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Education Keynote

Dietary Supplements for Seniors: Considerations for Safety and Support

Speaker: Cara Welch, PhD, Director of Office of Dietary Supplement Programs, U.S. Food & Drug Administration

Friday, November 10 | 2:30 – 3:00 pm EST

Introduction

Samuel (Sam) Lin, MD, PhD, MBA, MPA, MS
Chair, AMA Senior Physicians Section

Moderator

Ved V. Gossain, MD
Immediate Past Chair, AMA Senior Physicians Section

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Sponsored by the AMA's Senior Physicians Section (SPS)

Learning Objectives

Upon completion of this activity, the physician will be able to:

- Define the term dietary supplement and ingredient labeling
- Review considerations for product safety and accuracy
- Examine the requirements for claim substantiation

Dietary Supplement Authorities

- The Dietary Supplement Health and Education Act of 1994 (DSHEA)
  - Defined the term “dietary supplement”
  - Established requirements for new dietary ingredient premarket review
  - Established allowable health-related or structure/function claims
  - Authorized Good Manufacturing Practice requirements
  - Established dietary supplement specific adulteration and misbranding provisions
- Dietary supplements are a category of food

Regulatory Framework

- DSHEA was designed to balance:
  - Consumer's right to access to safe, high-quality, and accurately labeled dietary supplements
  - FDA's mandate to protect the public from unsafe and otherwise unlawful products

Regulatory Framework

- Premarket
  - New dietary ingredient notification review
- Postmarket
  - Facility inspection
  - Good manufacturing practices (GMP) requirements
  - Dietary supplement labeling requirements
  - Structure/function claim notification review
  - Adverse event report review

Landscape

- Since the 1994 enactment of DSHEA, the dietary supplement market has grown
  - $4 billion to more than $60 billion
  - Approximately 4,000 products to 100,000+ different labels
- The market is not only bigger, it's different
  - Globalization of the supply chain and the explosion of the internet as a retail and distribution channel
  - Products are precisely formulated, incorporating designer ingredients and complex mixtures
- 75% of Americans report taking dietary supplements*
  - 40% of supplement users are 55+ in age

*2023 CRN Consumer Survey on Dietary Supplements

Definition of Dietary Supplement*

- Product intended to supplement the diet
- Product that is intended for ingestion
- Contains one or more dietary ingredients
  - Vitamin
  - Mineral
  - Herb or other botanical
  - Amino acid
  - Dietary substance for use by man to supplement the diet by increasing the total dietary intake
  - A concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients
- Does not include certain drug ingredients

* see section 201(ff) of the FD&C Act

Common Supplements

- Ingredient types
  - Multivitamins or individual vitamins
  - Minerals such as calcium, magnesium, and iron
  - Botanicals or herbs, botanical compounds, extracts
    - E.g., echinacea, ginger, caffeine, curcumin, green tea extracts
  - Amino acids like tryptophan and glutamine
  - Live microbials (commonly referred to as “probiotics”)
- Product forms
  - Pills, tablets, capsules, liquid, powder, gummies, etc.

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Dietary Supplement Adulteration Provisions

- Safety standard for dietary supplements*
  - If it is a dietary supplement or contains a dietary ingredient that
    - A. presents a significant or unreasonable risk of illness or injury…;
    - B. …there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;
    - C. the Secretary declares to pose an imminent hazard to public health or safety…; or
    - D. [cross-reference to “poisonous or deleterious” food adulteration provision].
  - In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated.

* see section 402(f) of the FD&C Act

Allowable Health-related Claims

- Health claims/qualified health claims
  - Characterizes the relationship of any substance to reducing risk of a disease
  - Reviewed and authorized by FDA
- Structure/function claims*
  - Describes the role of an ingredient intended to affect the structure or function in humans, general well-being claims, etc.
  - Not approved by FDA but firms must notify FDA of their claim within 30 days of marketing a product
  - Firms must have substantiation that the claim is truthful and not misleading
- FDA's review consists of ensuring the claim is not intending the product to treat, cure, prevent a disease

* see section 403(r)(6) of the FD&C Act

Adverse Event Reporting (safetyreportingportal.hhs.gov)

- FDA's MedWatch program receives dietary supplement adverse events
  - Safety Reporting Portal, email, phone calls, letters
- Brand owners are required by law to submit serious adverse events to FDA within 15 business days
  - Consumers and health care providers are encouraged to submit
- All dietary supplement adverse events are reviewed by ODSP medical officers
  - Identify any concerns with the firm, product, or ingredient
  - Determine if any follow-up information is necessary, e.g., facility inspection, consumer warning, product recall

Challenges

- Dietary supplement regulation is largely reliant on post-market surveillance
  - No premarket approval; limited premarket review
  - Supplements are allowed a variety of health-related claims, but labeling is easily changed
  - Oversight is constrained by available resources
- FDA has no systematic way to know when new dietary supplements are introduced or what they contain
  - Regularly playing catch up on the science behind the safety and claims

Public Health Perspective

A consumer should reasonably be able to expect three things from a dietary supplement:

- This product will not cause illness, injury, or death;
- This product contains what the label says, in the right amounts, and nothing else;
- There is a scientific basis to believe that this product will have the effect that it claims.

FDA Priorities

Our strategic priorities for dietary supplements align with reasonable consumer expectations:

- Consumer safety
  - Expectation: this product will not cause illness, injury, or death
- Product integrity
  - Expectation: this product contains what the label says, in the right amounts, and nothing else
- Informed decision-making
  - Expectation: there is some scientific basis to believe that this product will have the effect that it claims

Regulatory Activities

- Typical compliance and enforcement actions
  - Consumer safety alerts
  - Warning Letters, seizures, injunctions

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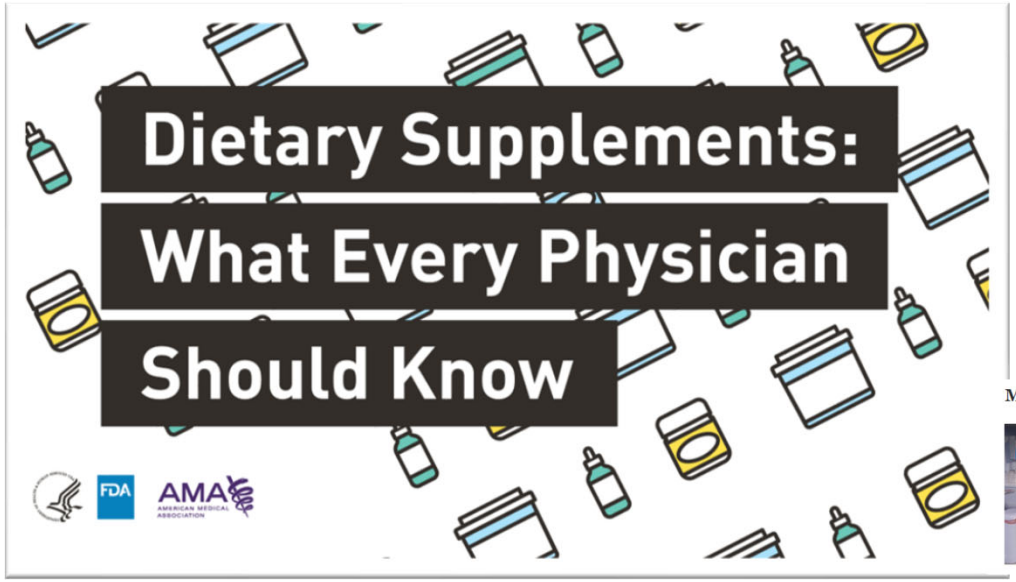
Regulatory Activities

- Strategies to enhance compliance
  - Communicate risk prioritization
  - Establish clear priorities
  - Clarify expectations for concerning claims or ingredients
  - Facilitate others' efforts to improve compliance

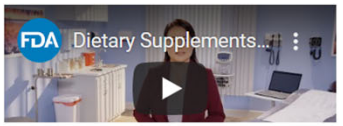
Informed Decision Making

- FDA launched a new education initiative titled Supplement Your Knowledge, to broaden public understanding of dietary supplements
  - Fact sheets and videos for consumers re: how DS are regulated, potential benefits and risks, how to report AERs
  - Curriculum for high school teachers
  - CME program (developed in collaboration with the AMA) for physicians and other healthcare professionals

Supplement Your Knowledge



Module 1: What Physicians Should Know – Part 1



Module 2: What Physicians Should Know – Part 2

Module 3: What You Need to Know About Dietary Supplements

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Thank you!

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Questions from Audience Members

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