DSHEA: Potential Inconsistency and Impact of the 100% minimum Label Claim

May 15th 2019
DSHEA is held to a higher minimum label claim vs Drug

**DSHEA:** Minimum of **100%** of Label Claim throughout shelf life
- 21 CFR 101.9(g)(4)(i) requires that dietary supplements, containing a Class I nutrient, e.g. vitamin, mineral, protein, or dietary fiber must contain, ‘at least equal to the value declared on the product label’ i.e. 100% of the label claim.

**DRUG:** Minimum of **90%** of Label Claim throughout shelf life
- Per USP and ICH Q6 Standards

**Supplements Ex US:** Minimums less than 100% are typical
- Directive 90/496/EEC – 80% (+/- 20% tolerance)
- ANVISA’s 2018 dietary supplement guidance – 90%

A Higher Minimum defines the Lower Stability Limit (LSL) at End Of Shelf Life (EOS)......
Typical Supplement Overage Calculation

Starting Point

<- CFR 101.9: LSL = 100%

1 Ref: Tolerances for food supplements: An introductory guide, IASDA
Typical Overage Calculation

95% CI

<- Stability Loss

<- CFR 101.9: LSL = 100%

Ref: Tolerances for food supplements: An introductory guide, IASDA
Intentional Overage Calculation

Process Variability ->
+/- 3SD

Starting Point

95% CI

LRL

URL

99% CI

Expected value at release

<- Stability Loss

<- CFR 101.9: LSL @ EOS = 100%

Ref: Tolerances for food supplements: An introductory guide, IASDA
Intentional Overage Calculation

Process Variability ->
+/- 3SD

URL
99% CI
LRL
95% CI

Expected value at release
Input Target

Process Loss

<- Stability Loss

<- CFR 101.9: LSL @ EOS = 100%

Ref: Tolerances for food supplements: An introductory guide, IASDA
DSHEA’s higher minimum label claim is inconsistent with drugs and drives higher overages.

• The label claim minimum defines the starting point for compliant overage calculations.

• A 100% minimum label claim drives an additional 10% overage* vs a minimum label of claim of 90%.

• A 90% minimum label claim would match the typically higher standards associated with drugs.

• Discuss.....

* For nutrients that have significant stability loss