



# Dietary Supplement Labeling Compliance Review Seminar

November 12-13, 2019

## Agenda

### Day One

#### Introduction

J. Hoadley /G. Leon (8:00 – 8:15 am)

#### 1. Historical Perspective

- ◆ Requirements for food labeling in the early acts
- ◆ Changes in labeling requirements resulting from enactment of NLEA
- ◆ Enactment of DSHEA

J. Hoadley (8:15– 8:30 am)

#### 2. Needed Tools and References

- ◆ Identification and explanation of tools and references needed when conducting a compliance food label review

G. Leon (8:30 – 8:45 am)

#### 3. Introduction to Label Review

- ◆ Establishing product's jurisdiction
- ◆ Determining the degree of completeness and accuracy of label information
- ◆ Understanding the terms like 'package', 'labeling', 'label', PDP and Information Panel
- ◆ Definition of Dietary Supplements

G. Leon (8:45 – 9:30 am)

#### BREAK

(9:30 – 9:45 am)

#### 4. Identity Statement

- ◆ Requirements for statement of identity
- ◆ Assessment of the appropriateness of the identity statement

G. Leon (9:45 – 10:30 am)

#### 5. Net Quantity of Contents Statements

- ◆ Requirements
- ◆ Assessment of the appropriateness of a given label

G. Leon (10:30 – 11:15 am)

#### 6. Declaration of Ingredients, Food Allergens & Hemp

- ◆ Requirements for Dietary Supplement ingredients
- ◆ Allergen declaration
- ◆ Differences from foods
- ◆ Declaration of Hemp dietary ingredients

J. Hoadley (11:15 – 12:30 pm)

#### LUNCH

(12:30 – 1:30 pm)

#### 7. Name and Place of Business and COO

- ◆ Requirements
- ◆ Requirement for labeling regarding adverse event reporting on dietary supplement labels
- ◆ Assessment of the appropriateness of a given label

G. Leon (1:30 – 2:00 pm)

#### 8. Nutrition Labeling – Supplement Facts

- ◆ NEW requirements, e.g. Mandatory nutrients, added sugars, dietary fiber, Daily Values, etc.
- ◆ Quantitative declarations: serving size, nutrient amounts, percent of daily value, rounding rules, compliance
- ◆ Appropriate formats

G. Leon (2:00 – 3:15 pm)

#### BREAK

(3:15 - 3:30 pm)

#### 9. Group Exercise for mandatory labeling

- ◆ Label review process in small groups; discussion of findings
- ◆ Requirements to convert current labels to the new SF regulation

G. Leon/ J. Hoadley (3:30– 5:00 pm)

## Day Two

### 10. Nutrient Content Claims

- ◆ Absolute and relative Nutrient Content claims
- ◆ Recognizing claims on the label
- ◆ General requirements for claims
- ◆ Nutrient Content claims with special requirements

G. Leon (8:00 – 10:00 am)

**BREAK** (10:00 - 10:15 am)

### 11. Health Claims

- ◆ Authorized health claims, FDAMA claims, qualified health claims
- ◆ Recognizing claims on the label
- ◆ General requirements for claims, definitions of specific claims

J. Hoadley (10:15 - 11:00 am)

### 12. Structure/Function Claims

- ◆ FDA's regulation on disease statements vs. non-disease statements

J. Hoadley (11:00 - 12:00 pm)

**LUNCH** (12:00 - 1:00 pm)

### 13. Labeling of Foods in Special Categories

- ◆ Special dietary foods, medical foods,

J. Hoadley (1:00 – 1:30 pm)

### 14. Other claims

- ◆ Natural
- ◆ Organic
- ◆ Made in USA
- ◆ No GMO
- ◆ Gluten-free

J. Hoadley (1:30 - 2:00 pm)

**BREAK** (2:00 – 2:15 pm)

### 15. Bioengineered Food Disclosure

- ◆ Definition, Requirements and Applicability.
- ◆ Effective date, Compliance date
- ◆ Exemptions
- ◆ List of Bioengineered Foods
- ◆ Format of BE Disclosure

G. Leon (2:00 – 2:15 pm)

### 16. Group Exercise for claims

- ◆ Hands-on exercise in reviewing all mandatory and voluntary labeling information
- ◆ Participants will be involved in the label review process through group discussion and participation
- ◆ Revision of current labels to the new requirements of the final rules
- ◆ Groups will present their findings

J. Hoadley / G. Leon (2:15 – 4:00 pm)

### 17. Individual Review Exercise

- ◆ Identify and correct errors in mock-up label

J. Hoadley / G. Leon (4:00pm – 4:45 pm)

**18. Seminar Evaluation** (4:45 – 5:00 pm)