation of apoquel®.

Finally, although the studies evaluated different formulations of oclacitinib, studies summarized in the dosage characterization for the original approval of NADA 141-345 indicate anti-pruritic effects, and effects on lesions caused by atopic dermatitis, in dogs administered oclacitinib at doses lower than the approved dose. Although this data does not support overall effectiveness at lower doses, it further supports that the recommended dosing regimen with apoquel® chewable will be effective despite the difference in C_{max} observed following a single dose of apoquel® chewable.

The FOI Summary for the original approval of NADA 141-345, dated May 14, 2013, contains a summary of studies that demonstrate the substantial evidence of effectiveness of apoquel® (oclacitinib tablet) for the control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs.

3. Comparative Dissolution Profiles

The *in vitro* dissolution profiles of the 3.6, 5.4, and 16 mg apoquel® chewable tablets were completed in 900 mL of 0.05 M acetate buffer, pH 4.5, quality control (QC) medium at 37°C with United States Pharmacopeial Convention (USP) Apparatus 2 at 50 rpm. Samples were analyzed using High Performance Liquid Chromatography (HPLC) methods. In addition, dissolution studies were conducted in other dissolution media, including pH 1.2, pH 7.5, and a pH 7.5 medium with 0.1% sodium lauryl sulfate (SLS), while the other dissolution conditions (e.g., Apparatus, rotation speed) were kept the same.

The 3.6, 5.4, and 16 mg apoquel® chewable tablets had mean oclacitinib release greater than 85% within 15 minutes in QC and pH 1.2 media. Similar dissolution profiles were shown between the 3.6 mg tablet and 5.4 mg (biobatch) in all dissolution media. For comparison between 16 mg tablet and 5.4 mg (biobatch), similar profiles were shown in all dissolution media, except for a slower release in pH 7.5 medium for the 16 mg tablet.

The results of the dissolution studies allow the results for the 5.4 mg apoquel® chewable tablet evaluated in the *in vivo* PK study (Study No. A461N-US-21-B66) to be inferred for safety and effectiveness considerations of the 3.6 and 16 mg tablets.

4. Palatability Study

Title: Oclacitinib Chewable Tablets Palatability Study in Client-Owned Dogs. (Study No. A163C-US-19-A40)

Study Dates: September 30, 2019 to September 20, 2020

Study Locations:
Bradenton, FL
Grand Rapids, MI
Johnston, IA
Gilbert, AZ
Albuquerque, AZ
Houston, TX
San Diego, CA
Zachary, LA
Springfield, MO
Baton Rouge, LA

Study Design:

Objective: To evaluate the palatability of three strengths of apoquel® chewable.

Study Animals: 121 client-owned dogs (pure and mixed breed; 68 males and 53 females) were enrolled. The dogs ranged from 1.0 to 14.0 years of age and weighed 3.7 to 60.7 kg body weight.

Experimental Design: The study was conducted in accordance with Good Clinical Practice (GCP) guidelines. Enrollment eligibility included dogs diagnosed with allergic dermatitis or atopic dermatitis and, per the examining veterinarian, were prescribed to receive apoquel® chewable twice daily to manage clinical signs.

Pregnant or lactating dogs were not eligible for enrollment. Dogs with a history of or current diagnosis of malignant neoplasia, dogs that were enrolled in any other clinical study, dogs that had received oclacitinib FCT within 7 days prior to Study Day 0, and dogs in which blood samples were unable to be collected at the Day 0 visit were excluded from enrollment.

Table II.3. Treatment Groups

Treatment	Dose	Dosage Regimen	Number of Palatability Assessments (Days)	Number of Dogs
apoquel® chewable	0.4-0.6 mg/kg	Twice daily for 7-14 days*	7	120

*7 days was the minimum dosing regimen. The Examining Veterinarian or designee could dispense up to 14 days of treatment.

Drug Administration: Owners administered apoquel® chewable at labeled doses twice daily on Study Days 0, 1, 2, 3, 4, 5, and 6. All treatments were administered using individual body weights collected on Study Day 0 to determine the dose administered to each dog. Owners assessed the palatability of apoquel® chewable after each administration.

Measurements and Observations: Palatability was assessed at each dose administration with the owners first offering the tablet(s) by placing it in the dog's empty food bowl or offering it by hand for five minutes. If not consumed, the owner offered the tablet(s) in food or they placed the tablet(s) in the back of the dog's mouth.

Results: 121 dogs were enrolled in the study over 10 sites. Of the 121 enrolled dogs, 120 were evaluated for palatability. One dog was removed from the palatability summary because the owner offered the tablet within a treat in the first five minutes. Of the remaining 120 dogs, out of a total number of 1662 administrations, 1522 (91.6%) were accepted voluntarily within five minutes, 134 (8.0%) were consumed with assistance (with food treats or by pilling) outside of the five minute offering time, and 6 (0.4%) doses were unable to be administered.

Table II.4. Summary of apoquel® chewable Acceptance

Tablet Acceptance Method	Percent of Doses
Free choice (hand or empty bowl)	91.6%
With food or placement in dog's mouth	8.0%
Tablet not accepted	0.4%

Adverse Reactions: Five dogs experienced seven adverse reactions during the study which included an accidental overdose (1), lethargy (1), and GI distress (flatulence (1), diarrhea (2) and vomiting (2)). No supportive therapy was administered, and all dogs returned to normal.

An accidental overdose occurred when an enrolled dog consumed 50 tablets at once. No adverse health event was reported immediately following consumption and follow up examination and bloodwork of the enrolled dog did not report any signs of acute toxicity.

Conclusion: Dogs consumed 91.6% of their doses within five minutes of offering from an empty bowl or owner's hand. Of the 8.4% of doses unconsumed after five minutes, 8.0% were administered with food or forced intake and 0.4% of doses were refused. Mild and self-limiting gastrointestinal signs are possible drug-related adverse reactions.

III. TARGET ANIMAL SAFETY

The safety of apoquel® chewable is supported by a pharmacokinetic study comparing apoquel® chewable to apoquel® (oclacitinib tablet) FCT (Study No. A461N-US-21-B66; summarized above under Effectiveness). Because the extent of exposure and the upper bound of the 90% CI for C_{max} met the criteria for bioequivalence, the study provided a bridge to the safety studies conducted with apoquel® FCT.

The FOI Summary for the original approval of NADA 141-345, dated May 14, 2013, contains a summary of studies that demonstrate the target animal safety of apoquel® (oclacitinib tablet) in dogs.

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 apoquel® chewable:

This product is not for human use. Keep this and all drugs out of reach of children. For use in dogs only. Wash hands immediately after handling the tablets. In case of accidental eye contact, flush immediately with water or saline for at least 15 minutes and then seek medical attention. In case of accidental ingestion, seek medical attention immediately.

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 apoquel® chewable, when used according to the label, is safe and effective for control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

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 rule out other diseases in the diagnosis of allergic and atopic dermatitis, and to monitor the safe use of the product, including treatment of any adverse reactions.

B. Exclusivity

apoquel® chewable, as approved in our approval letter, does not qualify for marketing exclusivity under section 512(c)(2)(F) of the FD&C Act.

C. Patent Information

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

VII. Appendix 1: Details of Correction

In the Measurements and Observations section for Study No. A461N-US-21-B66, the days of the body weight measurements were corrected from Study Days 0 and 7 to Study Days 0 and 14. The correction was made on July 21, 2023.

The original text for the Measurements and Observations section:

> Measurements and Observations: Clinical observations (cage-side) were made at least once in the morning and once in the afternoon, at least 4 hours apart, throughout the study. Body weights were measured on each day of dosing (Study Days 0 and 7). Blood samples were collected within 4 hours prior to dosing and at 0.33, 0.67, 1.0, 1.33, 1.67, 2, 2.5, 3, 6, 10, 24, and 32 hours post dose.

Corrected text for the Measurements and Observations section:

> Measurements and Observations: Clinical observations (cage-side) were made at least once in the morning and once in the afternoon, at least 4 hours apart, throughout the study. Body weights were measured on each day of dosing (Study Days 0 and 14). Blood samples were collected within 4 hours prior to dosing and at 0.33, 0.67, 1.0, 1.33, 1.67, 2, 2.5, 3, 6, 10, 24, and 32 hours post dose.

In the Experimental Design section for Study No. A163C-US-19-A40, the paragraph about dogs excluded from enrollment was corrected to state that dogs that had received oclacitinib FCT within 7 days prior to Study Day 0 were excluded from enrollment. The correction was made on July 21, 2023.

The original text for the Experimental Design section:

> Experimental Design: The study was conducted in accordance with Good Clinical Practice (GCP) guidelines. Enrollment eligibility included dogs diagnosed with allergic dermatitis or atopic dermatitis and, per the examining veterinarian, were prescribed to receive apoquel® chewable twice daily to manage clinical signs.
>
> Pregnant or lactating dogs were not eligible for enrollment. Dogs with a history of or current diagnosis of malignant neoplasia, dogs that were enrolled in any other clinical study, dogs that had received apoquel® chewable within 7 days prior to Study Day 0, and dogs in which blood samples were unable to be collected at the Day 0 visit were excluded from enrollment.
>
> **Table II.3. Treatment Groups**

Treatment	Dose	Dosage Regimen	Number of Palatability Assessments (Days)	Number of Dogs
apoquel® chewable	0.4-0.6 mg/kg	Twice daily for 7-14 days*	7	120

> *7 days was the minimum dosing regimen. The Examining Veterinarian or designee could dispense up to 14 days of treatment.

Corrected text for the Experimental Design section:

> Experimental Design: The study was conducted in accordance with Good Clinical Practice (GCP) guidelines. Enrollment eligibility included dogs diagnosed with allergic dermatitis or atopic dermatitis and, per the examining veterinarian, were prescribed to receive apoquel® chewable twice daily to manage clinical signs.
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> Pregnant or lactating dogs were not eligible for enrollment. Dogs with a history of or current diagnosis of malignant neoplasia, dogs that were enrolled in any other clinical study, dogs that had received oclacitinib FCT within 7 days prior to Study Day 0, and dogs in which blood samples were unable to be collected at the Day 0 visit were excluded from enrollment.
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