Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Guideline for Variation on Products Classification Application

OPS-G-003-V1-231126

Guideline for Variation on Products Classification Application

Version 1.0

Operations Sector

Saudi Food & Drug Authority

Kingdom of Saudi Arabia

For comments on guidance:

Classificationfeedb@sfda.gov.sa

For products classification requests:

PCS@sfda.gov.sa

Saudi Food & Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed.

Document Control

Version	Author	Date	Comments
1.0	Products Classification Department	29/11/2023	Final

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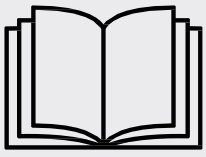

1.Introduction

1.1. Objectives

SFDA provides an electronic-Products Classification service (ePCS) in order to assist stakeholders to classify products easily with a view to achieve greater consistency, transparency and quality of classification decisions related to their products. However, there are some queries raised by applicants who wish to make variations on the classification application, in which some may affect the classification decision.

Therefore, SFDA has developed this guideline to assist applicants on the details of the various categories of variations, which affect the classification request and to provide recommendations on the preparation of the variation application. It is important to note that the SFDA reserves the right to request any additional information and data not specifically described in this document, in order to assess adequately the classification request. Moreover, Applicants should be aware that deficient, redundant or irrelevant information documentation could lead to rejection of the application.

1.2. Scope

This document applies to change(s) made to product classification requests that are under study by the Products Classification Department (PCD) in the Saudi Food & Drug Authority (SFDA).

2. Type of Variations:

The variation can be categorized into two categories:

Type A: Minor variations

Such minor variations does not affect the classification decision, neither require reclassification; however, a notification letter for variation could be submitted to PCD either via **pcs@sfda.gov.sa** or through the electronic Products Classification System (ePCS).

Type B: Major variations

Such major variations, which may have a significant impact on the classification decision and require a new classification request.

In order to facilitate the classification of variation, examples listed in appendix below are explicitly define the various types of changes.

Appendix 1:

Example of some major changes and most minor changes; which are categorized by the type of change

Type of variation	Examples	Documentation

A Minor	• Change in the administrative information such as:
	  - Name and/or address of the manufacturer
	  - Transfer the product to new marketing authorization holder (different legal entity)
	• Change in the name of the product
	• Change in the name of the active substance (if available)
	• Change in the pack size or container type
		An optional notification letter

B Major	• Change in the product's label or artwork information other than those listed as type A variation • Change in the compositions of the product (if available) • Change in the concentration of the compositions (if available) • Change in the mode of action of the product • Change in the mode of action of compositions (if available) • Change in the intended use and/or claim • Change in pharmaceutical form and rout of administration (if available) • Change in Instruction For Use (IFU) (if available)	**A new classification request****
** Please refer to Products Classification Guidance for information on how to submit a classification request		

Appendix 2

Comments on Variation on Products Classification Application

Please submit comments to the following E-mail: Classificationfeedb@sfda.gov.sa			
SN.	Item No.	Item text	Proposed Amendment
1			
2			
3			
4			
5			
6			
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8			
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10			

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