

#237

Guidance for Industry

Oncology Drugs for Companion Animals

DRAFT GUIDANCE

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For questions regarding this document, contact [Dr. Christopher Loss](#), Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240-402-0619, e-mail: christopher.loss@fda.hhs.gov.

Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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Guidance for Industry

Oncology Drugs for Companion Animals

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document makes recommendations to sponsors of investigational oncology drugs for use in companion animals (e.g., dogs, cats, and horses). The guidance discusses the contents of the target animal safety, effectiveness, and labeling technical sections of a new animal drug application (NADA) for oncology drugs administered as single agents. This guidance also includes recommendations on how to address human user safety concerns. For multi-drug regimens, we recommend that you contact the Center for Veterinary Medicine (CVM) to discuss your product development plan.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

You may follow the guidance document or may choose alternate pathways for approval. We recommend that you discuss your proposed study plans with CVM, especially if you choose to use an alternative pathway for approval. We encourage you to schedule a presubmission conference with CVM as you begin to make your investigational plans to ensure that you are completely informed on the requirements contained in the statute and regulations.

II. EFFECTIVENESS

A. Dosage Characterization

Dosage characterization includes information on the dose or dose range, route of administration, dosing interval, dosing duration, and evidence that the proposed dosage has an effect on the tumor type in the target species. Dosage characterization is submitted in the Effectiveness technical section and is included in the Freedom of Information (FOI) Summary.

For drugs administered based on body surface area (mg/m^2), dose exposure may need to be considered separately for smaller animals (e.g., ≤ 10 kg) based upon the drug product and pharmacokinetic profile. Smaller animals may have higher drug exposure compared to larger animals when dosed using body surface area. It is

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acceptable to have separate dosing tables using mg/m² dosing for larger animals and mg/kg dosing for smaller animals.

There are multiple ways for a sponsor to support dosage characterization including, but not limited to:

1. Dose escalation studies

Dose escalation studies may be performed to determine the maximum tolerated dose (MTD). With chemotherapy, achieving the MTD is often the goal during therapy. These studies may be performed in the clinical setting with target species experiencing naturally occurring tumors, or in laboratory studies in the target species.

2. Pilot field studies

Pilot field studies in the target species may help determine the appropriate dosage and the safety profile. Pilot field studies may also be conducted to determine which tumor types are responsive to the drug.

3. Foreign field studies

Results from field studies conducted outside the United States (US), i.e., foreign field studies, can provide evidence that the proposed dosage has an effect in the target population.

4. Pharmacokinetic studies

Pharmacokinetic studies may be performed to determine the frequency of dosing. For oral dosage forms, pharmacokinetic studies may be performed to determine the bioavailability under fed and fasted conditions.

5. Scientific literature

Scientific literature may support dosage characterization.

B. Field Effectiveness Study

The purpose of a field study is to evaluate the safety and effectiveness of the oncology drug in the target animal for the proposed indication(s) under the actual conditions of use. Field studies, whether conducted in the US or in other countries, should use the same concomitant medications and standard of veterinary practice as in the US, according to an established protocol.

The following are considerations for the design and conduct of the field effectiveness study:

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1. Endpoints

For all of the endpoints, a clinically relevant difference between the treated and comparator group should be defined prior to study conduct.

Many endpoints evaluate progression of the tumor. Response Evaluation Criteria in Solid Tumors (RECIST)¹ and World Health Organization (WHO) criteria² both describe criteria to evaluate disease progression. The following endpoints are based on RECIST and WHO criteria. Modifications to these criteria may be proposed, or an alternative method of assessment may be proposed.

a. Overall survival (OS)

In field studies, OS is defined as the time from randomization to death. This endpoint is unambiguous and is not subject to investigator interpretation. When using OS as an endpoint, the study design and effectiveness analysis should take into account subsequent cancer therapies and euthanasia.

b. Time to tumor progression (TTP) and Progression free survival (PFS)

In field studies, TTP is defined as the time from randomization to time of progressive disease. PFS is defined as the time from randomization to objective tumor progression or death (including euthanasia).

The study protocol should include a detailed definition of disease progression because determining progression is a subjective assessment. The protocol should define, prior to study conduct, the specific time points when TTP or PFS are evaluated. Evaluations should assess likely disease sites (i.e., primary tumor, secondary tumors, and metastatic sites). The same assessment technique should be used at each follow-up and the same evaluation schedule should be consistently used for all enrolled patients. It is important that the TTP be documented close to the actual occurrence of the event. Therefore, the frequency of evaluation of these endpoints should take into consideration the expected timing and rate of progression of the tumor. The sponsor should prospectively define when to assign progression and the

¹ Eisenhauer EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1). *Eur J Cancer*, 2009; 45: 228-247.

² Park JO, Lee SI, Song SY, et al. Measuring Response in Solid Tumors: Comparison of RECIST and WHO Response Criteria. *Jap J Clin Oncol*, 2003; 33(10): 533-7.

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protocol should clearly state the method used to assign the date of progression. The method used will depend on tumor type and the expected rate of tumor progression.

An animal may be lost to follow up before progression or death is observed. In this case, the data point (TTP or PFS) is right-censored³ because it is known to be above a certain value but by an unknown amount. The protocol should specify the conditions for right-censoring. Examples include owner decision to withdraw from the study, adverse event that warrants cessation of therapy, and, for TTP, death unrelated to disease or treatment. In most cases, the right-censored value is the last complete scheduled assessment which documented lack of progression.

c. Progression free survival rate (PFS rate)

PFS rate is defined as the proportion of patients that are alive and progression-free at a specified time point. Methods for assessment are similar to TTP and PFS. The expected rate of tumor progression should be considered when selecting the time point for evaluating the PFS rate.

d. Objective response rate (ORR)

Objective response is defined as the sum of partial responses (PRs) and complete responses (CRs). ORR is the proportion of patients with an objective response at a specified time point. The time point when the ORR assessment is performed should represent a clinically relevant duration of response. RECIST is a common method used for assessing ORR.

e. Other

Other endpoints may be considered on a case-by-case basis.

2. Treatment groups

Studies supporting substantial evidence of effectiveness should be well-controlled, utilizing an active control, placebo control, untreated control, or historical control. Refer to 21 CFR 514.117(b)(4) for more information.

³ Right censored - A data point is right censored if it is known that it is above a certain value but by an unknown amount. For example, the overall survival for a subject that is known to be alive up to a certain time point but lost to follow up after that has an observation that is right censored at the time point.

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The ratio of patients receiving the investigational drug versus the control should be considered when designing the study. For example, cancers with low incidences of spontaneous partial responses may allow for fewer patients in a placebo control group compared to the group treated with the investigational drug.

The study should be masked appropriately to control potential bias, taking into consideration different observable drug effects and routes of administration of the investigational drug and the control group.

3. Inclusion/Exclusion criteria

The patient population enrolled in the study affects the indication and labeling language. Therefore, you should consider the following when choosing the patient population for enrollment:

- Previous and concurrent treatments (e.g., use of corticosteroids, other chemotherapy, surgery, radiation)
- Metastases
- Tumor stages or grades
- Tumor locations

4. Patient assessments

The study protocol should define intervals for assessment of patients. All anatomical sites of possible disease occurrence should be assessed to determine if progression has occurred. For PFS and TTP, it is essential to accurately capture progression, therefore monitoring may need to occur more frequently than traditionally conducted in clinical practice.

Additional safety assessments may be necessary for particular drug classes to monitor for specific target organ effects. For example, a dog treated with an anthracycline drug may need echocardiograms to monitor for cardiotoxicity.

5. Statistical Considerations

The study should enroll a sufficient number of subjects to adequately power the primary statistical test, taking into account subject attrition, censoring, and other factors that can affect the efficiency of the tests. The study should be powered to detect a clinically relevant effect size. Appropriate stratification factors should be considered; for example, tumor grade, tumor location, or mutation type. Agreement with CVM is recommended prior to study conduct regarding the difference in treatment groups that would be considered clinically relevant.

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6. Dose reductions, delays, and interruptions

Dose reductions, delays, and interruptions may be used to manage adverse reactions. If dose reductions, delays, and interruptions are part of the dosing schedule, they should be pre-defined in the protocol so that all investigators use them consistently. Effectiveness and safety of the reduced dose should be demonstrated in the field study.

For products that are eligible for conditional approval⁴, the dose reductions, delays, or interruptions should be justified in the reasonable expectation of effectiveness technical section.

7. Adverse Events (AE)

The most current Veterinary Co-operative Oncology Group-Common Terminology Criteria for Adverse Events (VCOG-CTCAE)⁵ for grading AEs should be used in the clinical field study. This system supplies descriptive terminology and a severity scale for each AE term. Grading AEs in this manner will allow for uniform description of AEs across oncology drugs. Adverse events not covered under VCOG-CTCAE should be captured utilizing other appropriate methods.

8. Standard of Care Treatments

The effectiveness of an investigational new animal drug may be evaluated in conjunction with standard of care. Standard of care can include, but is not limited to, surgery, radiation, or other chemotherapeutics. Standard of care should be justified through use of literature or other means. We recommend you contact CVM prior to conduct of the study to discuss study design options that include standard of care interventions.

9. Informed Consent

The informed consent should include language that conveys the safety risks to the patient, to other animals in the household, and conveys human user safety risks to the owner. The information should include instructions for safe handling of the drug, if applicable, and instructions for safe

⁴ Applications for conditional approval allow a drug sponsor to legally market a new animal drug intended for a minor use or a minor species after proving it is safe under 21 U.S.C. § 360b(d), but before collecting all the necessary effectiveness data. The drug sponsor can keep the product on the market for up to five years, while collecting effectiveness data required by 21 U.S.C. § 360b(d), if FDA approves the sponsor's annual renewal requests.

⁵ Veterinary Co-operative Oncology Group. Veterinary Co-operative Oncology Group - Common Terminology Criteria for Adverse Events (VCOG-CTCAE) following chemotherapy or biological antineoplastic therapy in dogs and cats v1.0. *Vet Comp Oncol*, 2004 Dec; 2(4): 195-213.

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disposal of urine, feces, and vomit from the animal to minimize potential drug or active metabolite exposure to the owner.

C. Reasonable Expectation of Effectiveness

The Reasonable Expectation of Effectiveness technical section replaces the Effectiveness technical section when a sponsor is pursuing conditional approval. The drug must be determined by CVM to be a minor use in a major species (e.g., cat, dog, or horse) or be intended for use in a minor species.

We recommend you contact CVM early in your development plan regarding the approach to demonstrate reasonable expectation of effectiveness. Demonstration of reasonable expectation of effectiveness may include pilot studies, literature, and other sources. The information to support reasonable expectation of effectiveness may also include safety information in the target population.

III. TARGET ANIMAL SAFETY

The purpose of the target animal safety (TAS) study is to identify the margin of safety and provide veterinarians with information regarding the safe use of the drug.⁶ Safety studies conducted in the laboratory should be carried out in compliance with FDA's good laboratory practices (GLP) regulations (21 CFR Part 58).

A. Multiple Levels of Exposure

For oncology drugs with a low margin of safety, modifications of the dose levels administered to the animals in the TAS study may be necessary to avoid unnecessary toxicity or death. The highest recommended (1X) dose should be evaluated in addition to two other dose levels above 1X, if possible. For drugs administered at the MTD, it may not be possible to evaluate doses above 1X.

If dose reductions will be used to manage toxicity, the reduced dose should be included in the TAS study as a multiple of the 1X dose (e.g., 0.8X dose). The reduced dose should demonstrate lower toxicity than the 1X dose to justify its use in managing toxicity.

B. Duration

Refer to [Guidance for Industry #185/VICH GL43, "Target Animal Safety for Veterinary Pharmaceutical Products,"](#) Section 2.4, entitled Dose, Frequency, and Duration of Administration. If a drug has a low margin of safety, a modification of the dosing interval and/or duration may be necessary, including temporary drug interruptions. A cumulative toxicity, such as cardiac toxicity with anthracyclines,

⁶ See [Guidance for Industry #185/VICH GL43, "Target Animal Safety for Veterinary Pharmaceutical Products,"](#) for more details.

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is also an example of when the duration of the target animal safety study may be modified. We recommend that you contact CVM prior to study conduct to discuss your specific drug and dosing schedule.

C. Evaluation of Toxicity

The study should be designed to capture the drug effects at the time points of maximum exposure and/or maximum toxicity. For example, drugs that cause hematopoietic toxicity should have a complete blood count at the time of the white blood cell nadir.

Toxicity should be graded using an appropriate system such as the VCOG-CTCAE. Collection of pharmacokinetic data during the study may be valuable in helping identify potential associations between drug blood levels and toxicity.

IV. HUMAN USER SAFETY

Human user safety covers human exposures resulting from actual conditions of use, and it is part of the Target Animal Safety technical section. Human user safety concerns should be addressed, including potential exposure to the drug and the active metabolites by: veterinary personnel, people handling the drug, and people in contact with the animal (including exposure to the patient's urine, feces, vomit, and saliva). Informed consent for the field studies is important to ensure that owners understand the risks of potential exposure to the drug and metabolites to people and animals that may come in contact with the patient. Veterinarians and technicians handling oncology drugs should refer to Occupational Safety & Health Administration (OSHA)⁷ for appropriate guidelines, recommendations, and regulations for handling antineoplastic agents.

Investigational and approved drug labeling and the client information sheet should address human user safety concerns. A client information sheet should be part of labeling for all oncology drugs. The client information sheet should be provided to the owner when the approved product is prescribed and also during the conduct of the field studies. See Appendix 1 for recommendations for drug labeling specific to oncology drugs including the client information sheet.

V. APPENDIX 1 - Recommendations for Drug Labeling

A. Package Insert

The package insert may include certain labeling information unique to oncology drugs, if applicable.

The Dosage and Administration section should include information on dosage reductions, delays, or interruptions used to manage adverse reactions.

⁷ <http://www.osha.gov/SLTC/hazardousdrugs/index.html>

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The Warnings section should contain additional information on human user safety when there is evidence of an association of a serious hazard with the drug. Warning statements should also refer to accidental exposure. Examples of statements could include:

- Recommendations for seeking professional medical help, and general treatment procedures
- Information for physicians on specific treatment procedures for potential exposure
- Specific first aid measures that can be undertaken to reduce potential harm (e.g., washing hands or eyes, inducing vomiting, wearing gloves, etc.)

B. Client Information Sheet

The following are examples of formats that may be used and they may be modified based on the characteristics of each drug. The client information sheet should use lay-terms or provide definitions for medical or scientific terms.

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For Oral Dosage Forms

Client Information Sheet
PROPRIETARY NAME (established name)

The Client Information Sheet contains important information about PROPRIETARY NAME. You should read this information before you start giving PROPRIETARY NAME to your pet and review it each time the prescription is refilled as there may be new information. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk with your veterinarian if you do not understand any of this information or if you want to know more about PROPRIETARY NAME.

For conditional approvals only:

PROPRIETARY NAME is conditionally approved by the FDA, and full demonstration of effectiveness (how well the drug works) is dependent on completion of a clinical trial. The use of conditionally approved new animal drugs is limited to a specific use, which can be found on the package insert. Additional information on drugs conditionally approved under section 571 can be found by searching <http://www.fda.gov> for “conditional approval.”

What is PROPRIETARY NAME?

- PROPRIETARY NAME is a *<drug class or mechanism of action>* used to treat *<indication>*, a form of cancer that affects *<dogs/cats>*.

What should I tell my veterinarian about my pet before he/she receives PROPRIETARY NAME?

- Tell your veterinarian about other medications your pet is taking, including prescription drugs, over the counter medications, heartworm preventatives, flea and tick medications, and vitamins and supplements, including herbal medications.
- Tell your veterinarian about your pet’s previous or current medical conditions.
- Tell your veterinarian if your pet is pregnant, nursing, or you intend to breed him/her.

How do I give PROPRIETARY NAME to my pet?

- PROPRIETARY NAME should be given to your pet by mouth (orally).
- PROPRIETARY NAME *<may/may not>* be hidden inside a treat; be certain that your pet swallows the entire *<tablet/capsule>*.
- Follow your veterinarian’s instructions for how much and how often to give PROPRIETARY NAME.

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Client Information Sheet
PROPRIETARY NAME (established name)

**Comment on missed doses if appropriate, e.g., “If a dose is missed, the next scheduled dose should be given as prescribed. Do not increase or double the dose.”*

See the **Handling Instructions** section below for directions on how to administer PROPRIETARY NAME safely to your pet.

How will PROPRIETARY NAME affect my pet?

- PROPRIETARY NAME is intended to treat your pet’s cancer. As with other cancer treatments, your veterinarian cannot predict whether your pet’s cancer will respond to PROPRIETARY NAME.
- Regular check-ups by your veterinarian are necessary to determine whether your pet is responding as expected, and to decide whether your pet should continue to receive PROPRIETARY NAME.

What are some of the possible side effects of PROPRIETARY NAME?

- Like all drugs, PROPRIETARY NAME may cause side effects, even at the prescribed dose. Serious side effects can occur, with or without warning, and may in some situations result in death.
- The most common side effects which may occur with PROPRIETARY NAME include: *<list adverse reactions here>*.
- Other side effects may occur. For more information about side effects ask your veterinarian.

Stop PROPRIETARY NAME immediately and contact your veterinarian if you notice any of the following changes in your pet:

- *<List items here>*

Handling Instructions:

Because PROPRIETARY NAME is an anti-cancer (chemotherapy) drug, extra care must be taken when handling the *<tablets/capsules>*, giving the drug to your pet, and cleaning up after your pet.

- PROPRIETARY NAME is not for use in humans.
- You should keep PROPRIETARY NAME in a secure storage area out of the reach of children and pets. Do not store near food or with your medications.

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Client Information Sheet
PROPRIETARY NAME (established name)

- Do not come in direct contact with PROPRIETARY NAME.
- If you are pregnant, a nursing mother, or may become pregnant and you choose to administer PROPRIETARY NAME to your pet, you should be particularly careful and follow the handling procedures described below.

**Provide a cautionary comment for men if this product or products in its class can affect male fertility.*

- PROPRIETARY NAME may harm an unborn baby (cause birth defects). For pregnant and nursing women, accidental ingestion of PROPRIETARY NAME may have adverse effects on pregnancy or the nursing baby.
- **If PROPRIETARY NAME is accidentally ingested, seek medical advice immediately. It is important to show the treating physician a copy of the package insert, label, or client information sheet.**

The following handling procedures will help to minimize exposure to the active ingredient in PROPRIETARY NAME for you and other members of your household:

- Anyone in your household who gives PROPRIETARY NAME to your pet should wear disposable chemotherapy-approved gloves and wash their hands after handling <tablets/capsules>. Check with your veterinarian to ensure you have the appropriate gloves.
- Minimize the number of people handling PROPRIETARY NAME.
- When handling the tablets:
 - ✓ Do not split or break the <tablets/capsules> to avoid disrupting the protective film coating.
 - ✓ PROPRIETARY NAME should be administered to your pet immediately after removal from the bottle.
 - ✓ Protective disposable chemotherapy-approved gloves should be worn if handling broken or moistened tablets. If your pet spits out the PROPRIETARY NAME <tablets/capsules>, the <tablets/capsules> will be moistened and should be handled with protective gloves.

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Client Information Sheet
PROPRIETARY NAME (established name)

- ✓ If the PROPRIETARY NAME <tablets/capsules> is “hidden” in food make sure that your pet eats the entire dose to minimize the potential for exposure to other household members.
- Return any unused PROPRIETARY NAME to your veterinarian.

Because PROPRIETARY NAME is an anti-cancer drug, extra care must be taken when handling and cleaning up after your pet during treatment and for X days after the last treatment.

The following handling procedures will help minimize exposure to the active ingredient in PROPRIETARY NAME for you and members of your household.

- Cleaning up after your pet:
 - ✓ Avoid direct contact with urine, stool, vomit, and saliva during treatment and for **X days** after the last treatment with PROPRIETARY NAME.
 - ✓ When cleaning up urine, stool, vomit or saliva, you should wear disposable chemotherapy-approved gloves and collect the contaminated material with disposable absorbent material (such as paper towels) and place them into a plastic bag. Carefully remove the gloves and place them in the bag and tie or fasten it securely for general household disposal. Wash your hands thoroughly afterwards.
 - ✓ You should not wash any items soiled with urine, stool, vomit, or saliva from your pet with other laundry.
 - ✓ Do not let your pet urinate or defecate in areas where people may come in direct contact with the urine or stool.
- Because PROPRIETARY NAME may be present in the pet’s saliva during treatment and for **X days** after the last treatment, take precautions in handling the dog’s toys.

This client information sheet contains a summary of important information about PROPRIETARY NAME. For more detailed information about PROPRIETARY NAME, talk with your veterinarian.

To report a suspected adverse reaction (side effect) call xxx-xxx-xxxx. For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

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For Injectable Dosage Forms

Client Information Sheet
PROPRIETARY NAME (established name)

The Client Information Sheet contains important information about PROPRIETARY NAME. You should read this information before your pet receives PROPRIETARY NAME and review it each time your pet receives treatment as there may be new information. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk with your veterinarian if you do not understand any of this information or if you want to know more about PROPRIETARY NAME.

For conditional approvals only:

PROPRIETARY NAME is conditionally approved by the FDA, and full demonstration of effectiveness (how well the drug works) is dependent on completion of a clinical trial. The use of conditionally approved new animal drugs is limited to a specific use, which can be found on the package insert. Additional information on drugs conditionally approved under section 571 can be found by searching <http://www.fda.gov> for “conditional approval.”

What is PROPRIETARY NAME?

- PROPRIETARY NAME is a *<drug class or mechanism of action>* used to treat *<indication>*, a form of cancer that affects *<dogs/cats>*.

What should I tell my veterinarian about my pet before he/she receives PROPRIETARY NAME?

- Tell your veterinarian about other medications your pet is taking, including prescription drugs, over the counter medications, heartworm preventatives, flea and tick medications, and vitamins and supplements, including herbal medications.
- Tell your veterinarian about your pet’s previous or current medical conditions.
- Tell your veterinarian if your pet is pregnant, nursing, or you intend to breed him/her.

How is my pet given PROPRIETARY NAME?

- Your veterinarian will give PROPRIETARY NAME *<route of administration>* during an office visit.

How will PROPRIETARY NAME affect my pet?

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Client Information Sheet
PROPRIETARY NAME (established name)

- PROPRIETARY NAME is intended to treat your pet’s cancer. As with other cancer treatments, your veterinarian cannot predict whether your pet’s cancer will respond to PROPRIETARY NAME.
- Regular check-ups by your veterinarian are necessary to determine whether your pet is responding as expected, and to decide whether your pet should continue to receive PROPRIETARY NAME.

What are some of the possible side effects of PROPRIETARY NAME

- Like all drugs, PROPRIETARY NAME may cause side effects, even at the prescribed dose. Serious side effects can occur, with or without warning, and may in some situations result in death.
- The most common side effects which may occur with PROPRIETARY NAME include:
<list adverse reactions here>.
- Other side effects may occur. For more information about side effects ask your veterinarian.

Contact your veterinarian immediately if you notice any of the following changes in your dog:

- *<List items here>*

Because PROPRIETARY NAME is an anti-cancer (chemotherapy) drug, extra care must be taken when handling and cleaning up after your pet for X days after treatment.

The following handling procedures will help minimize exposure to the active ingredient in PROPRIETARY NAME for you and members of your household.

- Cleaning up after your pet:
 - ✓ Avoid direct contact with urine, stool, vomit, and saliva for **X days** after your pet is treated with PROPRIETARY NAME.
 - ✓ When cleaning up urine, stool, vomit or saliva you should wear disposable chemotherapy-approved gloves and collect the contaminated material with disposable absorptive material (such as paper towels) and place them into a plastic bag. Carefully remove the gloves and place them in the bag and tie or fasten it securely for general household disposal. Wash your hands thoroughly afterwards. Check with your veterinarian to ensure you have the appropriate gloves.

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Client Information Sheet

PROPRIETARY NAME (established name)

- ✓ You should not wash any items soiled with urine, stool, vomit, or saliva from your pet with other laundry.
- ✓ Do not let your pet urinate or defecate in areas where people may come in direct contact with the urine or stool.
- Because PROPRIETARY NAME may be present in the pet's saliva for **X days** after treatment, take precautions in handling the dog's toys.

This client information sheet contains a summary of important information about PROPRIETARY NAME. For more detailed information about PROPRIETARY NAME, talk with your veterinarian.

To report a suspected adverse reaction (side effect) call xxx-xxx-xxxx. For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.