Four Issues for the U.S. Supplement Market

(and how the industry is responding)

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Four Issues for Discussion:

- Legalization of CBD

- *Supplement Facts* Changes

- FDA Modernization of Regs

- Retailer, Third-Party Certification

1. A Legal Pathway to Market CBD in Food and Dietary Supplements

- Prior to December 2018, all *cannabis sativa,* including both hemp and marijuana, was considered a Schedule 1 controlled substance in the U.S.
- The 2018 Farm Bill, a comprehensive package of legislation affecting agriculture, removed hemp and its non-THC constituents from the Controlled Substances Act. Article must contain <.3% THC.
- Many falsely viewed that new law as removing ALL legal barriers to the sale of hemp and CBD. <u>It did not.</u>

CBD: Is it Legal in the US?

- FDA maintains CBD and “whole spectrum hemp extract” containing CBD, are prohibited from use in food or supplements for reasons unrelated to the CSA, its THC content, or its relationship to marijuana.
- FD&CA defines a “dietary ingredient” and expressly excludes any “article” that was first subject to substantial clinical investigations as a drug prior to being sold as a food or supplement. 21 USC §321(ff)(3)(B)
- But the provision also allows FDA to use its discretion through notice and comment rulemaking to alloinw use of the article a food or supplement—even if the drug was subject to substantial clinical investigations first.

So Is It Legal, Or Not?

- FDA has issued numerous warning letters (but no further enforcement) against CBD products making illegal drug (disease) claims.
- The agency continues to insist CBD is illegal in food and supplements, but asserts it is open to exploring “a legal pathway to market.”
- Then FDA proposes that a regulatory pathway could take 3-5 years; a legislative approach from Congress may be faster.
- Meanwhile, FDA concedes it is exercising enforcement discretion and only prosecuting those cases where the product is making unlawful disease claims.

How Does the Industry Respond?

- FDA Public Meeting scheduled for May 31.
- Most major retailers have resisted the temptation to sell food and supplements containing CBD; a couple are selling topical products without making claims.
- Small retailers and online platforms are selling CBD or whole hemp extract in all forms.
- CRN has announced it will consider CBD marketers for membership.
- Industry continues to pressure FDA and Congress to act, and to impose other supplement requirements on products marketed as supplements.

2. *Supplement Facts* Label Changes

- A 2017 FDA regulation mandates changes to the *Nutrition Facts* and *Supplement Facts* labels, effective January 2020.
  - The Percent Daily Values have changed for many nutrients to reflect updated science.
  - Added sugar must be disclosed prominently.
  - Fiber has been defined to eliminate some carbohydrates
  - International units (*iu*) have been replaced with milligrams (mg) or micrograms (mcg)
  - Folic acid listed as folate

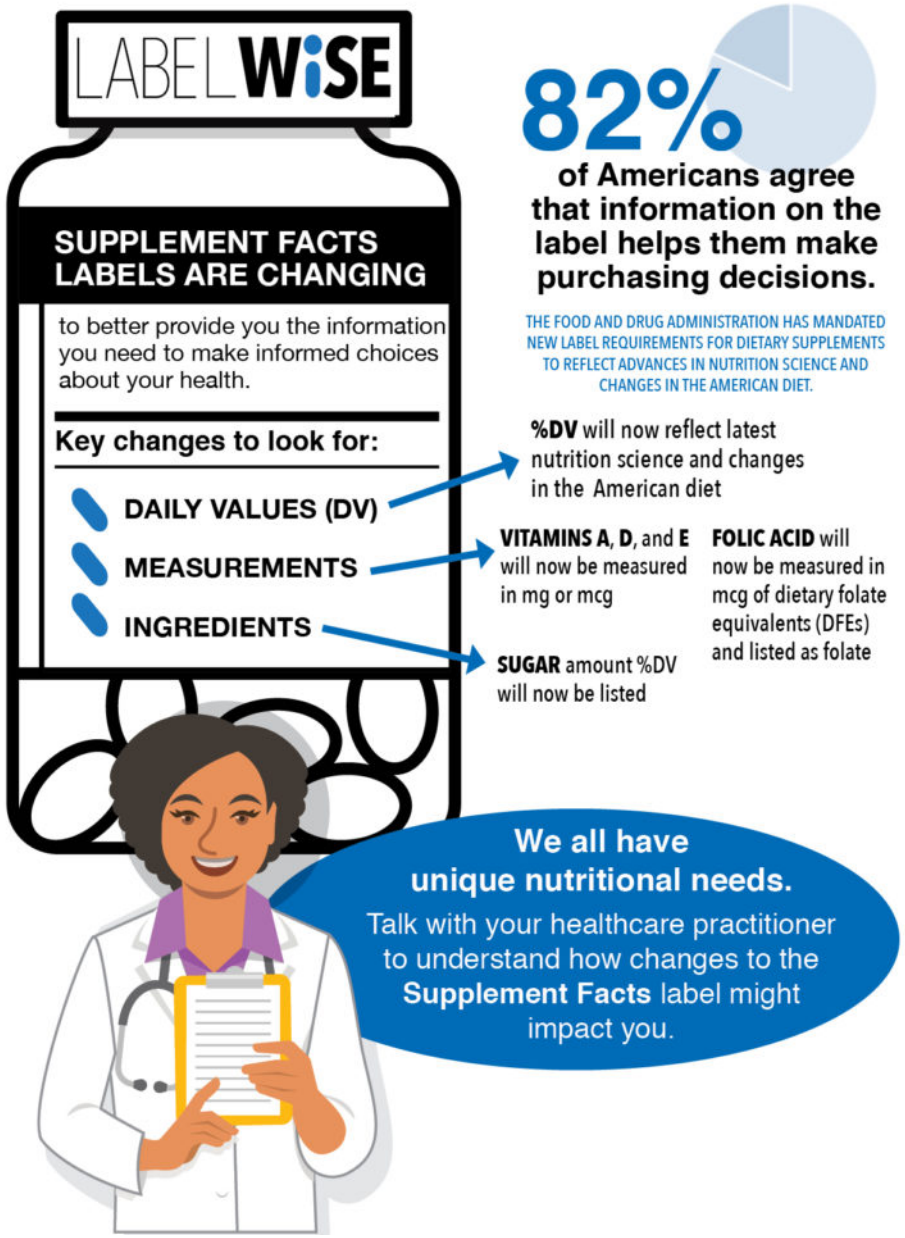
How Industry Responds

- CRN launches an education campaign to address consumer and retailer questions and concerns about the impending changes to the *Supplement Facts* Label.
- The campaign will fill the knowledge gap and assure the label changes are expected, viewed positively and perceived as helpful.
- Messaging underscore that the dietary supplement industry is regulated.
- The label has not been updated in over 20 years. In that time, science has developed and the American diet has changed.
- *Supplement Facts* labels are changing to better provide information consumers need to make informed choices.

LABEL WISE
A GUIDE TO UNDERSTANDING
Supplement Facts

Campaign Toolkit

- **www.BeLabelWise.org**
- **Fact Sheet**
  Produced by CRN to guide discussions
- **Infographic**
  Produced by CRN/optimized for social sharing
- **Microsite: BeLabelWise.org**
  Produced by CRN to curate materials
- **Explainer Video**
  Created with outside vendor
- **Social Media Content**
  Produced by CRN for sharing by members/partners
- **Bylines/Blog Posts**
  Produced by CRN for partners to share



3. FDA Recommendations to Modernize Dietary Supplement Regulation

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight

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For Immediate Release February 11, 2019

" a routine part of the American lifestyle"

"I've personally benefitted from the use of dietary supplements"

"as a physician, [I] recognize the benefits of certain supplements "

"It's clear to me that dietary supplements play an important role in our lives as we strive to stay healthy."

"DSHEA imposes a number of requirements around the manufacture and labeling of dietary supplements."

"we achieve the right balance between preserving consumer access…while…protect[ing] the public from unsafe and unlawful products."

FDA Recommendations

- Gottlieb's statement promised a public meeting this spring on "responsible innovation" to be held May 16th
- New rapid-response tool to alert consumers to unsafe products
- Updated compliance policy for NDIs
- Botanical Safety Consortium
- New enforcement strategies
- Additional steps "to modernize DSHEA":
  - Dietary supplement exclusivity
  - A product listing requirement

How Industry Responds

- Industry preparing to raise issues around definition of dietary ingredients (e.g., “nutritive value,” synthetic botanical constituents, items that increase daily intake)
- Clarity around New Dietary Ingredients
  - Grandfather date that separates “old” and “new” ingredients
  - Alternatives to NDIs: in the food supply, GRAS self-affirmation
  - When is an ingredient chemically altered?
- How can FDA incentivize innovation?
  - Master files for NDIs and piggy-backing on supplier safety data
  - Actual enforcement of IP from a “public safety” agency

FDA Proposes a Mandatory Registry

"A mandatory listing requirement could provide significant benefits by improving transparency in the marketplace and promoting risk-based regulation. It could also help facilitate efficient enforcement of the law and establish new mechanisms to identify bad actors who put the public at risk and undermine consumer confidence in the entire industry."

Statement of FDA Commissioner Scott Gottlieb, Feb. 11, 2019

"This proposal would require all products marketed as "dietary supplements" to be listed with FDA and give FDA authority to act against non-compliant products and the manufacturers and/or distributors of such products. This would allow FDA to know when new products are introduced, quickly identify and act against dangerous or otherwise illegal products, and improve transparency and promote risk-based regulation."

FDA Justification for Budget Estimates, Statement to Congress, March 18, 2019

FDA asks:

"[I]s it possible to design a product listing regime that helps us protect consumers and level the playing field for responsible industry participants by making it easier for us to take swift action against illegitimate and dangerous products, such as products that are tainted with drug ingredients? And is it possible to do this without disrupting the balance struck by DSHEA, and without imposing any significant new burdens on responsible firms? The answer to these questions may very well be yes."

Statement of FDA Commissioner Scott Gottlieb, Feb. 11, 2019

A Mandatory Product Listing: How Industry Responds

- The U.S. voluntary industry registry, the ***Supplement OWL***, launched in 2017, continues to grow.
- Industry evaluating the concept of an FDA-administered database and developing a position.
- Consideration given to “must-haves” from FDA and possible trade offs and concessions. Stay tuned….

4. Retailer Demands for Quality Assurance / Third-Party Certification

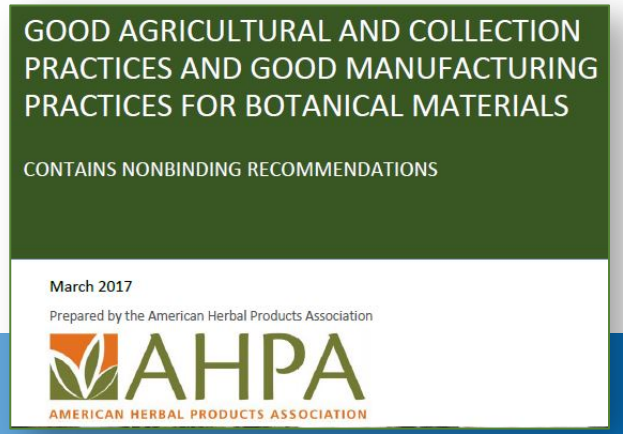
- Retailers increasing imposing their own requirements for quality and certification of GMPs, in addition to federal regulations.
- Increasing need for harmonized standards for third party audits for GMP certification and supply chains to create uniformity of audit standards and create efficiencies for both manufacturers and retailers.

How Industry Responds

- Industry-led initiatives to develop harmonized standards for both supply chain quality/integrity and for GMP inspections
- Benchmarking of third party standards and certification of the auditors.
- Encouraging major retailers to forestall their own requirements for widely agreed upon standards to promote efficiency as well.

GRMA
GLOBAL RETAILER AND MANUFACTURER ALLIANCE
Building quality standards together

SSCI



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Building quality standards together

- New ANSI-accredited standards to evaluate a dietary supplement firm's adherence to cGMPs.
- Coming soon: Auditing scheme using these standards and trained auditors accepted by retailers as satisfying their cGMP requirements.

Thanks for listening!

For more information, see our website at www.crnusa.org

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