Guideline

Central Administration for Pharmaceutical Products
General Administration of Veterinary Pharmaceuticals

GUIDELINES ON
NAMING OF VETERINARY PHARMACEUTICALS
2024

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1 Introduction

1.1 Objective

This document is developed to provide a clear guidance for companies on the criteria that need to be considered when selecting the invented names for medicinal products intended for veterinary use, to reduce name-related medication errors and for safety issues.

1.2 Background

The name of the medicinal product "may be either an invented name not liable to confusion with the common name, or a common name or scientific name accompanied by a trade mark or the name of the marketing authorization holder".

Careful considerations should be given to the name in order to minimize the risk of mix ups between different products.

The checking of the proposed invented name is a part of EDA's role in evaluating the safety of veterinary medicinal products within the authorization procedure, as the invented name could create a public health concern as a potential safety risk. In particular, the invented name should not:

- be liable to cause confusion with the invented name of an existing medicinal product.
- be misleading with therapeutic or pharmaceutical connotations, or with respect to composition.
- be similar to INN or incorporate INN stems.

The applicant would be expected to review the proposed invented name, applying the criteria outlined in this guidance, before requesting that an invented name to be considered. Approval of a trade name by the authority does not relieve the company of its responsibility when potential hazards occur after marketing of the product.

The applicant/MAH is sole responsible for checking all legal requirements and criteria for trademark registration and ownership.

1.3 Scope

The scope of this guidance is to provide applicants with information about criteria applied when reviewing the acceptability of names intended for veterinary use.

2. Definitions & Abbrevitions

MAH: Marketing Authorization Holder

Invented name is the trade name of a medicine.

INN (International Nonproprietary Name) is a unique name that is globally recognized and is public property, developed by World Health Organization to facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. It is also known as a generic name.

INN stem: Stems define the pharmacologically related group to which the INN belongs.

Ex: (-mycin) stem stands for antibiotics, produced by Streptomyces strains ex: erythromycin, gamithromycin, kanamycin, kitasamycin, lincomycin, neomycin, paromomycin, salinomycin, spiramycin, spectinomycin, streptomycin, tulathromycin, azithromycin, dihydrostreptomycin, clarithromycin, clindamycin.

The common name is the name of the active substance contained in the product; is the INN (International Nonproprietary Name) or, if an INN does not exist, the usual common name.

An umbrella segment of an invented name is a section of invented name that is used in more than one medicinal name to create a brand or range of products.

Qualifiers are relevant words or parts of words (abbreviations) that have an information content that is closely related to a medicinal product.

3. Criteria Used in Assessing the Suitability of Invented Names for Use in Veterinary Medicines

3.1 General Criteria

3.1.1 The same invented name must be used during a "Line-extension" application.

3.1.2 Obtaining a trademark for the proposed trade name is not considered justification for accepting a proposed trade name. It should be highlighted that the issue of whether a particular invented name will or may constitute an infringement of another entity's intellectual property rights cannot be one of the EDA's concerns and is therefore not taken into account in the consideration of the acceptability of a proposed invented name.

3.1.3 An invented name for a medicinal product shall primarily consist of one word.

3.1.4 An invented name must not be liable to confuse with INN names of active substances.

3.1.4 The invented name cannot be too general like "Analgesic tablets".

3.1.5 The invented name of a medicinal product should not be comprised wholly of initial letters (acronyms) or abbreviations nor include punctuation marks.

3.1.6 The invented name should not be a real word, i.e. have a meaning, including known names, and it should not be significantly similar to the known word in English or in other language (e.g. Galaxxy). Exception to this rule is that the name of a medicinal product can include a registered trademark or the name of the marketing authorization holder.

3.1.7 The invented name must not consist of a proper noun (personal name or place name).

3.1.8 The invented name of a medicinal product should not be offensive or have an inappropriate connotation.

3.1.9 The strength

- Different strengths of the same medicinal product should be expressed in the same unit: for example, 250 mg, 500 mg, 750 mg, 1000mg, and NOT 1g.
- Trailing zeros should not appear (5 mg and NOT 5.0 mg) as it is easy to miss the decimal point and dispense a tenfold overdose (administering 50 mg instead of 5 mg).

- Use of leading zero (ex: 0.5 not .5).
- For safety reasons, it is important that 'microgram' is not abbreviated. The abbreviation **mcg** rather than **µg** should be used in cases where this cannot be accommodated on a small label (e.g., vial label). The use of common error-prone abbreviations in a proprietary name may be misinterpreted and therefore should generally be avoided. (www.ISMP.org/tools/errorproneabbreviations.pdf)
- Numbers without units of measure should not be used to express product strength.
- The strength can be expressed in weight, weight per unit volume or weight, or in percentage. However, Expressing the product strength as "%" is not endorsed. Single dose or multiple dose container has an impact on the expression of the strength.
- The declared dosage should correspond to the dosage of the innovator.
- Whole numbers should be used whenever possible. Fractional strengths can be more error-prone and confusable, a situation that must be considered when new strengths are added to existing product lines.
- Use a thin space, rather than a comma, to separate digits into groups of three (e.g., 10 000).

3.2 Safety concerns

3.2.1 The invented name of a medicinal product should not have potential look-alike and sound-alike (LA/SA) similarity, which could cause confusion in print, handwriting or speech with the invented name of another medicinal product or common name or excipient.

3.2.2 Since the beginning and end of a word are most memorable, a similarity between the beginning and the end of names is particularly important.

3.2.3 Name attributes:

- ✓ When assessing the potential for a confusion between two names the criteria present in **Appendix 2** should be considered.
- ✓ An important aspect of the evaluation procedure is the assessment of phonetic and orthographic similarity with other invented names using specialized software (POCA).

- ✓ The first part of the drug name plays a significant role in contributing to name confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are a major contributing factor in the confusion of drug names.

3.2.4 Product attributes:

- ✓ In addition to similarity of the names, similarity in the product characteristics between two products may increase the risk of confusion and should be systematically assessed by applicant.
- ✓ These product characteristics include:

• The indication(s);

• Target species;

• The pharmaceutical form(s);

• The route of administration(s);

• The strength(s);

• The setting for dispensing and use;

• The legal status/classification for supply (i.e. medicinal product subject to medical prescription, medicinal product not subject to medical prescription, medicinal product subject to restricted or special medical prescription).

• (Potential) New pharmaceutical forms and/or routes of administration and/or target species for the medicinal product concerned as well as for the other medicinal products with a similar invented name, as appropriate.

• Assessment of potential for harm to the animal in case of a mix-up.

Example: the degree of similarity in names is no longer acceptable, e.g. in the case of two oral dosage forms with active substances which are contraindicated for one another.

3.2.5 The invented name of a medicinal product should not include the full invented name or significant portion of another medicinal product. Exceptions may apply on a case-by-case basis depending on the potential for confusion and the level of similarity identified.

3.2.6 The invented name should not incorporate medical abbreviations (e.g., QD, BID) or others commonly used for prescription communication because the incorporation of such Abbreviations could inadvertently be a source of error.

3.2.7 The invented names should not be similar or allude to the name of pharmaceutical companies. They should not be misleading in regards to the MAH of the product.

3.2.8 The invented name of a medicinal product should not convey a promotional message. An invented name is considered promotional if it makes claims relevant to:

- Overstatement of product efficacy.
- Minimization of risk.
- Broadening of product indication.
- Unsubstantiated superiority claims.
- Being overly fanciful.

For example, a proposed proprietary name for a chronic disease contains or sounds like "cure," it would overstate the clinical benefit by misleadingly implying that the product can cure the chronic condition.

3.2.9 The invented name of a medicinal product should not be misleading with respect to the qualitative or quantitative composition, or the pharmaceutical form. Applicants should consider the future life-cycle of the medicinal product, and post-authorisation changes which may lead to discrepancies between the product profile and the invented name.

- The invented name is misleading with respect to the composition and therapeutic effects of the medicinal product if it is too similar to or derived from the name of an ingredient which is not contained in the product, or if the name contains an INN stem

reserved by the WHO Council for a group of substances into which the active substance contained in the product does not belong.

- The invented name is misleading with respect to the therapeutic effects of the medicinal product if it contains indications which are not described in the Summary of the Product Characteristics, or it highlights only one of many indications or target species.

- If the medicinal product contains more than one active ingredient, the invented name should suggest all the ingredients, not just some of them, or it may be considered misleading.

3.2.10 The invented names that look or sound like other medical terms, diagnostic tests should be avoided.

3.2.11 Applicants should consider the phonetic characteristics of an invented name and the potential difficulties in pronunciation. Ex.:

- The name should be easy to pronounce.
- The use of repeated vowels or consonants in the prefix of the invented name should in principle be avoided.
- Very short invented names composed of, for instance, a string of vowels or consonants may be inappropriate to identify medicinal products.
- In addition, applicants should give due consideration to any other element which may hamper readability and identification of the product.

3.2.12 If the invented names are considered too long to be accommodated on very small Containers, they may be rejected.

3.2.13 The invented name of a medicinal product should not incorporate product-specific attributes such as:

- Dosing intervals (e.g. NameBID).

- Dosage form (e.g. NameTab).

- Route of administration (e.g. Nameoral).

- Manufacturing characteristics (e.g. “NameLyophylized”).
- Target Species (eg: “NameChick”).

Avoiding the suggestion of a product-specific attributes such as target species, dosage form or route of administration in the name will enable a company to use the same invented name for future dosage forms of the product without making the invented name misleading. For flexibility in product development, it may be advisable to limit the inclusion of such attributes in the proposed proprietary name. If considering a proprietary name that includes or refers to product-specific attributes, sponsors should be mindful that future changes, such as changes in dosage form or route of administration, could render the root proprietary name inaccurate and thus unusable for future formulations.

3.2.14 The name of the medicinal product should not be identical with the names of human medicinal products, food supplements, cosmetic products or other products.

3.2.15 We discourage sponsors from proposing proprietary names that consist of a mixture of letters or numbers placed together (e.g., IVS458). Such names may not be understood as drug names that are typically composed of letters only, or they could be misconstrued as another element associated with the drug product or prescription, such as dose or route of administration. Names constructed in this manner could lead to medication errors depending on the nature of the misinterpretation.

3.2.16 However, even though the name of the medicinal product had been previously assessed as not liable to confusion for a specific pharmaceutical form, it does not mean that it will be automatically acceptable for another pharmaceutical form because such a name – from a practical point of view – may have different parameters when assessing the potential for confusion.

3.2.17 Incorporation of Company’s Name:

- Invented name should not incorporate the manufacturer’s full name or part of the name across multiple products, as this may increase the similarity of invented names by the same company (e.g., “ABCName1,” “ABCName2,” “ABCName3”).

3.2.18 Use of Symbols:

- EDA discourages applicants from using symbols (i.e., "+" or "&") to link components in invented names because symbols can be misinterpreted or confusing (e.g., "+" can be read as "4"). Therefore, EDA encourages using words rather than symbols.
- Other symbols (-, =, *, #, „®", „©", „™ etc.) are not acceptable.

3.3 Use of International Nonproprietary Names (INN) in invented names.

3.2.5 Applicants are advised to take into consideration World Health Organisation (WHO) resolution (WHA46.19), where appropriate, i.e. "It would therefore be appreciated if invented names were not derived from international non-proprietary names (INNs) and if INN stems were not used in invented names". Applicant are strongly advised to take account of WHO recommendations that invented names should not be derived from INNs, especially an INN stem. Hence, the substantial closeness of the medicinal product name either in speech, print or handwriting with its own or a different INN is not endorsed.

3.3.2 The invented name should not incorporate INN stems in the position that WHO Council designates for the stem (e.g., Drugofenicol contains the stem "-fenicol" in the position that WHO Council designates for that stem) as this 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.

In rare circumstances, it might be acceptable to include INN stem in the WHO-designated position within the proposed invented 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 WHO.

3.3.3 The use of a two letter INN stem in an infix or suffix position in an invented name will be addressed on a case by case basis.

3.3.4 The Applicant is expected to review INN similarity or INN stem inclusion use before requesting that the proposed invented name(s) be considered.

3.3.5 Applicants should screen proposed invented names against the stem list created by the WHO Council to ensure INN stem is not present in the stem position in the invented name.

https://extranet.who.int/soinn/

https://www.who.int/teams/health-product-and-policy-standards/inn/stembook

https://poca-public.fda.gov/usan_search

3.3.6 Where the Applicant wishes to use the INN or common name:

- The INN or common name should be together with the name of the MAH (MAH name must comply with that mentioned in Commercial register). The company has two options to include MAH name with the common name:

  - MAH name beside the common name:
    INN/Common name-MAH name

  - MAH name below the common name:
    INN/Common name
    MAH name

- The name of the MAH cannot be an acronym, unless it is a company trademark registered as such, which clearly refers to and helps identify the applicant/MAH. The applicant should be able to confirm ownership of this trademark
- The INN name and the MAH name cannot be used together in a single word (ex: Xtiamulin).
- In case the active substance is present in authorized products in one form only, it is not necessary to distinguish the names by specifying the particular salt in the name of the medicinal product.
- In case the active substance is present in authorized products in more than one form (base, salt, ester), EDA recommends that common names of medicinal products containing various forms of the active substance are distinguished by specifying the particular salt/form of the active substance in the name of the medicinal product.
  E.g. 'active substance sodium XX mg tablets' rather than 'active substance XX mg tablets'
- The generic name used should relate to the strength:

  - ✓ If the strength is stated in relation to the base, the generic name of the base should be used.

- ✓ If the strength is stated in relation to the salt, the generic name of the salt should be used.

- Avoid abbreviations of salts when used at the beginning of a product name to avoid misinterpretations. **For example**, the abbreviation Na Salicylate to abbreviate Sodium Salicylate should be avoided. However, the abbreviation HCl for hydrochloride at the end of a name does not raise concern.
- There are circumstances where the EDA will insist on an invented name rather than an INN name. This is due to the risk to patients from interchanging between products containing the same active substances but having different bioavailabilities, leading to potential differences in therapeutic effects and safety. In such cases, it is important to distinguish between these products otherwise having the same drug content. Examples include:

  - Prolonged-release products
  - Some locally-acting products
  - Critical care medicines with a narrow therapeutic window of safety and efficacy.
  - When there in general is a need to differ products with different properties

- In case of a fixed combination of two or more active substances:
  - ✓ EDA recommends separating the names of the active substances in the common name of the medicinal product with a slash (/).
  - ✓ If the strength of individual components of the fixed combination product is expressed in units of volume, EDA recommends separating them in the expression of strength (as part of the full product name) with the symbol plus (+).

Examples:

Acceptable:

Tulathromycin/Ketoprofen MAH followed by the strength 100 mg/120 mg
Tulathromycin/Ketoprofen MAH followed by the strength 100 mg/mL + 120 mg/mL

Nonacceptable:

Tulathromycin + Ketoprofen MAH 100 +120 mg

Tulathromycin-Ketoprofen MAH 100/120 mg/mL

3.4 Criteria Used in Assessing the Acceptability of Umbrella Segments of Product Names:

3.4.1 An umbrella segment of an invented name is a section of invented name that is used in more than one medicinal name to create a brand or range of products.

3.4.2 Where an umbrella segment is proposed to be used for more than one product, the umbrella segment should not be used if its use is likely to result in safety or efficacy concerns resulting from confusion between the products sharing the same umbrella segment. and applicants are encouraged to develop new product names without umbrella segments for each product. Such concerns may arise, for example:

– if the products contain different active ingredients;

– if the products can be used in different populations;

– if their safety profile is different in different populations.

– if their interactions are different;

– if their features of and treatment for overdose are different;

– if their speeds of onset are different.

3.4.3 The first name (used/authorised for the first time) should be without any qualifier.

3.5 Criteria Used in Assessing the suitability of qualifiers /abbreviations:

3.5.1 Qualifiers are relevant words or parts of words (abbreviations) that have an information content that is closely related to a medicinal product.

3.5.2 Invented names and qualifiers should always be separated by a space.

3.5.3 Proposed qualifiers should not consist of a single letter or number (Arabic and Roman), because they may be confused with the strength and/or posology of the medicinal product. Numbers in general should only be used to indicate the strength of the

medicinal product. In certain cases, a number(s) may form part of a qualifier; however, this would be assessed on an individual basis.

3.5.4 The following should be taken into account when proposing a qualifier/abbreviation:

- Whether the qualifier/abbreviation provides further information on characteristics of the medicinal product (e.g. duration of action, device, route of administration, composition, patient population) or provides for a differentiation, which may help healthcare professionals and/or patients to prescribe/select the appropriate medicinal product.

- The potential risk to public health in case of a medication error potentially related to the qualifier/abbreviation versus the potential risk resulting from a more complex name or completely different name should be assessed.

- The EDA strongly encourages applicants to develop new product names without umbrella segments for each new product. The proliferation of multiple products with similar but not always identical active substances using connected names may result in confusion among healthcare professionals and possible inappropriate use of these medicinal products.

- The umbrella segment should not be used for a different product where there is a significant difference in active substance(s).

3.5.5 Applicants should provide in all cases an explanation on the inclusion of the qualifier.

Examples:

Comp, compositum, comb, Plus, Extra (contain more than one active ingredient)

Duo (contain two active ingredients)

Forte (higher dose than other medicinal products in a product range)

Small dogs-Medium dogs-Big dogs

LC (for preparations for intramammary use in cattle during lactation)

TS or DC (for preparations intramammary use in non-lactating cattle)

For prolonged release preparation:

CR – Controlled release.

LA – Long acting.

PR – Prolonged release.

SA – Sustained action.

SR – Sustained release.

XR – Extended release.

XL – Prolonged release, once daily dosing.

MR – The use of MR for a prolonged release preparation is no longer recommended. Modified release can indicate a gastro-resistant product or a prolonged release product, therefore the term is not specific for an individual product.

For Gastro-resistant Preparations:

EC – Enteric Coated.

GR – Gastro Resistant.

4 Reuse of Invented Names:

4.1 If a medicinal product has never been marketed, its name can (after cancellation/name change) be used for another medicinal product.

4.2 If a medicinal product was on the market, the name can usually be reused five years after its cancellation/name change, unless it is a well-known name which, due to its level of awareness, could lead to a misleading assumption (active substance,

indication...). EDA shall always consider the time for which the product has been on the market, how well it has been known to the public, what risks might arise from potential confusion of the products.

4.3 The use of a product name that may be confused with the name of a product whose marketing authorisation has been revoked or a product that has been recalled from the market, when products with identical active substance, identical or very similar indications, contraindications, interactions, etc. are concerned, is possible. EDA shall always consider what risks might arise from possible product confusion.

4.4 Where a product with an older name has never been placed on the market, its name may be used also for another active substance (and another MAH), if other rules specified in this guideline are met.

5 Post-authorisation issues related to invented names

5.1 Applicants should consider the future life-cycle of the medicinal product and post-authorisation changes which may lead to discrepancies between the product profile and the invented name. Changes to key aspects of the product profile which may have an impact on the acceptability of a name should be communicated by EDA Veterinay Naming Unit.

5.2 Medication errors resulting in dispensing and administering the wrong drug can occur when an invented name for a product marketed in Egypt is identical, or nearly identical in spelling and pronunciation, to the invented name of a foreign product containing an entirely different active ingredient marketed only in a foreign country.

5.3 If a marketed product's trade name causes medication errors, the company should work with EDA to resolve the situation. If the product does not comply with applicable requirements and the company is unwilling to resolve the issue, the company may be subject to enforcement actions.

6 For Imported medicines:

The name of imported medicine must be identical as the name in the country of origin. The name must not be translated unless it contains a word belonging to one of the national languages.

6. References

1- Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure.

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-acceptability-names-veterinary-medicinal-products-processed-through-centralised-procedure_en.pdf

2- CVM GFI #240 Proprietary Names for New Animal Drugs.

https://www.fda.gov/media/111947/download

3- Guideline on the acceptability of names for human medicinal products processed through the centralized procedure, EMA/CHMP/287710/2014-Rev. 7.

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure_en.pdf

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5- SFDA Guidance for Naming of Medicinal Products Version 2.1.
https://www.sfda.gov.sa/en/regulations/65966

6- Best Practices in Developing Proprietary Names for Human Prescription Drug Products (2020).
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry

7- REG–29 version 4 Guideline on Assessment of Acceptability of Medicinal Product Names for the Purposes of Marketing Authorisation Procedure. https://www.sukl.eu/medicines/reg-29-verze-4

8. PDUFA Pilot Project Proprietary Name Review – Concept paper, September 2008.
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11. QRD recommendations on the expression of strength in the name of centrally authorised human medicinal products.
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/quality-review-documents-recommendations-expression-strength-name-centrally-authorised-human_en.pdf

12. WHO official website.
https://www.who.int/teams/health-product-and-policy-standards/inn

13. American Medical Association.
https://www.ama-assn.org/about/united-states-adopted-names/usan-council

14. Law no.127 for year1955.
15. Guideline for the naming of medicinal products (Norwegian Medical Products Agency)
https://www.dmp.no/en/approval-of-medicines/approval-and-follow-up-of-marketing-authorisation-ma/relevant-information-regarding-approval-and-maintenance-of-the-MA/guideline-for-the-naming-of-medicinal-products

16. Naming of medicines (Danish Medicines Agency)
https://laegemiddelstyrelsen.dk/en/licensing/licensing-of-medicines/naming-of-medicines/

Appendix 1 - Screening Checklist for Proposed Name

- This checklist does not include all the potential concerns discussed in this guidance regarding the selection of an appropriate invented name.
- Answering yes to any of these questions indicates a potential area of concern that should be carefully evaluated as described in this guidance.

1. Is the proposed name obviously similar in spelling and pronunciation to other names?

Proposed names should not be similar in spelling or pronunciation to invented names, established names, or ingredients of other products.

2. Is there a INN stem in the proposed name?

Proposed names should not incorporate a INN stem in the position that WHO designates for the stem.

3. Is the proposed name is misleading with respect to the therapeutic effects and composition?

Proposed names is misleading in the following cases:

- If it contains indications which are not described in the Summary of the Product Characteristics, or it highlights only one of many indications or target species.
- If the medicinal product contains more than one active ingredient, the invented name should suggest all the ingredients, not just some of them.
- if it is too similar to or derived from the name of an ingredient which is not contained in the product.

4. Is the proposed name of a medicinal product should incorporate product-specific attributes?

It should not incorporate product-specific attributes as Dosage form, Route of administration, target species, and Dosing intervals.

5. Is the proposed name a real English word?

It should not be a real English word.

6. Is The name of the medicinal product identical with the names of human medicinal products, food supplements, cosmetic products or other products?

It should not be identical with the names of human medicinal products, food supplements, cosmetic products or other products

7. Is the proposed name incorporate the manufacturer's full name or part of the name across multiple products?

As this may increase the similarity of invented names by the same company (e.g., "ABCName1," "ABCName2," "ABCName3").

8. Does the proposed name of a medicinal product convey a promotional message?

The proposed name should not convey a promotional message such as overstatement of product efficacy, minimization of risk, broadening of product indication, unsubstantiated superiority claims, or being overly fanciful.

9. Are inert or inactive ingredients referenced in the proposed name?

Proposed 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.

10. Is the proposed name of a discontinued product?

Invented names should not use the proposed name of a discontinued product.

11. Are there medical or other abbreviations in the invented name?

Invented names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or any abbreviations.

Appendix 2 – Criteria Used to Identify Product Names that Look or Sound Similar to a Proposed Invented Name

This should not be considered as an exhaustive list.

Look-alike	- Identical prefix - Identical infix - Identical suffix - Length of the name - Similar spelling Length of the name - Upstrokes (e.g. ‘h’, ‘l’, capital and lower case e.g. ‘P’, ‘d’) in similar locations. - Down strokes (e.g., ‘p’, ‘q’, ‘y’) in similar locations. - Cross-strokes (e.g., ‘x’, ‘t’) in similar locations. - Dotted letters (e.g., ‘i'). - Ambiguity introduced by scripting letters (many letters look similar when scripted, e.g. ‘P’ may appear as 'B', 'D', or 'R'; lower case 'r' may appear as 'e', 'v' or 'l'; lower case 'a' may appear as any vowel; lower case 'x' may appear as lower case 't', 'f' or 'y' etc.). - Same letters but in different order (e.g., Termix and Trevisc - the "er" and "re" can be interpreted as the same and do not provide protection from name confusion). - First letter and/or sound is identical. - Last letter is identical. - Number and position of the common letters. - Number of distinguishing letters (i.e. letters not in common).
Sound-alike	- Identical prefix - Identical infix - Identical suffix - Same number of syllables - Similar Stresses (e.g., Trycel and Triafil have similar stresses: TRY-cel and TRIA-fil; try-CEL and tria-FIL). - Placement of vowel sounds is similar (e.g., 'e' may sound like 'a' or 'i'; 'i'

	may sound like 'a' or 'e'; 'a' may sound like 'e' or 'i' etc.) - Placement of consonant sounds is similar (e.g., 'n' may sound like 'm', 'dn', 'gn', 'kn', 'mn', 'pn'; 't' may sound like 'd', 'b' or 'pt' etc.) - First letter and/or sound is identical. - Last letter is identical.

Document History

Items	**4th Version**	**5th Version**
Appendix 1 – Screening Checklist for Proposed Name	------	added
Appendix 2 – Criteria Used to Identify Product Names that Look or Sound Similar to a Proposed Invented Name	------	added
3.3 Use of International Nonproprietary Names (INN) or United States Adopted Name (USAN) in invented names.	3.3 Use of International Nonproprietary Names (INN) or United States Adopted Name (USAN) in invented names.	3.3 Use of International Nonproprietary Names (INN) in invented names.