



Mandatory Product Listing

Transparency is the best disinfectant



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.

- FSMA facility registration doesn't tell FDA what's being made in a facility.
- ODS database is not mandatory, comprehensive or even current.
- FDA can get labels during an inspection, but it only inspects about 5% of the industry each year.

A mandatory registry would allow FDA to see what products and ingredients are available to U.S. consumers—something it can't see now.



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.

- The ODS database is voluntary. Without a regulatory requirement to participate, there is no legal incentive to put labels in the system.
- It's compiled by a contractor to ODS—companies may not even know their labels are included.
- There is no accountability for the accuracy of the entries.
- “On market” and “off market” designations are not current or accurate.
- Even Amazon or Google searches and CRN's *Supplement OWL* are not complete snapshots of the market.

Only a mandatory listing will give an accurate and complete view of the marketplace.



Claim #3: *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; it will help the agency be more responsive to illegal behavior.



- FDA's resources are extremely stretched—OSDP has a \$10.5M budget for a \$56B industry.
- A mandatory listing will allow FDA to approach its other enforcement responsibilities more efficiently, to identify potential public safety issues and prioritize enforcement.
- Just because industry members are not happy with FDA inaction in one respect is not an argument to hinder its authority in other respects.



Claim #4: *A mandatory product listing will turn into premarket approval for supplements.*



Reality Check: Mandatory listing can be implemented with safeguards to prevent potential abuses of this authority by FDA.

- “It’s a birth certificate—not a drivers license.” This construct can be enshrined in the legislation.
- The legislation can enumerate what information FDA is entitled to receive.
- A requirement to provide FDA with a copy of the labeling does not give FDA the ability to refuse to accept it.



Claim #5: *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.

- Product innovation and speed to market are hallmarks of this industry—MPL would not change that.
- FDA would be required to accept all labels it receives, even if it believed the product is illegal—the registry is a snapshot of the market as it exists: “the good, the bad and the ugly.”
- The registry will give FDA visibility to find such products, but it would still have to pursue existing legal processes to remove a product from the market.



Claim #6: *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.

- In 2017, CRN created ***The Supplement OWL***, www.SupplementOWL.org, a voluntary version of the mandatory label registry. Companies of all sizes successfully participate.
- Filing new labels in ***The Supplement OWL*** is a relatively easy experience—just ask our participants.
- Like the envisioned registry, brand owners are responsible for keeping their own entries current.
- Unfortunately, we can't compel participation in ***The Supplement OWL***.



Claim #7: *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.

- Failure to list would make the product misbranded under 21 USC 343 and marketing a product without listing it would be a prohibited act.
- Listing violations do not require lab testing, independent analysis, chain of custody and other obstacles that prevent quick prosecution. They are easy to enforce.
- A few high-profile enforcement actions would send a clear message to companies to provide their labels.



Claim #8: *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, but this is a start to creating a more transparent industry.

- Consumers assume FDA already knows what is in the market; they are surprised to learn that FDA doesn't even know how many products and ingredients are out there.
- Mandatory listing won't immediately address willful bad actors, but it will bring many firms that operate in the grey areas into the sunshine for FDA's evaluation.
- Mandatory listing does allow FDA to identify noncompliant labels, illegal ingredients that are listed and prohibited label claims—that's a good start!



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.

- Both industry and consumer organizations agree that mandatory listing is a reasonable step forward—FDA should know what products are in the marketplace.
- Mandatory listing is requested by FDA, and supported by groups as disparate as the AMA, NCL, CRN, CHPA, USP, The Pew Charitable Trust, and the Dietary Supplement Quality Collaborative.
- Larger and broader reforms of DSHEA (as proposed by either industry or consumer groups) do not have bipartisan or widespread agreement. Mandatory listing is something we can do this year to improve the supplement marketplace.





Mandatory product listing
will provide the
transparency for the
dietary supplement market
that FDA needs and
consumers deserve.



Learn more:

www.crnusa.org/MPL

