Clarification on Concentration Ratio Labeling

For the past 20 years, our products have been labeled with an overall concentration ratio of **5:1**. This ratio was based on the relationship between raw material input and final product output—specifically, **5,000 kg of raw herbs** producing **1,000 kg of finished concentrated granules**.

During an **on-site compliance inspection by Health Canada at the end of 2024**, we were advised that, according to current regulatory requirements, the labeled "concentration ratio" must reflect only the **medicinal ingredient**, and should **exclude excipients** such as dextrin. As a result, our previous method of labeling based on total finished granule weight is no longer considered compliant and must be revised.

Based on our actual manufacturing process, the concentration ratio of the medicinal ingredient varies depending on the herb. For example:

- **Astragalus (Huang Qi)**
  From 5,000 kg of raw material, extraction and concentration yield approximately **833 kg of extract** (equivalent to about **6:1**). This extract is then blended with dextrin to produce 1,000 kg of granules.
- **Albizia Flower (He Huan Hua)**
  From 5,000 kg of raw material, extraction yields approximately **500 kg of extract** (about **10:1**), which is then combined with approximately 500 kg of dextrin to form 1,000 kg of granules.
- **Oyster Shell (Mu Li)**
  From 5,000 kg of raw material, only about **250 kg of extract** is obtained (approximately **20:1**), requiring the addition of about 750 kg of dextrin to produce the final 1,000 kg granules.

These examples illustrate that the **actual concentration ratio of the medicinal ingredient varies significantly** among different herbs, and the previously labeled 5:1 ratio did not accurately reflect this distinction.

To comply with regulatory requirements, we are required to **re-register and update labeling for over 1,000 products**, specifying the **true concentration ratio of the medicinal ingredient (excluding excipients)**.

We would like to emphasize the following:

- This change is **for regulatory compliance purposes only**
- **No changes have been made to our manufacturing process**
- **Product formulation and quality remain unchanged**
- **The overall granule usage and dosing remain the same**

Therefore, **there is no need to adjust or reduce the current dosage**. This update does not indicate any increase or decrease in product strength—it simply ensures that our labeling aligns with current regulatory standards.

Per dose unit (1 g / 1 spoon):
Medicinal Ingredient:
Astragalus (Huang Qi) …… 0.8333 g (6:1 extract, DHE: 5 g Dry Herb)

DHE： Dry Herb Equivalent.

1g granule = 5 g Dry Herb regardless of extract ratio.

If you have any questions, please feel free to contact us.

关于浓缩比例标示调整的说明（Clarification on Concentration Ratio Labeling）

在过去二十年中，我们一直将产品的整体浓缩比例标示为 **5:1**。这一比例是基于生产投料与最终成品重量计算得出，即每投入 **5000 公斤原药材**，最终制成约 **1000 公斤科学中药颗粒**，投料与成品比例为 5:1。

在 **2024 年底卫生部（Health Canada）现场合规检查（on-site compliance inspection）**中，监管部门指出：根据现行法规，产品标签中所标示的“浓缩比例（concentration ratio）”应仅针对**药用有效成分（medicinal ingredient）**，而不应包含辅料部分（如糊精）。因此，我们原先以“最终颗粒总重量”计算的 5:1 标示方式需要进行调整。

根据我们的实际生产工艺，不同药材在提取过程中的浓缩比例存在差异，例如：

- **黄芪**：
  投料 5000 公斤，经水提、去渣后，浓缩得到约 **833 公斤浸膏（约 6:1）**，再加入适量糊精制粒，最终得到 1000 公斤颗粒。
- **合欢花（花类药材）**：
  投料 5000 公斤，经提取浓缩得到约 **500 公斤浸膏（约 10:1）**，再加入约 500 公斤糊精制成 1000 公斤颗粒。
- **牡蛎（不易溶出类药材）**：
  投料 5000 公斤，仅提取得到约 **250 公斤浸出物（约 20:1）**，需加入约 750 公斤糊精制成 1000 公斤颗粒。

由此可见，不同药材的**实际药用成分浓缩比例（medicinal ingredient ratio）**各不相同，而此前统一标示为 5:1 的方式，未能准确反映这一差异。

基于监管要求，我们需要对 **1000+ 产品进行重新注册与标签更新**，以明确标示**不含辅料的实际药用成分浓缩比例**。需要特别说明的是：

- 本次调整**仅为标签合规要求**
- **生产工艺未发生任何改变**
- **产品质量与配方保持完全一致**
- **最终颗粒的整体使用方式不变**

因此，**请勿调整或减少现有使用剂量**。本次变更并不代表产品浓度的提高或降低，仅是标示方式更加符合监管规范。

标签上 (per dose unit /1g / spoon) 药物成分： 黄芪 0.8333g (6:1, DHE 5g 生药) DHE:相等于生药材

1 克颗粒 = 5 克生药（不受浓缩比例影响）

如您有任何疑问，欢迎随时与我们联系。

Inspection Exit Notice / Avis de fin d'inspection

Health Canada / Santé Canada

PROTECTED B – PROTÉGÉ B

Categories of Products Included within the Scope of the Inspection / Catégories de produits incluses dans la portée de l'inspection

Natural Health Product / Produit de santé naturel

Categories of Products Excluded from the Scope of the Inspection / Catégories de produits exclues de la portée de l'inspection

N/A

Finished Dosage Forms / Formes posologiques définitives
Activities and Finished Dosage Forms In Scope / Activités et formes posologiques définitives dans la portée

Category / Catégorie	Activity / Activité	Dosage / Posologie	Non-Sterile / Non-Stérile	Sterile / Stérile
Natural Health Product / Produit de santé naturel	Package / Emballer	GRANULES / GRANULES	X	
Natural Health Product / Produit de santé naturel	Label / Etiqueter	GRANULES / GRANULES	X	
Natural Health Product / Produit de santé naturel	Import / Importer	GRANULES / GRANULES	X	
Natural Health Product / Produit de santé naturel	Manufacture / Fabrication	GRANULES / GRANULES	X	

Inspection Compliance Rating / Cote de conformité de l'inspection

Compliant / Conforme

Observations

#1	Status / Statut : Open / Ouverte Risk / Risque : 2 Natural Health Products Good Manufacturing Practices / Bonnes pratiques de fabrication des Produits de santé naturels 44 - Specifications / 44 - Spécifications **Inadequate/incomplete finished product specifications available for products.** The finished product specifications (FPS) provided for products were inadequate. For example, but not limited to, the FPS for Dang Gui (NPN [redacted]) had the following deficiencies: a. The detailed information respecting the medicinal ingredient's quantity per dosage unit was inadequate. The quantity of the medicinal ingredient was indicated as Dang Gui 1 g angelica sinensis (5:1 extract QCE 5g) on the FPS. However, based on the batch information provided for batch # [redacted]6, there was 0.8 g of dang gui (angelica sinensis) extract per 1 g of granules with a dry herb equivalent to extract ratio of 6:1.

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