PROPRIETARY NAMES

I. PURPOSE

The purpose of this document is to explain:

- what a proprietary name is,
- how to format a proprietary name in CVM documents, and
- the administrative process for evaluating a sponsor's proposed proprietary name.

II. WHAT IS A PROPRIETARY NAME?

The proprietary name is the exclusive name the sponsor or distributor assigns to a drug product. It is commonly known as the trade name and may include trademarked and non-trademarked words. The trademarked word or words are the unique words that distinguish the drug product from other drug products and are followed by a trademark (™) or registered (®) symbol. Following this are non- trademarked words, if present. The non-trademarked words can include species or dosage form, or other appropriate modifiers such as numbers or letters, and are located to the left of the established name.

III. HOW DO WE IDENTIFY AND FORMAT A PROPRIETARY NAME?

The reviewer identifies the proprietary name from the product labeling.[1] In product labeling, the proprietary name is identified as the word or words preceding the established name, which is usually in parenthesis. Any words after the established name are not considered by CVM to be part of the proprietary name and are considered additional clarifying words. Some or all of these additional clarifying words may be added after the established name in our documents, if necessary, to identify the product.

If provided by the sponsor, the trademark or registered symbol should be included in the proprietary name. Because this may change over the life of the product we do not

[1] Products may not have a proprietary name early in the development process, and whatever identifier is provided by the sponsor should be used in reviews and letters.

try to determine if the correct symbol is being used on the current labeling but instead just use the symbol as provided. To insert a trademark symbol in your review documentation, select the Insert ribbon in Microsoft and select the Symbol dropdown at the far right. Make sure the font is Verdana 10 point. In our documentation, the standard format for the trademark (™) and registered trademark symbols (®) is superscript. When you use the Symbol option, you must manually superscript the registered trademark symbol to have it properly formatted (®).

The same capitalization in the proprietary name should be used in our documents as presented on the labeling. See Appendix 1 for examples. If the current submission does not include labeling, the reviewer should look at the most recent labeling submission or the Volume 0. When reviewing labeling, the proprietary name should be indicated in the Reviewer Summary field in our Submission Tracking and Reporting System (STARS) to assist future reviewers in determining the proprietary name easily.

The proprietary name should be presented consistently in the review, letter, and other CVM generated documents associated with the submission. It is acceptable to use an abbreviated form of the proprietary name within the review as long as the complete proprietary name is used once, and the abbreviation is clearly defined. The documents associated with an approval package (e.g., MRA, FOI Summary, GBAAD) have instruction bubbles that state to use the proprietary name as determined from product labeling, and the proprietary name in the letter should be consistent with these documents. Therefore, in the event that the labeling in an approval package formats the trademark symbol in a manner that is acceptable but different from our standard (e.g., you may see the trademark symbol subscripted in the labeling we receive), throughout the approval package present the trademark symbol as it is formatted on the labeling.

Note that some generic drug sponsors use a non-proprietary name that is the same as the drug product established name. In this case, where templates specify insertion of the proprietary name (e.g., Proprietary Name or Proprietary Name (drug product established name)) the reviewer may either use N/A or the non-proprietary name, as appropriate.

IV. USE OF THE PROPRIETARY NAME IN INVESTIGATIONAL REVIEW DOCUMENTATION

Do not use the proposed proprietary name in review documentation that will be issued to sponsors for submissions made to investigational new animal drug (INAD) or generic investigational new animal drug (JINAD) files when the proprietary name for the product has not yet been approved. Therefore, the proposed proprietary name should not be used in letters or memorandums of conference sent to the sponsor.[2] We do this to avoid any unintended inference that CVM has approved the proprietary name. If the submission is made to the (J)INAD for a product where the proprietary

[2] Note in responding to G submissions made specifically to evaluate proposed proprietary names, it is appropriate to mention and use the names submitted when providing feedback to a sponsor on a name or names submitted. It is also acceptable to use the proprietary name and identify it as proposed in any letters sent to sponsors that accompany draft labeling or the draft Freedom of Information Summary (FOI) and in any comments made within draft labeling and the draft FOI summary. Alternatively, reviewers can use the term "TRADENAME" in these instances.

name has been approved (e.g., an INAD where the sponsor is adding an indication to an already approved new animal drug product or abbreviated new animal drug product), the use of the proprietary name in internal CVM-generated documents is optional and at the reviewer's discretion. For rare situations where the established name alone is not sufficiently clear (e.g., multiple products with the same established name), the non-trademarked words, dosage form, or other descriptive information should be included, as needed, to clearly identify the product in the letter or other prepared documentation. In our internal review documentation (e.g., memorandum to file, reviews, etc.), the reviewer may use the proposed proprietary name, if they choose. If the reviewer chooses to use the proposed proprietary name when the new animal drug product has not been approved, they should identify the name as a proposed proprietary name the first time the name is used in the review documentation. Subsequent use of the proprietary name throughout the review documentation does not require this clarifying language.

V. WHAT IS THE ADMINISTRATIVE PROCESS FOR EVALUATING A PROPRIETARY NAME?

When a proposed new proprietary name first appears in a submission (e.g., the sponsor includes a proposed new proprietary name in the request for opening an (J)INAD file, during the initial pre-submission conference) or in a 356v, the target animal division (TAD) reviewer should request that the sponsor submit a letter requesting CVM comment on their proposed proprietary name. This request can be conveyed to the sponsor by including a comment in the response letter for the submission in which the name first appears (for example, the ONADE template for the opening an investigational file ((J)INAD A-0000) acknowledgement letter includes boilerplate language for this). Alternatively, it may be conveyed informally during the review process in person, or via email or a phone call, if the reviewer feels that is more efficient.

The review of the proprietary name includes both trademarked and non- trademarked words. Our initial review of the proprietary name is not intended to be a formal agreement or final decision on the proprietary name. The final review of the name will be done as part of the Labeling technical section or application review process. In the final review, the proposed proprietary name will be assessed with any new information that has become available since the initial review, such as recently approved products with a similar name.

The process described in this document is also used if a sponsor proposes changing the proprietary name of a product before they submit an original or supplemental application. Note that some generic drug sponsors use a non- proprietary name that is the same as the drug product established name. In this case, this non-proprietary name is not trademarked, and not subject to the process used for evaluating a proprietary name.

A. Review of a G Submission

The sponsor should be advised to submit a letter requesting CVM evaluate their proposed proprietary name(s) as a G submission. The sponsor may provide up to two names for review. The TAD reviewer requests a consulting review from the Office of Surveillance and Compliance (OSC), Division of Surveillance, Post-

Approval Review Team (HFV-216) using Appian. In order to facilitate the review process, the TAD reviewer provides as much of the following information in the consulting review request to the OSC reviewer including, but not limited to:

- Established name
- Drug category
- Target animal species (and class if applicable)
- Proposed indication(s)
- Proposed dose or frequency of dose (Any information that we have is useful, even if we don't know the precise dosing schedule. For example, once a day, twice a day, once a month, etc.)
- Route of administration
- Dosage form
- Any additional information that may be useful for the review

Both the ONADE and OSC reviewers' comment on and discuss the acceptability of the name(s) in their reviews. As the primary reviewer, the ONADE reviewer also discusses the OSC consulting review in their review. When the OSC reviewer has concerns with the name, the ONADE reviewer should make sure they fully understand the concerns from OSC and document any discussion and decisions regarding the OSC concerns in their review. The ONADE reviewer should ask to be invited to the OSC Expert Panel Discussion that discusses the proprietary name.

ONADE sends an acknowledgement letter to the sponsor using boilerplate language depending on whether we have any concerns with the name. See Appendix 2 for boilerplate language.

B. Review of a Labeling Technical Section (M) Submission of Non-administrative Application

When ONADE receives the Labeling technical section or a non-administrative application, the TAD reviewer requests a consulting review from HFV-216 using Appian. The TAD reviewer should include instructions to the consultant in OSC to review the proprietary name in addition to the labeling review. A reference to the G submission should be provided if a previous proprietary name review was performed.

VI. ENTERING THE PROPRIETARY NAME IN STARS/ANIMALDRUGS@FDA

The proprietary name will be entered into STARS and/or AnimalDrugs@FDA after the application is approved. ONADE's Business Informatics Team (HFV-182) will enter the information into STARS from the Green Book and Animal Drugs at FDA or GBAAD form.

Changes to the proprietary name in STARS can be made by submitting a STARS correction form.

VII. VERSION HISTORY

March 30, 2010 – Beta test version

January 25, 2011 – The format of the proprietary names has been updated to match CDER conventions. A list of information that OS&C finds helpful in evaluating the name has been added. The section on how to format a proprietary name has been separated from the section on what a proprietary name is.

August 30, 2011 – Section III has been updated to include instructions on how the proprietary name is identified in electronic submissions.

April 9, 2013 – The document is revised to update the format of the proprietary names from having the drug substance established name in parenthesis to having the drug product established name in parenthesis. The drug product established name includes the active moiety, the route of administration, and the dosage form.

June 9, 2016 – Updated process for documenting proprietary name in reviews.

February 9, 2018 – Updated to add clarification on the formatting of non-proprietary names and an update to the examples in the Appendix.

October 2, 2020 – Revised to clarify how to appropriately insert and format the trademark symbols and to state that the trademark symbol used in our approval package documents should be formatted the same as it is in the labeling accompanying the approval package.

December 15, 2020 – Updated section IV to indicate how to refer to the proposed proprietary name in documents.

January 26, 2021 – Updated section III information to clarify further how to insert and format trademark symbols and to clarify that the proposed proprietary name can be used in correspondence that accompanies draft labeling and draft FOI as long as it is identified as proposed or alternatively the word TRADENAME can be used.

August 17, 2021 – Revised section IV to no longer state rare use of the proposed proprietary name in our letters is acceptable when needed to distinguish between multiple products with the same established name. Wording in that section was revised to state in situations where the established name is not sufficiently clear to identify the product, the non-trademarked words, dosage form or other descriptive information should be included to identify the product. It is still acceptable to use the proposed proprietary name in internal review documentation and identify it as such.

APPENDIX 1: EXAMPLES

Examples of proprietary names on labeling and how to format in CVM documents.

If the product label says: Anymectin® (anymectin topical solution) for Cattle, the

reviewer would write: Anymectin® when writing the proprietary name.

If the product label says: AnyMectin® (anymectin topical solution) Solution, the reviewer would write: AnyMectin® when writing the proprietary name.

If the product label says: Anymectin® for Cattle (anymectin topical solution), the reviewer would write: Anymectin® for Cattle when writing the proprietary name.

If the product label says: ANYMECTIN® (anymectin topical solution) for Cattle, the reviewer would write: ANYMECTIN® when writing the proprietary name.

If the product label says: Anymectin® 100 Type A Medicated Article (anymectin), the reviewer would write: Anymectin® 100 Type A Medicated Article.

APPENDIX 2: BOILERPLATE FOR THE G SUBMISSION PROPRIETARY NAME ACKNOWLEDGEMENT LETTER

Use the acknowledgment letter template, with the appropriate boilerplate language added after the opening paragraph (i.e., first paragraph) in the template. Choose one section below with the appropriate boilerplate language for:

- a proprietary name where we have no concerns, or
- a proprietary name where we have concerns.

A. Boilerplate Language for a Proprietary Name for Which We Have No Concerns:

We have completed an initial review and have no concerns at this time with the proprietary name <Proprietary Name> for <drug product established name> in <species and if applicable, class>. If you decide to change the proprietary name before you submit your new animal drug application ((A)NADA), please submit a request for comment on the new proposed proprietary name. We will conduct a final review and make a final determination on the acceptability of the proprietary name after we have reviewed all the data for all applicable technical sections and any other information available to us when you submit your Labeling technical section, application, or supplemental application.

B. Boilerplate Language for a Proprietary Name for Which We Have Concerns:

We have concerns regarding the proprietary name <Proprietary Name> for <drug product established name> in <species and if applicable, class>. Our concerns are <give reason for concern>. <describe concerns here, if necessary>. Please submit a meeting request if you would like to discuss your proposed proprietary name with us further.