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. The trademark or registered symbol should be included in the proprietary name, although since this may change over the life of the product we do not try to determine if the correct symbol is being used on the current label but instead just

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

copy the symbol as provided. The same capitalization 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 STARS to assist future reviewers in determining the proprietary name easily.

The proprietary name should be used consistently in the review, letter, and other CVM generated documents associated with the submission. Within the body of the review itself, an abbreviated form of the proprietary name may be used and should be clearly defined. The documents associated with an approval package (MRA, FOI summary, GBAAD) have instruction bubbles to use the proprietary name as determined from product labeling, and 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 "Proprietary Name" or "Proprietary Name (drug established name)" the reviewer may either use N/A or the non-proprietary name, as appropriate.

IV. 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 othe 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 or 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.

V. 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.

VI. 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.

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

Boilerplate language for the G submission Proprietary Name acknowledgement letter:

Use the acknowledgment letter template, with the appropriate boilerplate language added after the 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.

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 <established name> in <species>. 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.

Boilerplate language for a proprietary name for which we have concerns:

We have concerns regarding the proprietary name <Proprietary Name> for <established name> in <species>. 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.