OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

PROPRIETARY NAMES

I. PURPOSE

This document explains:

- what a proprietary name is,
- how to format a proprietary name in ONADE 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 (see Guidance for Industry (GFI) #240). It is commonly known as the brand name or trade name and may include trademarked and non-trademarked words (or numbers). 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. The trademarked word(s) may be followed by non-trademarked numbers/letters and/or words indicating the drug product strength and/or indicated species or dosage form.

III. HOW DO WE FORMAT A PROPRIETARY NAME

The reviewer identifies the proprietary name by using the label (on the immediate container or Type A medicated article label).[1] On the product label, the proprietary name is everything that precedes the established name, which is usually presented within parentheses. Note that some older labeling may not reflect the current presentation of the proprietary name followed by the established name in parenthesis. CVM does not consider words on the labeling that come after the established name to be part of the proprietary name.

If there is a trademark or registered symbol on the current label, it is included in the proprietary name. Because this symbol may change over the life of the product, we do not try to determine if the correct symbol is being used but instead just use the symbol as

[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.

provided. It is our policy that, regardless of the presentation of the symbol on the label, we will always include it in superscript format in the documents we prepare.

The same capitalization in the proprietary name as presented on the label is used in our documents. See Appendix 1 for examples. If the current submission does not include the label, the reviewer looks at the most recent labeling submission as indicated in the Volume 0.

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 (without the trademark or registered trademark symbols) within the review as long as the complete proprietary name is used once the first time the product is mentioned, and the abbreviation is clearly defined. The documents associated with an approval package (e.g., memorandum recommending approval (MRA), Freedom of information (FOI) Summary, Green Book, and Animal Drugs at FDA (GBAAD) form) have instruction bubbles that instruct the reviewer to use the proprietary name as determined from the product label, and that the proprietary name in the letter should be consistent with these documents.

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/ESTABLISHED NAME/ADDITIONAL WORDS IN REVIEW DOCUMENTATION

The reviewer identifies the product under review the first time it is mentioned in the review. For purposes of ONADE's review documentation, the identification includes the proprietary name, established name, and additional words (if needed) as described below. Afterwards, it is acceptable to use an abbreviated form of the proprietary name (without the trademark or registered trademark symbols) as long as the complete proprietary name is used once, and the abbreviation is clearly defined.

1. The proprietary name is formatted as it is on the label (i.e., use the same capitalization as on the immediate container or Type A medicated article label and include any trademark/registered symbol). See section V. for ONADE's policy regarding use of proprietary names for products which are not yet approved. See Appendix 1 for examples.

2. Use the trademark or registered symbol on the current label as provided, and in our documentation the standard format for the trademark (™) and registered (®) symbol is always superscript, regardless of how it appears on the label.

   Note: To insert a trademark symbol in your review documentation, select the Insert ribbon in Microsoft Word and select the Symbol dropdown. When you use the Symbol option, you must manually superscript the registered trademark symbol to have it properly formatted (®).

3. The established name, which appears after the proprietary name on the label, usually in parentheses. Write the established name in lower case. [2]

4. Any other additional words needed to clearly identify the product that is the subject of the review documentation. These words should appear in lower case, even if they appear on labeling as capitalized.

   Note: these additional words are optional. A reviewer may decide that additional words after the established name are necessary in letters and review documentation for a variety of reasons (examples below).

   - It may be helpful to include the dosage form if it is not part of the established name.

   - It may be helpful to include the species and/or animal class after the established name portion to distinguish products with the same proprietary and established names.

   The additional words may be taken from the label, but they do not have to be identical to what is on the label. For example, the label may say Anymectin® (anydrug) Paste and the reviewer may choose to write Anymectin® (anydrug) paste for goats to better identify what product is the subject of our document.

V. USE OF THE PROPRIETARY NAME IN INVESTIGATIONAL REVIEW DOCUMENTATION

Do not use the proposed proprietary name in letters, communications, memorandums of conference, or other review documentation that is issued to sponsors for submissions made to (generic) investigational new animal drug ((J)INAD) files when the proprietary name for the product has not yet been approved.[3] We do this to avoid any unintended inference that CVM has approved the proprietary name. If the submission is to the (J)INAD for a product with an approved proprietary name (e.g., an INAD for which the sponsor is adding an indication to an already approved (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 additional clarifying words such as dosage form or other descriptive information are 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), the reviewer may choose to use the proposed proprietary name. 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.

[2] The only exception to this is Type A medicated articles where the letter T and the letter A are capitalized.

[3] 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 FOI Summary and in any comments made within draft labeling and the draft FOI summary. Alternatively, reviewers can use the term "TRADENAME" in these instances.

VI. 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), the target animal division (TAD) reviewer requests that the sponsor submit a letter requesting CVM comment on their proposed proprietary name. This can be conveyed to the sponsor by including a comment in the response letter for the submission in which the name first appears (e.g., the ONADE acknowledgement letter template for opening an investigational file 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 proprietary name review 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 is done as part of the Labeling technical section or application review process. In the final review, the proposed proprietary name is assessed with any new information that has become available since the initial review, e.g., recently approved products with similar names.

The process described here 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, and not subject to the process used for evaluating a proprietary name.

A. Review of a G Submission

1. Issuing a Consult to the Office of Surveillance and Compliance (OSC) and Completing the ONADE Review and Letter

   The sponsor is advised to submit a letter requesting CVM evaluate their proposed proprietary name(s) as a G submission. The sponsor may provide up to three names for review. The TAD reviewer, who is the primary reviewer (PR), requests a consulting review from the OSC's Division Pharmacovigilance and Surveillance (HFV-240) using Appian. 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 (pharmacological class);
   - 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, e.g., once a day, twice a day, once a month);
   - route of administration;

- dosage form or Type A medicated article; and
- any additional information that may be useful for the review, e.g., how dispensed (Rx/OTC/VFD) or drug strength or concentration.

Both the ONADE and OSC reviewers comment on and discuss the acceptability of the name(s) in their reviews as described in CVM GFI #240. The ONADE reviewer asks to be invited to the OSC Expert Panel Discussion that discusses the proprietary name. If the ONADE reviewer has a comment about the OSC review or the proprietary name, it is discussed with the OSC reviewer and reflected in the ONADE review. As OSC is the subject matter expert for proprietary names, OSC makes the final determination on what comments are sent on the proprietary name. The OSC comments are transmitted in the letter.

ONADE sends an acknowledgement letter to the sponsor using the language conveyed by the OSC reviewer in the consulting review. The review language is added following the initial paragraph in the acknowledgement letter and replaces the last paragraph in the template. If there are concerns with the comments or wording included by OSC in the letter, the ONADE reviewer discusses any changes with the OSC reviewer prior to editing or sending the letter. The language includes the OSC contact information but the ONADE signature block.

2. Closing Out[4] the G Submission in Appian

When closing the G submission in Appian, the ONADE reviewer uses the normal division clearance chain with the final signature being the TAD Division Director. OSC staff are not included in the Appian clearance chain.

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

When ONADE receives the Labeling technical section or a non-administrative application, the TAD reviewer requests a consulting review from the Division of Pharmacovigilance and Surveillance (HFV-240) in OSC using Appian. The TAD reviewer includes instructions to the consultant in OSC to review the proprietary name in addition to the labeling review. If a previous proprietary name review was performed, then a reference to the G submission is provided. If the proprietary name was not previously reviewed in a G or has been changed since review of a G, OSC evaluates the name as part of their normal labeling consulting review.

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

The proprietary name is entered into our Submission Tracking and Reporting System (STARS) and/or AnimalDrugs@FDA after the application is approved. ONADE's Business Informatics Team (HFV-182) enters the information into STARS from the GBAAD form.

Changes to the proprietary name in STARS can be made by sending an email to the EDSR Mailbox. The subject line should be Change Proprietary Name. The ONADE

[4] Internal information redacted.

Business Informatics Team manages the mailbox. When the change in STARS has been made, the requestor will get a notification email from the EDSR Mailbox.

VIII. REFERENCES

Guidance for Industry (GFI)

GFI #240 Proprietary Names for New Animal Drugs

IX. 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.

March 7, 2022 – Revised to include section IV. Use of the Proprietary Name in Review Documentation to clarify how the overall name, include proprietary name, established

name, and clarifying words should be formatted. The G submission review process was significantly revised to reflect that OSC is the SME on proprietary name review.

June 1, 2022 – Revisions were made to section IV., including revisions to the title as a new term was erroneously created in the previous version. Otherwise, there were minor editorial changes in the document.

July 21, 2022 – Quality systems review for minor formatting updates. Updated references to OSC due to 2022 reorganization.

March 29, 2023 – Updated the information on standards to reflect the office switch to Arial 11-point font as our standard font. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.

May 16, 2023 – Updated section VI. B. to reflect the OSC reorganization. It now includes the name of the OSC Division of Pharmacovigilance and Surveillance (HFV-240). To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.

December 6, 2023 – Updated section VII. The STARS Correction Request Form has been retired. The instructions are now to send the request for a correction or change in proprietary name to the EDSR Mailbox.

August 27, 2024 – Updated to reflect that trademark/registered symbols will always be superscript in our documentation regardless of formatting on the product labeling. Defined the acronym STARS in section VII. Added a Reference Section to include the reference to GFI #240.

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.