Date of Approval: October 20, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION (NADA)

NADA 141-612

convenia® RTU for Dogs

(cefovecin injectable suspension)

Dogs

convenia® RTU for Dogs is indicated for the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius* and *Streptococcus canis* (Group G).

Sponsored by:

Zoetis Inc.

Executive Summary

convenia® RTU for Dogs (cefovecin injectable suspension) is indicated for the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius* and *Streptococcus canis* (Group G). convenia® RTU for Dogs is a suspension formulation of convenia® (cefovecin sodium; NADA 141-285) with an increased concentration of 160 mg/mL compared to the original 80 mg/mL formulation, for use in dogs only.

Cefovecin sodium is a third-generation cephalosporin antibiotic that works by inhibiting bacterial cell wall synthesis. As a beta-lactam antibiotic, it binds to penicillin-binding proteins in bacterial cell walls, disrupting the cross-linking of peptidoglycan chains essential for cell wall integrity, ultimately leading to bacterial cell death. This mechanism makes it effective against the gram-positive bacteria commonly associated with canine skin infections. The approval pathway for convenia® RTU for Dogs utilized plasma bioequivalence to bridge to the established safety and effectiveness of the reference product, convenia®.

Safety and Effectiveness

The effectiveness and systemic safety of convenia® RTU for Dogs was established through a bioequivalence study. This masked, parallel-designed pharmacokinetic study used 32 male Beagle dogs aged 10 months to 3 years, weighing 7.2 to 11.5 kg, and was conducted under Good Laboratory Practice (GLP) regulations. The study compared convenia® RTU for Dogs to convenia® using a single subcutaneous injection at 8 mg/kg body weight, with blood samples collected at multiple time points over 28 days to measure plasma concentrations and calculate pharmacokinetic parameters.

The bioequivalence study successfully demonstrated that convenia® RTU for Dogs met the Food and Drug Administration’s (FDA's) bioequivalence criteria. The geometric mean ratio (convenia® RTU for Dogs / convenia®) for area under the curve from the time of dosing to the last quantifiable concentration (AUC_{last}) was 0.912 and for the maximum concentration (C_{max}) was 0.992. Because the 90% confidence intervals for both AUC_{last} and C_{max} were contained within 0.80 and 1.25, bioequivalence was established between convenia® RTU for Dogs and convenia®. Additionally, there were no clinically relevant injection site observations related to treatment with convenia® RTU for Dogs or convenia®.

In addition to establishing systemic safety through bioequivalence to convenia®, safety was evaluated through a dedicated injection site safety study. This study used 16 Beagle dogs (8 male and 8 female) aged 14 to 15 months and weighing 5.4 to 9.5 kg. This parallel-designed study compared convenia® RTU for Dogs to saline control, with animals receiving 2 subcutaneous injections 7 days apart followed by a 7-day observation period. The study found no convenia® RTU for Dogs-related mortalities, clinical observations, injection site observations, body weight changes, food consumption changes, or alterations in clinical pathology parameters. However, there was a notable difference in immediate behavioral response to injection administration, with the convenia® RTU for Dogs group showing increased responses that intensified with the second injection. Despite these immediate responses, no persistent injection

site reactions such as erythema, edema, pain, heat, or lesions were observed throughout the study period.

User Safety

convenia® RTU for Dogs is not for use in humans. Keep out of reach of children. Take care to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package insert or the labeling to the physician.

Avoid contact with the eyes. In case of accidental eye exposure, flush the eyes immediately with clean water. If wearing contact lenses, eyes should be rinsed first, then remove contact lenses and continue rinsing. If irritation persists, seek medical advice and show the package insert to the physician.

The product may cause sensitization by skin contact. People with known hypersensitivity to cefovecin/cephalosporins and penicillins should avoid exposure to this product. In case of accidental spillage onto skin, wash the skin immediately with soap and water.

Wash hands after use.

Conclusions

Based on the data submitted, the FDA concluded that convenia® RTU for Dogs is safe and effective when used as directed on the label.

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I. GENERAL INFORMATION

A. File Number

NADA 141-612

B. Sponsor

Zoetis Inc.
333 Portage St.
Kalamazoo, MI 49007

Drug Labeler Code: 054771

C. Proprietary Name

convenia® RTU for Dogs

D. Drug Product Established Name

cefovecin injectable suspension

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Injectable suspension

G. Amount of Active Ingredient

160 mg/mL

H. How Supplied

convenia® RTU for Dogs is available as a 10 mL multi-use vial containing 1,600 milligrams of cefovecin as a ready to use suspension.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

convenia® RTU for Dogs should be administered as a single subcutaneous injection of 3.6 mg/lb (8 mg/kg) body weight. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete.

K. Route of Administration

Subcutaneous injection

L. Species

Dogs

M. Indication

convenia® RTU for Dogs is indicated for the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius* and *Streptococcus canis* (Group G).

II. EFFECTIVENESS

A. Dosage Characterization

convenia® RTU for Dogs is a suspension formulation of convenia® (cefovecin sodium; NADA 141-285) with an increased concentration. It is for use in dogs only. The dosage regimen for convenia® RTU for Dogs is identical to the dosage regimen for convenia® in dogs. The FOI Summary for the original approval of NADA 141-285 dated April 25, 2008, contains dosage characterization information for dogs.

B. Substantial Evidence

Effectiveness of convenia® RTU for Dogs was established using a plasma bioequivalence approach, comparing convenia® RTU for Dogs to convenia®.

1. Bioequivalence Study

   Title: Bioequivalence of a Cefovecin Ready-To-Use Formulation Compared With Marketed convenia® in Beagle Dogs. (Study No. A461N-US-18-991)

   Study Dates: September 20, 2023 to October 11, 2024

   Study Location: Concord, OH

   Study Design:

   Objective: The study objective was to demonstrate cefovecin blood-level bioequivalence between the test article, convenia® RTU for Dogs, and the reference article, convenia®. Additionally, injection sites for all dogs were evaluated.

   Study Animals: Thirty-two male, Beagle dogs, 10 months to 3 years of age, and 7.2 to 11.5 kg body weight.

   Experimental Design: This study was conducted in accordance with GLP regulations. This study was a masked, parallel-designed pharmacokinetic (PK) study with subcutaneous (SC) dosing. Animals were randomized to cages and then randomized to receive convenia® (cefovecin sodium) or convenia® RTU for Dogs.

Table II.1. Treatment Groups for Study A461N-US-18-991

Treatment Group	Dogs per Group	Dose Level (mg/kg)	Nominal Dose Concentration (mg/mL)	Nominal Dose Volume (mL/kg)	Dose Route
convenia®	16	8	80	0.1	SC
convenia® RTU for Dogs	16	8	160	0.05	SC

Drug Administration: Each animal was administered either convenia® or convenia® RTU for Dogs as a single SC injection in the mid-scapular region at a dosage of 3.6 mg/lb (8 mg/kg) body weight.

Measurements and Observations: General health observations were conducted at least once in the morning and once in the afternoon, at least 4 hours apart. Injection site observations were conducted twice daily, at least 6 hours apart from Day 0 to Day 5, and once daily thereafter until study completion on Day 28. Blood samples were collected within 4 hours prior to dosing and at 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 24, 28, 72, 168 (Day 7), 240 (Day 10), 336 (Day 14), 505 (Day 21), and 672 (Day 28) hours post dose.

Plasma Concentration Data Analysis: The cefovecin plasma concentration (log transformed, ln) data were modeled using a general linear mixed model for repeated measures. The model included the fixed effects of treatment, time, and the interactions of treatment and time. The random effect was the animal. Back-transformed least-squares means (geometric means) and 90% confidence intervals, as well as median, arithmetic means, standard deviation, coefficient of variation, and minimums and maximums were reported for each treatment and sample time.

A general linear mixed model was used to determine means and confidence intervals for the PK parameters AUC_{last}, area under the plasma concentration-time curve from time zero and extrapolated to infinity ($AUC_{0-\infty}$), C_{max}, half-life ($t_{1/2}$), and time to maximum concentration (t_{max}). AUC and C_{max} values were natural logarithm transformed prior to analysis. The model included treatment as fixed effect. Least squares means (geometric means or back-transformed least squares means for transformed variables) and 90% confidence intervals as well as median, arithmetic means, standard deviation, coefficient of variation, and minimums and maximums were reported for each PK variable by treatment.

Bioequivalence Analysis: Values below the lower limit of quantification (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 recorded as missing. PK parameters were estimated using non-compartmental analysis.

A comparison was made between formulation convenia® relative to convenia® RTU for Dogs for both AUC_{last} and C_{max}. Each variable was reported separately. The

ratio between treatment groups was determined as the back-transformed difference of least squares means of convenia® RTU for Dogs / convenia®. The back-transformed 90% confidence intervals associated with the ratios were also reported. The 90% confidence intervals were compared to the standard bioequivalence limits of 0.80 to 1.25. To conclude bioequivalence, the back-transformed 90% confidence interval must fall entirely within the 0.80 to 1.25 limits for both AUC_{last} and C_{max}.

Results: The PK parameters are summarized in Table II.2.

Table II.2. Summary of Cefovecin PK Parameter Estimates Following a Single 8 mg/kg SC Dose of Either convenia® or convenia® RTU for Dogs

Parameter and Treatment	n	Means†	90% Confidence Interval Lower Bound†	90% Confidence Interval Upper Bound†	Minimum	Maximum
convenia® RTU for Dogs AUC_{last} (h*µg/mL)	16	10800	10000	11600	7530	14000
convenia® AUC_{last} (h*µg/mL)	16	11800	11200	12500	9830	14600
convenia® RTU for Dogs $AUC_{0-\infty}$ (h*µg/mL)	16	11100	10300	11900	7610	14700
convenia® $AUC_{0-\infty}$ (h*µg/mL)	16	12200	11500	13000	10100	15300
convenia® RTU for Dogs C_{max} (µg/mL)	16	88.4	85.3	91.5	79.5	103
convenia® C_{max} (µg/mL)	16	89.1	86.3	91.9	79.6	99.9
convenia® RTU for Dogs $t_{1/2}$ (h)	16	135	128	141	109	169
convenia® $t_{1/2}$ (h)	16	139	133	145	113	162

Parameter and Treatment	n	Means†	90% Confidence Interval Lower Bound†	90% Confidence Interval Upper Bound†	Minimum	Maximum
convenia® RTU for Dogs t_{max} (h)	16	2.5	NA	NA	1.5	3
convenia® t_{max} (h)	16	1.5	NA	NA	1	4

† For AUCs, C_{max}, and $t_{½}$, the geometric means and the associated unadjusted confidence interval are presented; for t_{max} the median and associated minimum and maximum values are presented.

Bioequivalence for cefovecin was demonstrated because the 90% confidence interval for the geometric mean ratio of AUC_{last} and C_{max} comparing convenia® RTU for Dogs and convenia® was contained between 0.80 and 1.25 (Table II.3).

Table II.3. Assessment of Bioequivalence Between Single SC Injection 8 mg/kg Doses of convenia® and convenia® RTU for Dogs

Parameter	Geometric Mean Ratio (convenia® RTU for Dogs/convenia®)	90% Confidence Interval Lower Bound	90% Confidence Interval Upper Bound
AUC_{last} (µg*h/mL)	0.912	0.836	0.995
C_{max} (µg/mL)	0.992	0.948	1.04

Adverse Reactions: Soft, mucoid, or liquid feces were noted more frequently in the group treated with convenia® RTU for Dogs. See Table II.4.

Table II.4. Instances of Soft, Mucoid or Liquid Feces

	convenia®	convenia® RTU for Dogs
Total number of dogs affected*	6	17
Total number of days abnormal feces noted	10	28

* Some dogs had more than one type of abnormal feces, i.e. an instance of soft stool and later an instance of mucoid stool and are therefore listed more than once.

Conclusions: The geometric mean ratio (convenia® RTU for Dogs / convenia®) for AUC_{last} was 0.912 and for C_{max} was 0.992. Because the 90% confidence intervals for both AUC_{last} and C_{max} were contained within 0.80 and 1.25, bioequivalence was established between convenia® RTU for Dogs and convenia®. Additionally, there were no clinically relevant injection site observations related to treatment with convenia® RTU for Dogs or convenia®.

III. TARGET ANIMAL SAFETY

The safety of convenia® RTU for Dogs was, in part, established by demonstrating bioequivalence compared to convenia® (cefovecin sodium; NADA 141-285); see section II.B. The FOI Summary for the original approval of NADA 141-285 dated April 25, 2008, contains a summary of studies that demonstrate the target animal safety of convenia® (cefovecin sodium) in dogs.

The safety of convenia® RTU for Dogs is also supported by an injection site safety study (Study No. A365N-US-23-D64; summarized below).

A. Injection Site Safety Study

Title: A Two-Dose Subcutaneous Injection Study of Cefovecin RTU (7 Days Apart) Followed By a 7-Day Observation Period in Beagle Dogs. (Study No. A365N-US-23-D64)

Study Dates: October 4, 2023 to November 10, 2024

Study Location: Mattawan, MI

Study Design:

Objective: To evaluate the injection site observations of a ready to use (RTU) suspension of cefovecin sodium at 160 mg/mL when administered twice (7 days apart) by SC injection to adult Beagle dogs, followed by a 7-day observation period.

Study Animals: Sixteen Beagle dogs (8 male and 8 female), 14 to 15 months of age, and 5.4 to 9.5 kg body weight.

Experimental Design: This study was conducted in accordance with GLP regulations. This study was a parallel-design injection site safety study with SC dosing. Animals were randomly enrolled into either the saline or convenia® RTU for Dogs treatment group.

Table III.1. Treatment Groups for Study A365N-US-23-D64

Treatment Group	Dogs per Group	Dose[a] (mg/kg)	Nominal Dose Concentration (mg/mL)	Nominal Dose Volume[b] (mL/kg)	Dose Route
Saline	8	0	0	0.05	Subcutaneous
convenia® RTU for Dogs	8	8	160	0.05	Subcutaneous

[a] Dosed on Days 1 and 8
[b] Based on most recent body weight measurement

Drug Administration: Each animal was administered either Saline (0.9% Sodium Chloride for Injection) or convenia® RTU for Dogs as a SC injection in the mid-scapular region on Days 1 and 8 followed by a 7-day observation period.

Measurements and Observations: General health observations were conducted at least once in the morning and once in the afternoon, at least 4 hours apart. Clinical observations were performed once daily beginning on Day -22 and then twice daily throughout the dosing period. Injection site observations were conducted twice prior to initiation of dosing on Days -3 and -1; pre-dose, 0, 0.5, 2, 4, 8, and 24 hours post-dose on Day 1 and Day 8; twice daily on non-dosing days at least 6 hours apart; and once prior to study completion on Day 15. Body weights were measured at receipt, weekly during the acclimation period, and on Days -1, 7, and 15. Food consumption was measured daily. Clinical pathology parameters (hematology, coagulation, and clinical chemistry) evaluations were conducted on all animals on Day -7, pre-dose on Days 1 and 8, and Day 15.

In addition, at the time of dosing, the behavioral response of each dog to the injection was documented by the individual administering the dose using the following scale:

Table III.2. Dose Response Observations for Study A365N-US-23-D64

Assessment	**Behavior**
Normal Response	Dog was aware of injection but did not protest
Moderate Response	Dog had minor vocalization or wincing and quick resolution
Severe Response	Dog had marked vocalization or tried to bite or jumped or persistent attention to the injection site (e.g., scratching)

Results: Summarized dosing response data are provided in Table III.3. The control group remained largely unaffected at the time of dose administration. The convenia® RTU for Dogs group showed increased response to dose administration, especially on Day 8. Dosing responses were considered convenia® RTU for Dogs related; however, there were no indications of pain or other findings post injection (erythema, edema, heat, lesion) during the study.

Table III.3. Summary of Dosing Response Following Injection of Either Saline or convenia® RTU for Dogs

Treatment	Gender	Observation Day 1	Observation Day 8
Saline	Male	Normal	Normal
Saline	Male	Normal	Normal
Saline	Male	Normal	Normal
Saline	Male	Normal	Normal
Saline	Female	Normal	Normal
Saline	Female	Normal	Normal
Saline	Female	Normal	Normal
Saline	Female	Normal	Moderate
convenia® RTU for Dogs	Male	Severe	Severe
convenia® RTU for Dogs	Male	Normal	Severe
convenia® RTU for Dogs	Male	Normal	Moderate
convenia® RTU for Dogs	Male	Normal	Normal
convenia® RTU for Dogs	Female	Normal	Moderate
convenia® RTU for Dogs	Female	Moderate	Normal
convenia® RTU for Dogs	Female	Normal	Severe
convenia® RTU for Dogs	Female	Normal	Severe

Adverse Reactions: There were no convenia® RTU for Dogs-related general health observations, clinical observations, injection site observations, body weight changes, food consumption changes, veterinary physical examination findings, or alterations in clinical pathology parameters noted during the study.

Conclusions: The study demonstrated that convenia® RTU for Dogs, when administered to dogs twice, 7 days apart, at a dose of 8 mg/kg, was well tolerated. However, there was a notable difference in response to dose administration, with the convenia® RTU for Dogs group having more moderate and severe responses to injection compared to the control. No convenia® RTU for Dogs-related injection site observations (erythema, edema, pain, heat, lesion) were noted during the study.

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, FDA 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 convenia® RTU for Dogs:

WARNINGS: Not for use in humans. Keep out of reach of children.

Take care to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package insert or the labeling to the physician.

Avoid contact with the eyes. In case of accidental eye exposure, flush the eyes

immediately with clean water. If wearing contact lenses, eyes should be rinsed first, then remove contact lenses and continue rinsing. If irritation persists, seek medical advice and show the package insert to the physician.

The product may cause sensitization by skin contact. People with known hypersensitivity to cefovecin/cephalosporins and penicillins should avoid exposure to this product. In case of accidental spillage onto skin, wash the skin immediately with soap and water.

Wash hands after use.

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 convenia® RTU for Dogs, 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 administer the injection, provide adequate instructions for post treatment care, or to monitor the safe use of the product, including treatment of any adverse reactions.

B. Exclusivity

convenia® RTU for Dogs, as approved in our approval letter, qualifies for THREE years of marketing exclusivity beginning as of the date of our approval letter. This drug qualifies for exclusivity under section 512(c)(2)(F)(ii) of the FD&C Act because the sponsor submitted an original NADA that contains new studies that demonstrate the effectiveness and safety of convenia® RTU for Dogs.

C. Patent Information

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