



# Mandatory Product Listing

A CRN TOWN HALL EVENT

MAY 11, 2022





“

What was once a \$4 billion industry comprised of about 4,000 unique products, is now an industry worth more than \$40 billion, with more than 50,000—and possibly as many as 80,000 or even more—different products available to consumers.

”

— Scott Gottlieb, M.D.  
23<sup>rd</sup> FDA Commissioner

“

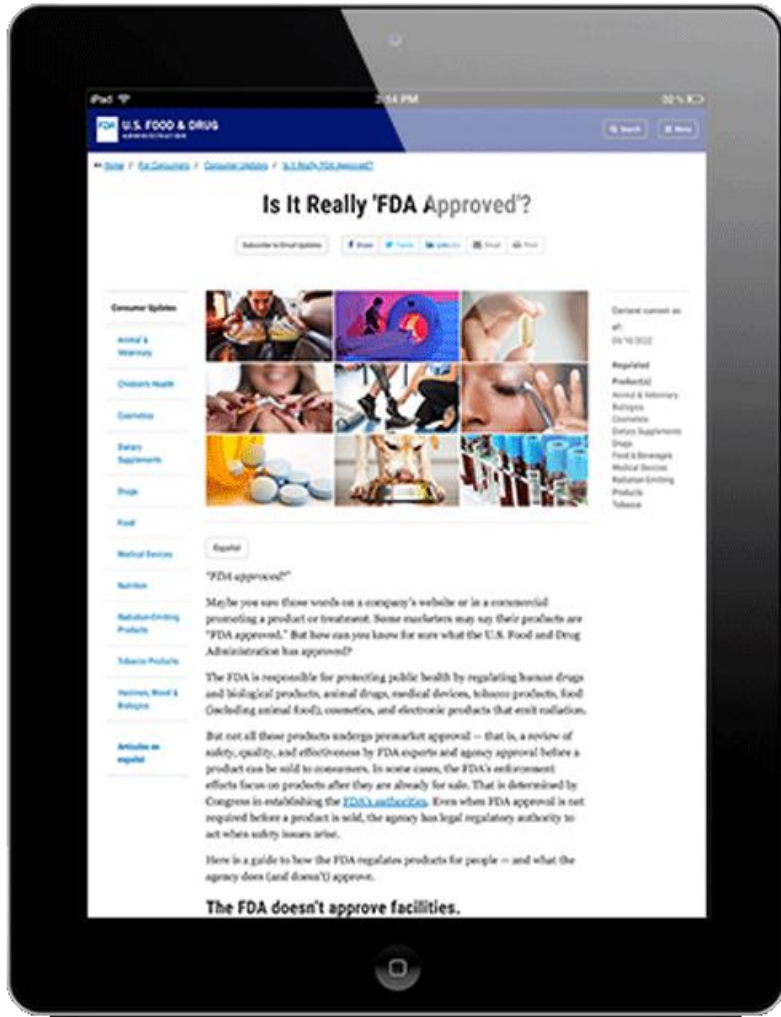
At the time DSHEA was passed there were an estimated 4,000 unique dietary supplement products available, today the FDA states that there are anywhere from **50,000–80,000+ products.**

However, there is **no way to accurately know the number because entities are not required by law to register** with the government.

”

— Kevin Kinney, D.C.





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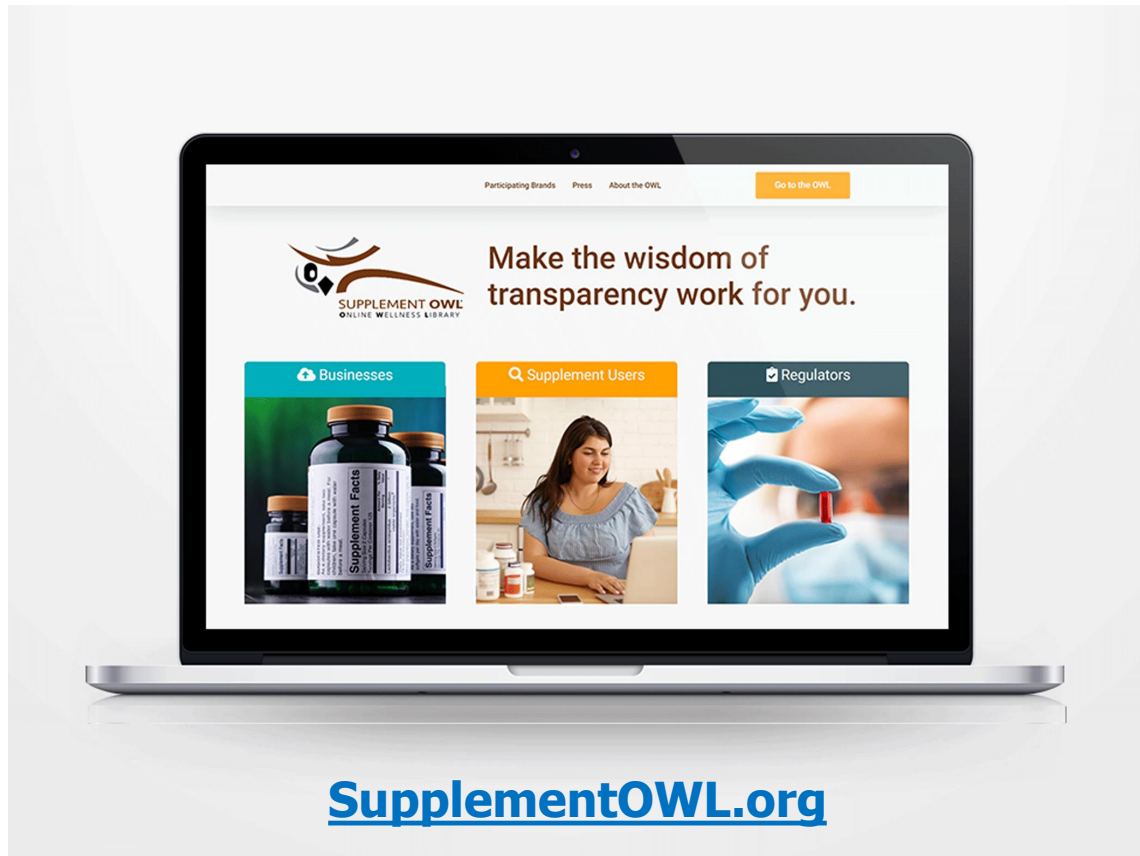
The FDA is not authorized to approve dietary supplements for safety and effectiveness.

**In fact, many dietary supplements can be marketed without even notifying the FDA.**

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— “Is It Really 'FDA Approved'?”  
U.S. Food & Drug Administration

# The Supplement OWL



Product Information	Label Statements	Contact Information	Ingredients
Delivery Form	Gummy		
Label Type	Supplement Facts		
Allergen Statements / Claims	FREE OF gelatin, synthetic colors, artificial flavors and preservatives, wheat, milk, eggs, soy, gluten, peanuts, tree nut allergens, fish, shellfish, and salicylates.		
Statement of Identity	Dietary Supplement		
Serving Size	2 Gummies		
Net Contents Quantity	60 Gummies		
Serving Directions	For adults, take two (2) gummies daily. May be taken with or without food.		
Servings Per Container	30		
Other Ingredients	Other Ingredients: Organic Cane Sugar, Organic Tapioca Syrup, Pectin, Citric Acid, Natural Flavor, Corn Starch, Sodium Citrate, Colors Added (Spirulina, Organi		

# What “They” Wanted

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- **Premarket review**  
(weight-loss and sexual enhancement)
- **Expanded reporting** for ALL  
adverse events
- **Private right of action** for  
consumers  
to directly enforce FD&CA
- **No more self-GRAS**
- **Tougher substantiation  
requirements**  
for claims



CENTER FOR  
Science IN THE  
Public Interest

# CRN Delivers!

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- **NO** user fees
- **NO** submission of your ingredient suppliers
- **NO** disclosure of proprietary blend formulas
- **NO** catchall provisions



# Why CRN Supports MPL

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Benefits to  
supplements go  
well beyond FDA  
enforcement.



- ✓ FDA
- ✓ State Attorneys General
- ✓ Retailers
- ✓ Consumers
- ✓ Industry



# MPL Benefits

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- Provides regulators **accurate data**
- Allows stakeholders to **differentiate legitimate and fraudulent** products
- **Helps FDA identify products** during crisis
- Promotes **GMP compliance**
- **More efficient use** of FDA's time and resources



# Legitimate or Fraudulent? Benefits of Differentiation

## FDA

- Easily detect non-compliant companies and products

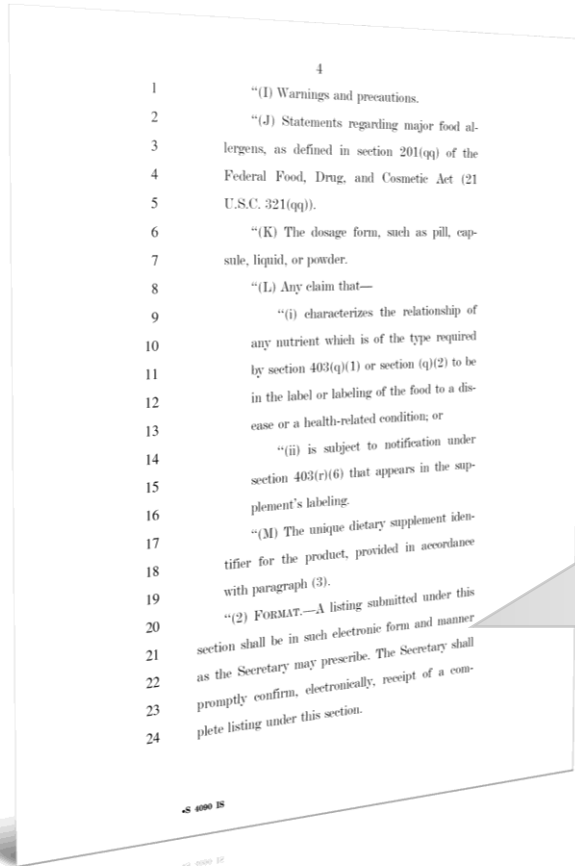
## Retailers

- Identify companies complying with transparency requirement
- Only stock products and ingredients from those companies

## Consumers

- Demand a higher level of transparency

# “It’s a birth certificate, not a driver’s license”



with paragraph (3).

21 “(2) FORMAT.—A listing submitted under this

22 section shall be in such electronic form and manner

23 as the Secretary may prescribe. The Secretary shall

24 promptly confirm, electronically, receipt of a com-

plete listing under this section.

## CLAIM #1

It's already easy for FDA to find dietary supplements in the market now.

## REALITY CHECK



Yes, FDA has some tools, but the agency can't regulate what it can't see.

## CLAIM #2

We already have  
the ODS database.  
We don't need  
another one.

## REALITY CHECK



The ODS database is not a complete listing  
of dietary supplements currently  
in the market.

## CLAIM #3

A mandatory product listing will turn into premarket approval for supplements.

## REALITY CHECK



Mandatory listing can be implemented with safeguards to prevent potential abuse of this authority by FDA.

## CLAIM #4

FDA can use the mandatory listing to keep products it doesn't like off the market.

## REALITY CHECK



If FDA is required to accept all labels for the listing, FDA gets transparency but not the ability to slow down market entry.

## CLAIM #5

It's too burdensome for companies. Small businesses can't comply.

## REALITY CHECK



CRN created a template for mandatory listing with the Supplement OWL four years ago. It works!

**94**

companies

**139**

brands

**13,185**

products



## CLAIM #6

Bad actors won't enter their labels—it's just one more administrative burden for the "good" companies to observe and "bad" companies to ignore.

## REALITY CHECK



Mandatory listing gives FDA an administrative violation that is easy to enforce.

## CLAIM #7

A mandatory listing won't solve all the industry's problems, so let's not do it.

## REALITY CHECK



We agree FDA has not enforced the law as aggressively as it should. This is a start to creating a more transparent industry.

## CLAIM #8

If FDA isn't using the enforcement tools it has, we shouldn't give the agency any more.

## REALITY CHECK



FDA has asked for mandatory listing. MPL will help the agency be more responsive to illegal behavior.

## CLAIM #9

Instead of mandatory listing, the industry needs a massive reform of DSHEA.

## REALITY CHECK



Mandatory listing is something we can all agree on. Congress should do what is achievable.

# What Happens Next?

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- S. 4090 introduced
- Possible HELP Committee legislation forthcoming
- Include MPL in User Fee Reauthorization?



# Take Action

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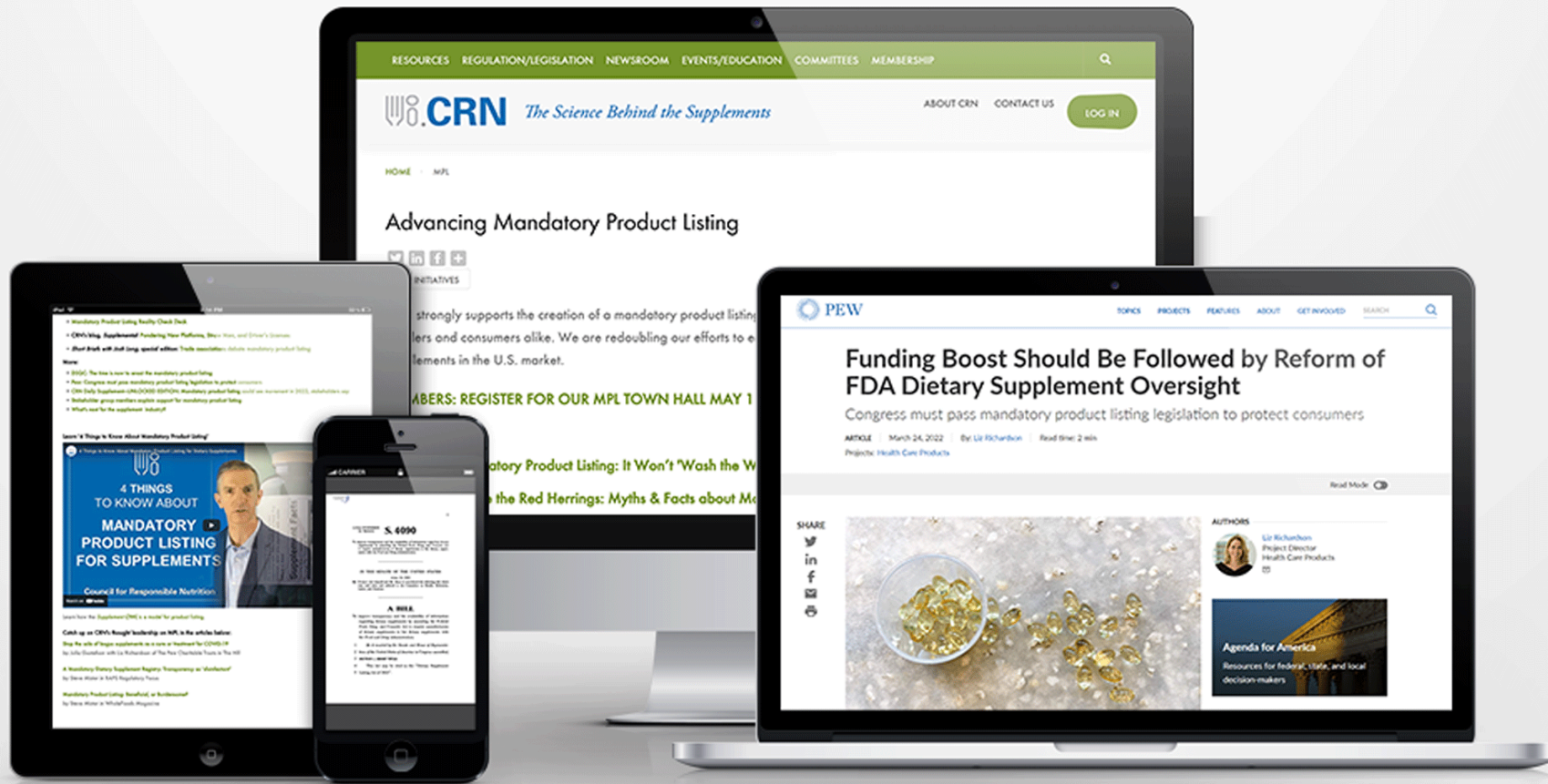
- Input into the legislative process is critical
- Contact your elected officials
- Thank Senators Durbin and Braun for their leadership
- Be heard—  
your industry, your voice!

[congress.gov/members/find-your-member](https://congress.gov/members/find-your-member)



# Your MPL Resource Center

[crnusa.org/MPL](http://crnusa.org/MPL)



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# CRN Member Questions