#240

Proprietary Names for New Animal Drugs

Guidance for Industry

Draft Guidance

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Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either https://www.fda.gov/AnimalVeterinary/default.htm or https://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
March 2018

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Proprietary Names for Animal Drugs

Guidance for Industry

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA of Agency) on this topic.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 provides recommendations to help new animal drug sponsors (you) develop **proprietary names**[1] that do not contribute to **medication errors,** negatively impact safe use of the drug, or misbrand the drug. This guidance provides a framework for evaluating proposed proprietary names before submitting them for review by the Center for Veterinary Medicine (CVM or we). It also explains how you can request that CVM evaluate a proposed proprietary name. This guidance does not address the **established names** of animal drugs.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe FDA'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.

II. REGULATORY AUTHORITY

Under section 502(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) a drug is misbranded if its **labeling** (including **labels**) is false or misleading in any particular. A drug product's labeling can be misleading because of the representations it makes, or because it omits material facts about possible consequences of using of the drug as intended.[2]

The Code of Federal Regulations (CFR) describes some of the ways that the proprietary name of a drug can make its labeling misleading. See 21 CFR 201.6(b) and 21 CFR 201.10(c).

III. DEFINITIONS

Brand name extension: *Brand name extension* is a term used to describe the reuse of an already-marketed **proprietary name** with the addition of a **modifier** to introduce a new product. Brand name extensions might also be referred to as *Family Trade Names* or *Umbrella Names*.

[1] Terms that initially appear in bold are defined in the definitions Section III.
[2] See Section 201(n) of the FD&C Act (21 U.S.C. 321(n)).

End user: The term *end user* includes, but is not limited to, the prescribing veterinarian, veterinary technician, farmers, animal owners, pharmacist, pharmacy technician, and other individuals who are involved in routine procurement, stocking, storage, and administration of medications.

Established name: Section 502(e)(3) of the FD&C Act (21 U.S.C. 352(e)(3)) states that: "The term 'established name,' with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) or clause (B) of this subparagraph applies, then the common or usual name, if any of such drug or such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply."[3]

Label: As defined in section 201(k) of the FD&C Act (21 U.S.C. 321(k)), the term *label* means "a display of written, printed, or graphic matter upon the immediate container of any article." If any word, statement, or other information is required by the FD&C Act to appear on the label, it must appear on the outside container or wrapper, if there is one, or be "easily legible through the outside container or wrapper."

Labeling: As defined in section 201(m) of the FD&C Act, the term *labeling* means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

Medication Error: A *medication error* is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[4]

Modifier: A *modifier* is a portion of the proprietary name. The modifier portion of a proprietary drug name might be a letter, number, word, device name, or combination of letters, numbers, and words attached to the beginning, middle, or end of a root proprietary drug name.

Product line: A group of products related in some manner (e.g., similar active ingredient or indication) under a single brand marketed by the same or related company.

Proprietary name: The *proprietary name* is the exclusive name of a drug product owned by a company under trademark law regardless of registration status with the U.S. Patent and Trademark Office. The proprietary name is sometimes also referred to as the *trade name* or *brand name*.

[3] The term "official compendium" is defined in section 201(j) of the FD&C Act.
[4] National Coordinating Council for Medication Error Reporting and Prevention; http://www.nccmerp.org/about-medication-errors

Root proprietary name: The term *root proprietary name* refers to the portion of a proprietary name, generally within a product line, that is or has already been marketed. For example, in the proprietary name "Drugname for Dogs" and "Drugname for Cats," the word "Drugname" is a root proprietary name, while the phrases "for Dogs" and "for Cats" are modifiers.

IV. BACKGROUND

CVM evaluates proprietary names as a part of the new animal drug approval process. Selecting a proprietary name is a critical element in the design and development of drug product labeling because **end users** may rely, in part, on the proprietary name to identify which product, among thousands of available products, is intended for a given animal. For this reason, accurate identification by the end user is essential. If end users cannot readily distinguish among proprietary names, the animal might receive the wrong product or it might not be possible to correctly identify the product used.

One aspect of CVM's review of proprietary names for new animal drugs focuses on the avoidance of medication errors. Examples of medication errors include incorrect drug selection, incorrect dosage or route of administration, or use in unintended species or classes. These types of errors may cause animal injury or a lack of drug effectiveness, which could contribute to outcomes like complication of a disease and possible death of an animal. Medication errors in food-producing animals may result in drug residues in edible tissues (including milk or eggs) that may cause residue violations for livestock owners, and may result in potentially unsafe food for consumers.

CVM considers whether the name can cause confusion or otherwise contribute to unintended misuse of the product in the medication use system. The medication use system for animal drugs in the United States (US) generally includes the following phases: selection and procurement, ordering or prescribing, order processing, dispensing, and administration. Opportunities for medication errors arise in each of these phases.

CVM also considers the entire medication use system when evaluating the potential of proprietary names to cause confusion and medication error. This includes the specific environment in which the product will be used (i.e., clinic, barn, home, etc.), the veterinary prescriber population, and/or the knowledge and experience of the animal owner or animal caretaker who will be administering the drug. For example, for a product expected to be used exclusively in beef cattle by beef cattle producers, the proprietary name review will consider a potential for confusion with other products used by beef cattle producers.

Additionally, CVM will compare the proposed proprietary name to other proposed proprietary names submitted to FDA for products not yet approved. Such proposed names are often

confidential; therefore, it is possible that CVM may identify conflicts with pending products of which the sponsors or public is not aware.[5]

Upon review, CVM might object to a proposed name if it may misbrand the product for reasons not solely related to medication error prevention. Among other things, the FD&C Act provides that a drug or device shall be deemed misbranded if its labeling is false or misleading in any particular (section 502(a) of the FD&C Act). Labeling may be misleading, for example, if it employs a fanciful proprietary name that suggests that a drug has some unique effectiveness or composition when it does not, or makes misrepresentations with respect to safety or effectiveness (see 21 CFR 201.10(c)(3)).

Distributor product labeling is not required to be reviewed and approved by FDA prior to distribution. Nevertheless, distributor products are subject to the provisions of 21 CFR 514.80(b)(5)(iii), so the principles laid out in this guidance are applicable to proprietary names of distributor products. Distributor products deemed misbranded are subject to the same sanctions applicable to any misbranded new animal drug.

V. NAMING ATTRIBUTES THAT MIGHT MISBRAND THE PRODUCT

This section identifies naming attributes that may lead to proprietary names that would misbrand a new animal drug product. We recommend that you evaluate proposed proprietary names for these attributes. Appendix A provides a checklist to aid in the assessment of proposed proprietary names and provides FDA's thinking with respect to each of these attributes.

A. Similarities in Spelling and Pronunciation

Proprietary names that look alike or sound alike can increase the risk of medication errors when selecting, prescribing, dispensing, or administering the product. Generally, proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other animal or human drug products. FDA may consider a proposed proprietary name to be misleading if it may be confused with the proprietary name or the established name of a different drug or ingredient because of similar spelling or pronunciation (see 21 CFR 201.10(c)(5)).

Proprietary names also should not incorporate the sponsor's name or a part of the sponsor's name across multiple products (e.g., "SponsorNameX," "SponsorNameY," "SponsorNameZ"). This practice can result in creating multiple similar proprietary names, which might increase the risk of confusion among the products. Confusion may occur when such products are stored alphabetically in distributor or pharmacy locations or when products are ordered from alphabetized lists.

[5] Proposed names may be associated with drug products subject to (generic) investigational new animal drug ((J)INAD) files, (abbreviated) new animal drug applications ((A)NADA), investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), or abbreviated new drug applications (ANDAs). In those instances when a conflict is identified with a proposed proprietary name of a pending drug application, FDA will generally accept the proposed name of whichever application is approved first and notify the other applicant that they must seek a new name.

B. Inert of Inactive Ingredients

Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that creates an impression that the ingredient's value is greater than its true functional role in the formulation because such names may be misleading (see 21 CFR 201.10(c)(4)).

C. Products with Multiple Active Ingredients

Proprietary names of drug products that contain more than one active ingredient should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)). Such names can mislead the end user by implying that the product contains only the ingredient(s) included in the name. (See section 201(n) of the FD&C Act).

D. United States Adopted Names (USAN) Council Stems

Proprietary names should not incorporate United States Adopted Name (USAN) stems in the position that the USAN Council designates for the stem. The USAN Council is generally responsible for selecting simple, informative, and unique established names for drug substances. USAN stems are standardized syllables within established names that relate new chemical entities to existing drug families and are intended to indicate a pharmacological or chemical trait of a drug. For example, the stem *–cillin* is used for penicillins, such as ampicillin, and the stem *–inib* is used for kinase inhibitors, such as oclacitinib. A single stem may be applicable to multiple drug products. Stems may appear at the beginning, middle, or the end of the established name. Each stem can emphasize a specific chemical structure type, a pharmacologic property, or a combination of these attributes.

Use of these stems in the position designated by USAN within proprietary names, even when such use is consistent with the USAN meaning, can result in the creation of multiple similar proprietary names and/or proprietary names that are similar to established names, leading to an increased risk of medication errors because of name confusion. You should screen proposed proprietary names against the stem list created by the USAN Council to ensure a USAN stem is not present in the stem position in the proprietary name.[6] In rare circumstances, it might be acceptable to include a USAN stem in the USAN-designated position within the proposed proprietary name. Such circumstances could arise if the proposed name includes a word that can only be spelled in the English language using a stem in the position designated by USAN.

[6] See the list of approved USAN stems, available at http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page.

E. Same Proprietary Name for Products Containing Different Active Ingredients

You should not use the same proprietary name or the same **root proprietary name** for products that do not contain at least one common active ingredient contained in the original marketed product. If products have the same root proprietary name but do not share any active ingredients with the original marketed product, end users may be confused about the products' ingredients and how each product should be used.

F. Reuse of Proprietary Names

You should not reuse the proprietary name of a discontinued product when marketing a different drug because there is a risk that users may continue to associate the name with the original discontinued product.[7] Proprietary names associated with discontinued drug products also may continue to appear in drug product reference texts for extended periods of time.

G. Names That Include Reference to Product-Specific Attributes

We recommend that you avoid incorporating product-specific attributes, such as manufacturing characteristics (e.g., "NameLyophylized"), dosage form (e.g., "Nametabs"), or route of administration (e.g., "Nameoral") as part of the proposed proprietary name. Including references to product-specific attributes in the proprietary name may be acceptable if the product-specific attribute is consistent with the terminology used in the product's labeling and does not pose additional risks for medication error. However, when developing proprietary names that include or make reference to product-specific attributes, you should also consider that future changes in the product, such as changes in dosage form or route of administration or manufacturing characteristics, may render the original proprietary name inaccurate.

H. Dosing Interval

We generally discourage you from proposing proprietary names that refer to the product's dosing interval, such as "NameQD" or "NameBID," even when the name accurately reflects the product's dosing instructions. This information is subject to change during the course of application review and during marketing. The approval of new dosing intervals, formulations, indications, or use in different target animal populations may result in the original proprietary name becoming misleading.

There are circumstances in which it might be appropriate for a proprietary name to include a reference to the product's dosing interval. For example, if you market several drug products with different dosing intervals, proprietary names that include this information (such as "Daily" and "Monthly") might help users distinguish between the products and appropriately select and administer the correct drug.

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[7] See Tu, CM, Taylor, K, and Chai, G. Use of Proprietary Names by Prescribers for Discontinued Brand Drug Products With Existing Generic Equivalents. Drug Information Journal, published online August 21, 2012, available at http://dij.sagepub.com/content/early/2012/08/21/0092861512456282.full.pdf+html.

I. Modifiers as Components of a Proprietary Name

Often, **modifiers** are included in a proprietary name to convey distinguishing product characteristics, for example "ER" for extended-release. Frequently, multiple new animal drug products containing at least one common active ingredient within a **product line** are named using a common root proprietary name with various modifiers to distinguish the products from one another.

Inconsistent use of modifiers and the absence of a standardized meaning for such terms can be confusing to end users. Veterinarians, animal caretakers, and consumers may understand and interpret modifiers used in animal drug proprietary names in different ways. When users do not readily understand the intended meaning of a modifier, they may make medication errors if they incorrectly select and/or use a product. Users may also omit modifiers when selecting, ordering, or prescribing drugs, potentially leading to medication errors.

Conversely, the inclusion of a modifier can in some cases mitigate the risk of drug confusion, thus enhancing safe use of a drug by aiding in differentiation between products. This may be particularly true in situations when two or more drugs have similar proprietary names, active ingredients, or conditions of use, thereby increasing the potential for product confusion. In those circumstances, inclusion of an appropriate modifier may help reduce the potential for confusion. An example is "Newdrug Horse" and "Newdrug Dog," where both drug products contain the same active ingredient, but in different concentrations for different species.

If you use a modifier, its meaning should be generally understood and should not be a source of confusion.

The following considerations could help you assess the suitability of using a modifier in a proprietary name:

1. Considerations for the selection and evaluation of a modifier.

   You should consider the following points carefully when deciding whether to include a modifier in a proprietary name and when evaluating the potential risk of a medication error associated with a specific proposed modifier.

   a. Do you currently market one or more products under the proposed root proprietary name? If so, evaluate the similarities and differences between the proposed product and the existing product(s). You should consider how to minimize the risk of confusion among the products, especially if the products have overlapping characteristics (such as immediate-release and extended-release products with the same active ingredient and dosage strength). You should also consider the potential for product confusion if the modifier is omitted by the prescriber or overlooked during dispensing or administration.

b. What is the rationale for the proposed modifier? Is it intended to differentiate the proposed product from other products or to convey a characteristic of the proposed product? Does the modifier contribute to safe and effective use of the product? Would marketing the proposed product without a modifier or under a different proprietary name raise concerns that could be addressed by an effective modifier in the proprietary name?

c. If a proposed modifier describes a product characteristic, does it accurately describe the product characteristic?

d. Where will the modifier be placed in the proprietary name? What is the rationale for this placement?

e. What is the modifier's intended meaning? What information is available to support that animal health professionals and/or consumers understand this meaning?

f. Is the proposed modifier currently used in the marketplace? We recommend checking whether the proposed modifier already is used in the marketplace and whether it has been used consistently with a commonly recognized meaning. If an existing modifier with the same intended meaning is in the marketplace and familiar to and understood by end users without error, it might be appropriate to adopt the existing modifier. When deciding whether to use a different modifier instead of an existing modifier with the same intended meaning, you should consider whether the proposed modifier conveys the intended meaning as clearly as, or more clearly than, the existing modifier.

g. Is there a risk that end users could misinterpret the modifier's intended meaning? What is the risk of medication errors if an end user confuses the modifier with some other element of a prescription or order (such as frequency, strength, route of administration)? What is the risk if a user omits a modifier when communicating a drug name?

2. Specific issues associated with particular types of modifiers.

a. Numeric Modifiers

CVM generally discourages the use of numbers in proprietary names. The meaning of numbers used as modifiers can be ambiguous and subject to misinterpretation. Both Roman and Arabic numerals have been mistaken for the strength, quantity, duration, or controlled substance class of prescription drug products. For example, using the number "3" in a proprietary name to represent the product strength might be misinterpreted to mean that three tablets are administered or that the product should be used for only 3 days when the name appears in a drug order or prescription.

The use of numbers in proprietary names may be useful if they help to distinguish the drug from similar products. For example, when two products exist with same or

similar proprietary names, but different strengths, numbers may enhance the safe use of a drug by allowing users to distinguish between drugs of various strengths provided that the numbers clearly convey that they relate to the strength of the product. *Drugname 10*, for a 10 mg tablet, may be confusing because it may not be obvious whether the number 10 refers to the strength or to the number of tablets. In contrast, *Drugname 10 mg* would less likely be confusing because the unit strength provides the context needed to understand the specific meaning.

Numbers are often included in proprietary names of Type A medicated articles.[8] For example, numbers may be used in proprietary names of Type A medicated articles to distinguish different concentrations of these Type A medicated articles in a product line with the same root proprietary name. If a number is used for this purpose in the proprietary name of a Type A medicated article, the number should match the active ingredient concentration listed on the Type A label to the same decimal point. Furthermore, numbers used in the proprietary names of all Type A medicated articles within a product line should be based on the same unit of measure for concentration, for example grams per pound (g/lb) or grams per kilogram (g/kg).

b. Descriptive Modifiers

Descriptive modifiers are words or abbreviations that describe some aspect of the product (e.g., indication, formulation, species, or class). Concerns may arise with descriptive modifiers that are ambiguous, misleading, or subject to misinterpretation. A primary factor you should consider when evaluating the appropriateness of a modifier associated with a proprietary name is whether the modifier's intended meaning is supported by the proposed labeling and whether it is understood by the end user.

c. Abbreviations (including Acronyms and Initials)

Abbreviations used as modifiers are less likely to cause confusion if their meaning is unequivocal and they are consistently and correctly understood by the intended users of the product. However, the meaning of some abbreviations can be ambiguous and subject to misinterpretation.[9,10] For example, "LA" could be interpreted as either "large animal" or "long acting." Also, using abbreviations for indicating target species or class in proprietary names may be ambiguous and thus lead to medication errors. For example, "S" may be interpreted as referring to swine, sheep, or steer; "C" may be interpreted as referring to cattle, cat, chicken, or canine. Therefore, these abbreviations should not be used as part of the proprietary name. If you want to

[8] Type A medicated articles are concentrated forms of animal drugs intended solely for further manufacture of other approved Type A medicated articles, or Type B or C medicated feeds (21 CFR 558.3(b)(2)). Type A medicated articles cannot be legally fed directly to animals. They are sold to feed mills or livestock producers and are intended to be further diluted by mixing into feed before feeding to animals.

[9] The Joint Commission's Official "Do Not Use" List of Abbreviations, 2016, available at https://www.jointcommission.org/facts_about_do_not_use_list/.

[10] The Institute for Safe Medication Practices' List of *Error-Prone Abbreviations, Symbols,* and *Dose Designations*, 2015, available at https://www.ismp.org/tools/errorproneabbreviations.pdf.

include the target species in the proprietary name, the target species should be spelled out (e.g., *Newdrug for Swine*).

d. Modifiers Describing Drug Release Characteristics

In order to review proprietary names containing modifiers that describe drug release characteristics, determination of the drug release characteristics for the product should be established prior to evaluation of the proprietary name.

J. Brand Name Extensions

Proprietary names that include **brand name extensions** are evaluated to consider whether the:

- products share at least one common active ingredient
- products are differentiated by labeling (carton and container)
- modifiers used are appropriate and effectively differentiate the product among members of the same product line

In some cases, brand name extensions have posed problems when the same root proprietary name is used for multiple products without modifiers that adequately differentiate among the products. Some brand name extensions have complicated the process of identifying and properly selecting an appropriate product by creating or reinforcing a false belief among consumers and animal healthcare professionals that all products with a shared root proprietary name also have the same active ingredients or same indication(s) for use. The potential for confusion among products with the same root proprietary name might also be reinforced by visual cues created by the use of uniform trade dress and/or store or clinic displays that group products by brand name rather than by active ingredients or intended uses. The types of errors that may result from the confusion of brand name extensions include the use of the product for the wrong indication, the administration of an unnecessary active ingredient, and the use of a product in the wrong species or class of animals.

For example, “Newdrug” is the proprietary name for a tablet containing “active ingredient #1” for treatment of intestinal worms in dogs. If you want to expand your product line to include “active ingredient #1” in a new dosage form for use in swine, “Newdrug Injectable Suspension” may be acceptable.

Further, for a combination of “active ingredient #1 and active ingredient #2” for use in dogs, “Newdrug Plus” may be acceptable.

In contrast, the use of the proprietary name “Newdrug Oral Suspension” would not be appropriate for an oral suspension containing only “active ingredient #2” or an entirely new active ingredient for treatment of intestinal worms in dogs.

K. Proprietary Names of Drug Products Marketed Outside the US

You should not propose a proprietary name that is identical or nearly identical to that of a marketed foreign product that contains a different active ingredient, even if the proposed product will be marketed only in the US. Medication errors resulting in dispensing and administration of the wrong drug may occur when a proprietary name for a product marketed in the US is identical, or virtually identical in spelling and pronunciation, to a foreign product containing an entirely different active ingredient marketed in a foreign country.

Please note that if a proposed proprietary name is already in use in a foreign market, this will not necessarily be a justification for CVM concurrence with use of the same proprietary name for the same or similar product in the US market.

L. Use of Symbols

CVM encourages using words rather than symbols (i.e., "+" or "&") to link components in proprietary names because symbols can be misinterpreted or confusing on labeling or when hand written (e.g., "&" can be read as "8").

M. Other Misbranding

A proprietary name may misbrand a product for reasons not solely related to medication error prevention. A proprietary name could result in such misbranding if it is false or misleading, such as by making misrepresentations with respect to safety or effectiveness.

CVM recommends against using proprietary names that imply comparison to other drug products or treatments. For example, CVM likely would object to a proposed proprietary name that contained "best," "max," or "pro" because they imply superiority over other drugs.

VI. SUBMISSION OF REQUEST FOR EVALUATION OF PROPOSED PROPRIETARY NAMES FOR APPROVED LABELING OF NEW ANIMAL DRUGS

A. When to submit a proprietary name for review

You are encouraged to submit proposed proprietary name(s) of new animal drugs for preliminary review and comment by CVM, early in the product development process. The preliminary review will determine if CVM has any concerns about the proposed proprietary name based on the information available at the time of the review.

If concerns about the proposed proprietary name(s) arise during the preliminary review, we recommend submitting an alternative proposed proprietary name(s) for review prior to approval of a new animal drug. Submitting proposed proprietary name(s) for preliminary review early in the development process may help avoid delays in the new animal drug approval process.

B. What to submit

The request for review of the proprietary name(s) should include the following information:

1. The proposed proprietary name(s) and intended pronunciation(s).

2. Product characteristics, such as:

    - Established name
    - Pharmacological class
    - Target animal and class, if applicable
    - Proposed indication(s)
    - Proposed dose or frequency of dose
    - Route of administration
    - Dosage form
    - Type A medicated article

3. Any additional information that could help in the review (e.g., the derivation of the name or the name of the product if approved in another country).

C. Where to submit

Requests for review of proprietary names for new animal drug applications, including generic applications, should be submitted to the appropriate Division in the Office of New Animal Drug Evaluation (ONADE) under the appropriate file[11] for the drug product. Requests for review of proprietary names for indexed products should be submitted to the Office of Minor Use and Minor Species (OMUMS).

D. Final assessment before new animal drug approval

CVM will reassess the proprietary name during the final review of labeling prior to approval. During the final review of the labeling, CVM determines if there are concerns with the proprietary name based on previously unavailable information. Examples include changes in the drug product characteristics or the approval of another drug application in the interim with a proprietary name that is similar in spelling or pronunciation to that of the proposed drug.

[11] Files include INAD, JINAD, NADA, or ANADA.

VII. SUBMISSION OF REQUEST FOR EVALUATION OF PROPOSED PROPRIETARY NAMES FOR DISTRIBUTOR PRODUCT LABELING OF NEW ANIMAL DRUGS

A. When to submit a distributor product proprietary name for review

Distributor product labeling is required to be submitted at the time of initial distribution (see 21 CFR 514.80). However, applicants may voluntarily request an advisory review of the distributor labeling proprietary names prior to initial product distribution. CVM encourages applicants to do so in order to avoid the use of a false or misleading proprietary name.

Requests for advisory review of proposed proprietary names should be submitted at least 120 days prior to printing final distributor product labeling. Following review, CVM will respond to the applicant with comments explaining any identified proprietary name compliance issues. This allows the applicant to become aware of potential compliance issues prior to printing final distributor product labeling.

B. What to submit

For an advisory review of the distributor's product proprietary name, applicants should submit a special drug experience report (DER) accompanied by a completed Form FDA 2301[12] and a complete set of the distributor labeling. The submission should be identified as Request for Pre-dissemination Review.

C. Where to submit

Requests for review of proprietary names for distributor products should be submitted to the Division of Surveillance, Office of Surveillance and Compliance, as a DER accompanied by a completed Form FDA 2301.

[12] You can find this and other FDA forms at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/AnimalDrugForms/.

VIII. APPENDIX

Screening Checklist for Proposed Proprietary Name
(This checklist does not include all the potential concerns discussed in this guidance regarding selection of an appropriate proprietary name.**)**

Answering yes to any of these questions indicates a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical or other abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or abbreviations that have no established meaning.
Y/N	**Are inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names must not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of drug products that contain more than one active ingredient must not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN Council designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product.