100% Label Claim and Overages

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What’s wrong with that?

Originated from legislation of fortified foods, NLEA preceding DSHEA.

Lack of an upper limit!

Lack of an upper limit invites to add overages to compensate for loses

Over time, expensive proposition, not free of risks.

Monograph specifications have a band of acceptance, with lower and upper limit

Monograph specifications for strength of dietary ingredients consider:
  – Variables in manufacturing process
  – Precision and accuracy of the analytical determination
Overages in Dietary Supplements

General Notices statement:

- An official product shall be formulated with the intent to provide 100% of the quantity of each ingredient declared on the label. Where the minimum amount of a substance present in a dietary supplement is required by law to be higher than the lower acceptance criterion allowed for in the monograph, the upper acceptance criterion contained in the monograph may be increased by a corresponding amount.

- Typical acceptance criteria in USP monographs are symmetrical with respect to 100% considering the analytical variation of the assay procedure and unavoidable variations in manufacturing process.

- Where analytical variation was very high, asymmetric limits for assay/strength were included in monographs (microbial/biological assays)

- Formulations should be developed to achieve stability

- Compensation of loses of nutrients over time should be used as the last resort and limited to products where toxicity due to vitamin overdose is not a safety concern (not at high doses of vitamin A and D)
Overages vs Monograph Specifications

- Overage in Master Formulas not the same as release specifications
  - Loses during manufacturing process should be included
- Monographs were developed over a long period
- Evolution of Analytical technology (Microbial Assays, animal assays vs UPLC)
- Manufacturing process improvements, stabilization strategies (vitamin coatings, beadlets, separation of incompatible substances, antioxidants, photosensitivity, pH control, etc.)
What is the purpose of a stability study?

- To determine the expiration date
- Conclusion of stability study should be a determination of a shelf life period

What is NOT

- To determine the overage to achieve a 100% at a prefixed expiration date!
- Unstable formulations will contain at expiration date an amount of degradation products equal to the overage added to the formulation. Do you know the toxicity of those degradation products?
- Responsible companies should educate retailers about the need for shorter expiration dates in certain dietary supplements (gummies)
42(3) Stimuli to the Revision Process: Factors to Consider in Setting Adequate Overages of Vitamins and Minerals in Dietary Supplements

STIMULI TO THE REVISION PROCESS
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Factors to Consider in Setting Adequate Overages of Vitamins and Minerals in Dietary Supplements

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ABSTRACT
Currently, U.S. law requires that all fortified foods, including dietary supplements, containing a Class I nutrient, e.g., vitamin, mineral, protein, or dietary fiber must contain, at minimum, 100% of the label-claimed amount of the Class I nutrient. Thus, it is important for dietary supplement manufacturers to ensure that the content of nutrients in a dietary supplement meets the requirement of 100% of the label-claimed amount throughout the shelf life of the product. Dietary supplement manufacturers typically formulate products to contain nutrients in amounts greater than the label-claimed amount (i.e., average amounts or overages) to compensate for loss due to degradation of the nutrients during the product’s shelf life, and to compensate for the inherent variability of the manufacturing process and product testing. However, it is desirable for manufacturers to minimize overages, to help prevent individuals from consuming higher amounts of nutrients than desired, especially amounts that exceed, without warning, the tolerable upper intake levels (ULs). The use of USP public quality standards, detailed in compendial monographs, can assist manufacturers in reducing overages. This Stimuli article discusses factors, such as nutrient degradation, analytical testing, and manufacturing process variabilities, for dietary supplement manufacturers to consider when determining overages of nutrients in products. Furthermore, this Stimuli article recommends several strategies, such as the use of stabilized ingredients, formulation adjustment by strength, and improved manufacturing processes, to minimize manufacturing variability that may assist manufacturers reduce nutrient overages in their products.
Some Suggestions to Minimize Overages

- Stabilize the formulations to avoid loss of nutrients
- Run stability studies to determine the “real” shelf life
- Consider retailers education about shortening the shelf life of certain dietary supplement formulations
- Dietary supplements are foods, food is perishable!
Thank You

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