FOOD AND DRUGS AUTHORITY

GUIDELINE FOR NAMING OF MEDICAL DEVICES

Document No. : FDA/MCH/MDD/GL-NMD/2019/01
Date of First Adoption : DECEMBER 01, 2020
Effective Date : JANUARY 04, 2021
Version No. : 01

TABLE OF CONTENTS

1.0. Introduction

This guideline is developed in line with Section 118 subsection 8 of the Public Health Act, 2012 (Act 851) which states as follows that a product name should not;

a) constitute a safety hazard,

b) be misleading,

(c) be established or based on international non-proprietary names, or

(d) stems from a related substance or for any other sufficient reason determined by the Authority

One of the most possible outcomes of inappropriate product name has been associated with unsuitable use of the product, unclear label abbreviations, acronyms and improper labeling and packaging designs. This guideline is developed in order to provide applicants with clear guidance on naming for their medical devices in line with acceptable international standards.

The FDA may therefore request changes to a brand name, if found to:

a) Be unsafe
b) Misbranding
c) Bears close resemblance to a registered product
d) mislead as to the composition of the product or the use

Approval of the name does not imply that the marketing authorization holder is absolved of any responsibility in the incidence that actual or potential adverse reactions occur due to the brand name.

ACRONYMS

US FDA*:* United States Food and Drugs Administration

FDA*:* Food and Drugs Authority

MAH*:* Marketing Authorization Holder

INN: International Non-proprietary Name

WHA: World Health Assembly

WHO: World Health Organization

2.0. Scope

This guideline is applicable to all classes of medical devices as well as combination products.

The principles outlined in this guideline are also applicable to applications for variation of names of registered medical devices.

3.0. Acknowledgments

This guideline was developed based on:

1. The US FDA's Good Guidance Practices document.
2. European Medicines Agency's Guideline on the acceptability of names for human medicinal products processed through the centralized procedure
3. FDA Medical Devices Guidelines

4.0 Criteria applied when reviewing proposed brand names

The criteria listed below should be seen as general principles.

Applicants should ensure that the proposed name complies with the criteria outlined in this guideline before submitting an application for name reservation or marketing authorization. Requirements and considerations taken during review are outlined hereafter: -

4.1 Safety concerns and other public health concerns in brand names

4.1.1.1 The brand name of a medical device should not be liable to cause confusion in print, handwriting or speech with the brand name of another device.

When assessing the potential for such confusion, the following aspects are considered:

i. The indication(s);

ii. The class of medical device

iii. The type of medical device

iv. Radiation emitting medical devices

v. Medical devices for special medical condition

vi. The degree of similarity *versus* the potential for harm to the patient in case of mix-up.

4.1.1.2 It should be noted that the FDA will consider potential for confusion of proposed brand names with already registered brand names of authorized, suspended and revoked/withdrawn products as part of the review process. Also, the proposed brand name of the Medical device must not bear close resemblance to the generic name.

4.1.1.3 When considering potential for confusion with the name of a withdrawn/revoked marketing authorization, in principle, a period of 3 years should have elapsed after the official invalidity of the marketing authorization (e.g. publication in the national gazette notice, FDA website, etc.). This period could be reduced to 1 year if the product withdrawn/revoked/cancelled was not marketed after registration.

4.1.2 The brand name of a device should not convey misleading connotations. Examples of false representation are:

i. Incorrect, inadequate or incomplete identification

ii. Use of prefix 'FDA' or other similar indication suggesting Government agency approval or endorsement of the product.

4.1.3 The brand name of a medical device should not be misleading with respect to the following:

i. Ambiguity, half-truth and trade puffery

ii.

iii. Expressions of opinion or subjective statements

iv. Deceptive pictorial matter

v. Misleading testimonials

vi. Misleading list of parts or components

4.1.4 Consideration should be given to the phonetics and the potential difficulties a proposed brand name may create in terms of pronunciation in the official language of Ghana.

4.1.5 The brand name should not convey a promotional message with respect to the therapeutic and/or pharmaceutical characteristics and/or the composition of the product.

4.1.6 The brand name should not be offensive or have an inappropriate connotation in any of the official Ghanaian languages.

4.1.7 The brand name should not convey or suggest a spiritual association or be comparative or superlative in any way.

4.1.8 The brand name should not comprise wholly of initial letters (acronyms) or code numbers or include punctuation marks.

4.1.9 The importance of other elements such as labelling and pack design should be taken into consideration as contributing factors for the safe use of a medical device. These aspects should be discussed at the time of the review of mock-ups. The following are examples where labelling and pack design may play a role in the final decision of acceptability of brand names: -

a) The actual display of a brand name in the printed material may increase the level of similarity between two brand names or may convey a misleading connotation.

b) The labelling and pack design may support the meaning of a qualifier which otherwise would have been rejected.

4.2 Product specific concerns in proposed brand names

4.2.1 For non-prescription products, the use of qualifiers/abbreviations within the brand name should aid selection/identification/differentiation of the product by the patient and should minimize the risk of inappropriate use.

In order to help self-selection and compliance by patients/consumers, it is acceptable that brand names have a positive connotation and/or be informative; labelling and pack design could be considered as contributing factors to this end. Carton and container labels are particularly critical for over-the-counter products.

4.2.2 Where the Applicant wishes to use instead of the brand name the common name or scientific name, together with a trademark or the name of the marketing-authorization holder/applicant, they should take into account the following rules: -

4.2.3 The brand name of a fixed combination product should be sufficiently different from those of the individual active substances and/or those of other fixed combinations containing the same active substance(s).

The whole brand name of individual active substance(s) should not be inserted into the proposed brand name for the fixed dose combination.

4.2.4 As multiple applications can have an independent life (e.g. may develop a different indication at a later stage), the proposed brand names of such applications should not lead to confusion.

5.0 Regulatory aspects related to the acceptability of proposed brand names

Brand names for variation/extension/ applications should be the same as those of the existing medical device. The addition of a qualifier to an already approved brand name constitutes a different brand name, **which would require submission as new marketing authorization application.**

In case the applicant wants to submit a separate marketing-authorization application for, e.g., a new indication, a different brand name shall be used.

The FDA may request the MAH to change the brand name of an already approved product if the approved brand name is deemed inappropriate.

5.1 Change of the brand name

The brand name can also be changed at a post-authorizations stage through an application for variation if the MAH wishes to change the name.
Post-authorizations procedural requirements are outlined in the FDA Guidelines on Variations of medical devices.

6.0 References and useful websites

1. Guideline on the acceptability of names for human medicinal products processed through centralized procedure

2. WHO website: http://www.who.int/en/

3. FDA Guidance on Safety Considerations for Product Design to Minimize Medication Errors: Guidance for Industry

4. The US FDA's Good Guidance Practices document