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GUIDANCE DOCUMENT

Classification of Products at the Cosmetic-Drug Interface



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GUIDANCE DOCUMENT

**Classification of Products
at the Cosmetic-Drug Interface**

**Health Products and Food Branch
Health Environments and Consumer Safety Branch**

FOREWORD

Guidance documents are meant to provide assistance to industry and professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

This Guidance Document is an interpretation of the *Food and Drugs Act*, the *Food and Drug Regulations*, the *Cosmetic Regulations*, and the *Natural Health Products Regulations* and provides a principled approach on the classification of products at the cosmetic-drug interface.

This document should be read in conjunction with other applicable guidance documents.

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1.0 INTRODUCTION

1.1 Objective

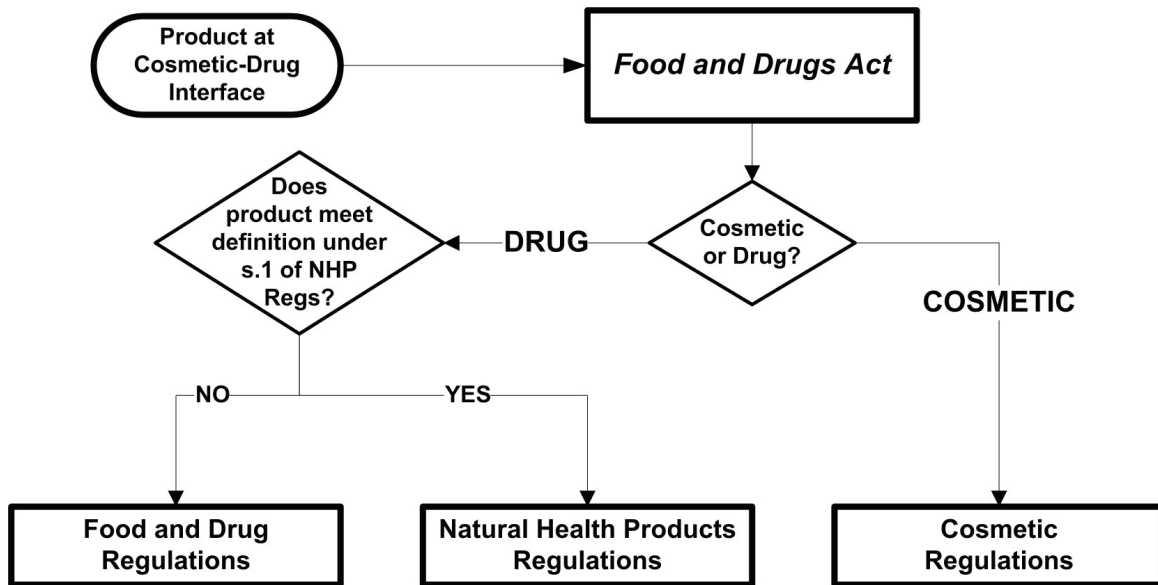
In Canada, personal care products are regulated under the *Food and Drugs Act*. Depending on how the product is represented for sale and its composition, a personal care product could fall under one of three sets of regulations under the Act: the *Cosmetic Regulations*, the *Food and Drug Regulations* or the *Natural Health Products Regulations*.

The purpose of this guidance document is to provide an understanding of the factors that guide classification decisions by Health Canada in relation to external use products which may share characteristics of both ‘cosmetic’ and ‘drug’, as currently defined under the *Food and Drugs Act*. The criteria identified in this document outline the decision-making process in determining the appropriate regulatory regime that applies to a given product at the cosmetic-drug interface (PCDI), being sensitive to stakeholders’ interests but without compromising health and safety standards. This guidance document is in keeping with international practices of documenting approaches to classification decisions.

The criteria in the document are clarified with the intent to increase consistency in decisions by regulators, and to make decisions more predictable to stakeholders. This document is intended to be used in conjunction with other regulatory tools (e.g. guidance, policies, regulations, legislation, etc.).

Under the current *Food and Drugs Act*, natural health products are considered to be a subset of “drugs” and are defined as a substance set out in Schedule 1 of the *Natural Health Products Regulations*, a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; b) restoring or correction organic functions in humans; or c) modifying organic functions in humans, such as modifying those in a manner that maintains or promotes health. These products are regulated under their own set of regulations, the *Natural Health Products Regulations*, which came into force in 2004. In this guidance document, when applying the criteria for cosmetic vs. drug, the term “drug” includes natural health products. The scope of this guidance is not intended to assist in the determination of whether a drug is further sub-classified as a natural health product.

The following diagram illustrates the regulatory regimes defined by the *Food and Drugs Act*:



1.2 Definitions

cosmetic (Section 2 of the *Food and Drugs Act*):

any substance or mixture of substances manufactured, sold or represented for use in cleaning, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.

drug (Section 2 of the *Food and Drugs Act*):

includes any substance or mixture of substances manufactured, sold or represented for use in

- the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- restoring, correcting or modifying organic functions in human beings or animals, or
- disinfection in premises in which food is manufactured, prepared or kept;

natural health product (Section 1 of the *Natural Health Products Regulations* pursuant to the *Food and Drugs Act*):

a subset of drugs pertaining to medicinal ingredients of natural origin, defined in the *Natural Health Products Regulations* as "a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- (b) restoring or correcting organic functions in humans; or
- (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.”

The following two terms are not defined within existing legislation and have no official status. They are used merely as descriptive terms for the purposes of classification.

personal care product (PCP):

For the purposes of this document, defined as a substance or mixture of substances which is generally recognized by the public for use in daily cleansing or grooming. Personal care products may fall into one of three regulatory categories in Canada: cosmetics, drugs or natural health products.

product at the cosmetic-drug interface (PCDI):

A subset of personal care products, which are not easily distinguished as either a drug or cosmetic, as defined in the *Food and Drugs Act*.

The following are the programs within Health Canada that regulate personal care products.

NHPD: Natural Health Products Directorate (Health Products and Food Branch)

PSD: Product Safety Directorate (Healthy Environments and Consumer Safety Branch)

TPD: Therapeutic Products Directorate (Health Products and Food Branch)

1.3 Scope and Application

The classification approach taken in this document applies to a broad range of products at the cosmetic-drug interface. It is recognized that at a minimum, these products are perceived to have cosmetic attributes such as cleansing, improving or altering the complexion, skin, hair or teeth. These products may also have claimed or inherent drug attributes. Examples of these types of products include anti-dandruff shampoos, skin whiteners, antiperspirants and sunburn protectants. Depending on their representation for sale and composition, one of three sets of regulations under the *Food and Drugs Act* may apply.

Health Canada determines product classification using the guiding principles below. In the case where product classification is not immediately apparent, the criteria specified in this guidance will be applied.

Classification decisions apply to all affected products, regardless of their prior regulatory status. No exemptions will be granted based on a product's previous classification as cosmetic or drug.

1.4 Background

In Canada, cosmetics and drugs are regulated under the *Food and Drugs Act*. A PCDI can be regulated by one of three sets of regulations under the Act: the *Cosmetic Regulations* administered by PSD, the *Food and Drug Regulations*, administered by TPD, or the *Natural Health Products Regulations*, administered by NHPD. It is important to note that a product's classification is based on its function, purpose, and representation for use (explicit or implied) as outlined in the definitions of the Act. The regulations under the *Food and Drugs Act* are designed to address known or potential risks for each product category. In instances where the classification of a PCDI is not immediately evident, Health Canada classifies the product as a drug or a cosmetic on a case by case basis, taking into account factors relating to its presentation and composition.

2.0 GUIDING PRINCIPLES

The following principles apply:

1. The primary consideration will be to maintain the protection of public health and safety, consistent with the objectives of Health Canada and the applicable regulatory framework.
2. The definitions of 'cosmetic' and 'drug' in the *Food and Drugs Act* must be respected.
3. Risk alone does not qualify a substance as either a cosmetic or a drug. The regulatory frameworks under the *Food and Drugs Act* provide a tier of controls to mitigate the risks of the many and varied products captured by the definitions.

The distinction between drugs and cosmetics is based on two main factors:

a) **Representations made about the product.** The key consideration for the classification of a product is its proposed claim(s), defined in the Act as "representation for sale". A claim can be a word, a sentence, a picture, a symbol, a paragraph or an implication on product labels, package inserts or advertisements. Together, these claims are used to create a net impression of what the product is and does.

b) **The composition of the product.** Although the composition of a product alone does not necessarily determine its classification, the presence of an ingredient, or its concentration, may make the product unsuitable for classification as a cosmetic or as a drug.

While both factors are important, ultimately the intended purpose of the product takes precedence in the classification decision.

3.0 CRITERIA

Respecting the definitions of ‘cosmetic’ and ‘drug’ in the *Food and Drugs Act*, the following criteria and considerations break down the main factors in order to clarify the analysis and decision-making process. The criteria in Sections 3.1 to 3.3 below are not given equal weight in support of a decision, as some factors may be more important to consider in one circumstance versus another. Not all criteria need be applied if a decision can be reached after the examination of one or a few criteria. In the event that the standard criteria do not lead to a clear decision, supplementary considerations may be taken into account (see Section 3.4). The final decision is dependent on the overall consideration.

3.1 Representation

Is the product represented in a manner suggesting it is used for treating, diagnosing, preventing, or curing disease; or restoring, correcting or modifying organic functions in human beings?

“Representation” includes indications of use, claims presented as a word, a sentence, a picture, a symbol, a paragraph or an implication on product labels, package inserts or advertisements. Further, representations may be explicit or implied.

The *Act* clearly states that a classification decision is made on the definition and the representation for sale of a given product. For drugs, misleading or deceptive claims are general offences under the *Food and Drugs Act*. For cosmetics, a certain degree of discretion and judgement is exercised with respect to “puffery”¹, unless it strays into the therapeutic arena. False or misleading claims for cosmetics are offences under section 7(1) of the *Consumer Packaging and Labelling Act*. Products for which therapeutic claims are made are evaluated as drugs.

Another main distinguishing feature of representation is the aspect of specific dose instructions to ensure efficacy which is generally associated with drug products. Proof of efficacy is

¹ “Puffery” is defined as “hyperbole about a product that does not contain factual claims of merit.” (McGraw-Hill. 2003. *Mass Media Law*. 13th ed.) This is consistent with the international use and understanding of the term.

essential for drugs to ensure that the benefits of use outweigh the risks. There should be no risk from the lack of efficacy of a cosmetic, which are applied on an as-desired basis. This should not be confused with directions for safe use, which are required for all products pursuant to the *Food and Drugs Act*.

Is the product likely to be understood by consumers to have characteristics of a drug?

Perception includes the purpose for which the general public uses the product and whether it is likely to be understood by consumers to have characteristics of a cosmetic or drug. Perception is further influenced by the extent or level of action promised by a product, in addition to the consumer's expectations for the level of regulatory control applied. For example, products claiming benefits comparable to the effects of cosmetic surgical procedures or drugs would be considered therapeutic. To a lesser extent, placement and location of sale may also be taken into consideration. While perception would not be considered the sole basis for a decision, in certain cases, it may have an influence on how a product is used by consumers.

3.2 Composition

Does the product's composition suggest it is an agent for treating, diagnosing, preventing, or curing disease; or restoring, correcting or modifying organic functions in human beings?

A drug exhibits therapeutic or pharmacological activity, such as interacting with a receptor site to achieve a biological response. Modification of an organic function can range from minor to major, which falls within the definition of a drug as per the *Act*. This is determined by the mode of action, which is defined as the means by which a product achieves its intended effect.

Some ingredients are inherently drugs. For example, corticosteroids are internationally recognized as drugs. On the other hand, an ingredient may have a cosmetic function until it reaches a certain threshold, at which point it has a therapeutic or pharmacological effect.

In a case where a product makes a therapeutic representation, there is inherently one or more ingredients in the composition that contribute to this effect. As such, any substance supporting a therapeutic claim for a product is likely to be considered an active ingredient.

3.3 Level of action

Does the product exert solely a superficial effect?

In order to be a cosmetic, the product must exhibit a lack of percutaneous absorption and should not have to be absorbed systemically to achieve the effect. Products that are administered through ingestion, inhalation, or by injection (intramuscular, subcutaneous, intravenous, etc), with the sole exception of tattoo ink, are not considered to be cosmetics.

However, it is generally understood that cosmetics may exert a negligible organic effect which is local and transient. An example of the latter would be a moisturizer which hydrates by adding water to the epidermis.

3.4 Other considerations

The following may also be taken into consideration:

- a) **Inherent risk-benefit balance related to product efficacy.** Risk of a product is generally mitigated under its applicable regulation. If a drug product is not efficacious, it can potentially incur a risk (e.g. an ineffective anti-caries toothpaste creates the risk of developing cavities). On the other hand, if a cosmetic does not demonstrate efficacy, it should not incur an added risk.
- b) **Cases of precedence or past decisions.** While these are to be kept in mind, they should be open to reconsideration in the event of new policies and knowledge.
- c) **Classification schemes of other regulatory authorities.** Health Canada may consider how its global partners classify certain products. This consideration must be tempered by differences in product category definitions, legal systems, and policies, as well as the current regulatory constraints under which Health Canada operates.

4.0 IMPLEMENTATION

The criteria outlined in this guidance document are used by Health Canada to classify various PCDIs in a consistent manner. For any reclassification decisions, a *Product Assessment Against Criteria (PAAC)* will be prepared for stakeholder consultation. Final assessments are communicated to stakeholders via an announcement on the Health Canada website. Any affected product category will undergo an appropriate transition process.

This guidance document may be reevaluated from time to time based on future regulatory or policy amendments.