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# Supplement OWL Progress: Mirror For Industry Support For Transparency, Mandatory Registration?

*Advisory Board Members Michelson, Ramanathan Discuss Future Of VMS Registration In US*

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## Executive Summary

Advisory board for CRN-operated Supplement OWL recently reached out to industry for "ultimate reason" of recruiting participation. "Transparency has never been more important and this registry is a demonstration of this industry's commitment to candor and honesty with our regulators, retailers and consumers," they say.


*Source: Alamy*

The Supplement Online Wellness Library may represent the transparency the US dietary supplement industry could offer consumers and that the Food and Drug Administration favors making a requirement for manufacturers and marketers.

At its four-year anniversary, though, the Supplement OWL operated by the Council for Responsible Nutrition also could reflect that that a majority of firms marketing vitamins, minerals and supplements aren't in favor of listing their products on a website that includes their competitors' products, too.

CRN announced in May that more than 11,000 products had been registered on Supplement OWL. Most estimates about the size of the US VMS market are between 70,000 and 80,000 products available to consumers.

Members of the Supplement OWL advisory board on 8 July answered HBW Insight questions about the site's progress and about the potential for mandatory registration for VMS products sold in the US. *(See related story for additional comments by the board members.)*

"We are urging all companies that market dietary supplements to participate in the Supplement OWL and reminding industry how recent developments to the registry can improve overall user experience for all audiences. I'm confident that over time we will continue to grow participation," said Guru Ramanathan, industry consultant and president of Guru Ramanathan LLC.

"There is a great deal of industry pride in the OWL's creation and rightfully so. Like other industry self-regulatory initiatives, the OWL is a great example of the industry coming together for the greater good. While

the registry today has over 12,000 (and growing) visible products, the Supplement OWL Advisory Board recognizes there is more work to be done," Ramanathan added in his responses submitted via email.

The experience of another advisory board member, Russ Michelson, Reckitt Benckiser Group PLC's global regulatory head for VMS, since he began working in the sector could illustrate why some stakeholders may oppose or have questions about registering their products on an online list accessible for consumers.

"I knew a self-regulatory registry could be done having seen so many versions of it in markets outside of the US, but I honestly didn't expect it to happen in the US as it felt like a safe and established supplement industry that didn't need change. By the time I joined the industry workforce around 2005, I had already been a consumer of supplements for a while, so I certainly thought 'Why would this market need any new process? It seems fine'," Michelson said in his response.

**With VMS Product Registration 'Inevitable' In US, CRN's OWL Moves 'In Right Direction'**

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Supplement OWL advisory board members Guru Ramanathan and Russ Michelson answer HBW Insight questions about the site's progress and the potential for mandatory registration for dietary supplements sold in the US.

Read the full article here ›

Additionally, from an international perspective "the US was the biggest and most established market," he said, and "only the 'less established' markets seek a screening or a listing."

"I had faith that the US system was the best and made the most sense, so at the time I didn't see a need for anything to change. Of course, I wasn't exactly right in this thinking and it became clearer as I got more involved in the US regulatory world later in my career, that the US system was certainly not perfect."

The Supplement OWL also has changed since its launch, which should help attract more firms to register their products, says Ramanathan.

"To grow something industry wide will take time and require a stair-step approach. Starting with the initial version of the OWL, we've had to implement continuous improvement principles and it has since undergone a series of developments to streamline the process for adding product information to the registry. We also relaunched the website with an updated design. We anticipate that these enhancements will help not only improve user experience but encourage broader registry use and participation," he said.

## 'Consider Placing Supplement Labels In Supplement OWL'

The Supplement OWL site launched in April 2017 with nearly 2,600 labels. Earlier in 2021, CRN built on a previously announced series of upgrades to the back-end aspects of the registry that eased entry of product information by redesigning the site to prioritize user experience, host a broader registry audience and allow easier industry participation in product listing. (Also see "Wellness Industry Group News: CRN Redesigns OWL, AHPA Comments On FSMA Proposal" - HBW Insight, 4 Mar, 2021.)

The site provides navigation for three user groups – business participants, consumers and regulatory officials. Listing products on Supplement OWL is mandatory for CRN members and voluntary for other firms.

*Source: CRN*

GURU RAMANATHAN: "LIKE OTHER INDUSTRY SELF-REGULATORY INITIATIVES, THE OWL IS A GREAT EXAMPLE OF THE INDUSTRY COMING TOGETHER FOR THE GREATER GOOD."

In May, the Supplement OWL advisory board published an open letter to the US supplement industry to encourage participation. The listing of products already in the registry "could not have happened without the support of so many companies and the combined commitment to a more transparent marketplace," the board said.

The members added, though, that the letter wasn't celebrating the Supplement OWL's progress.

The "ultimate reason for this letter is to humbly ask that you consider placing your dietary supplement labels in the Supplement OWL. Transparency has never been more important and this registry is a demonstration of this industry's commitment to candor and honesty with our regulators, retailers and consumers," they said.

## OWL Provides Model For FDA Registry

The FDA has worked on language for a proposal to submit to members of Congress that would codify a mandatory listing process. CRN drafted its own

version of draft legislation to serve as a resource for the FDA and the trade group has offered to assist the agency. (Also see "Potential For US Requiring Supplement Registration Underscored During FDA's Hiatus From Inspections" - HBW Insight, 17 Jul, 2020.)

*Source: CRN*

RUSS MICHELSON: WITH "SO MANY COMPANIES ARE ALREADY FAMILIAR WITH HOW TO ACTIVELY USE IT, THEN ADVOCATING FOR THE OWL TO BE THE FORMAT USED BY FDA IS AN OBVIOUS MOVE."

Legislation likely would require supplement marketers, international as well as domestic, to provide notice and labeling to the agency for every product they make available for sale in the US. The information also would be entered in a database that would be accessible online, similar to the Supplement OWL.

The House Appropriations Committee's report published with its legislation including the FDA's fiscal year 2022 budget requested that the agency impose mandatory product registration for supplements. (Also see "US House Appropriators Have Little Left To Say About Allowing Cannabinoids In Supplements" - HBW Insight, 1 Jul, 2021.)

Ramanathan expects the FDA will want additional input from the industry before imposing product registration, and he and Morrison suggest Supplement OWL as a model.

"A mandatory FDA requirement would require a clear proposal on all the new rights and responsibilities. And for such a proposal to receive fair industry comment the details are very important, so that we aren't creating a solution for problems that may not exist," Ramanathan said.

"This is where the details matter. With a clear plan on what the FDA wants, and what they will provide the industry, we can begin to address the format. The Supplement OWL could absolutely serve as a model for how the FDA could format its mandatory product listing, which is why broad industry participation is so critical. The Supplement OWL Advisory Board encourages all companies who market dietary supplements to submit their product labels to enhance transparency for the industry."

Michelson says that with "so many companies are already familiar with how to actively use it, then advocating for the OWL to be the format used by FDA is an obvious move."

"With over 100 brands and more than 12,000 labels currently in the OWL, why reinvent the wheel? I can tell you from personal experience that I feel comfortable uploading my own labels into the OWL, whether individually or through the mass upload feature. I know how to maintain my labels, how they will be displayed on the site, and how to search by ingredient, product name or brand name," he said.

Supplement OWL as a model "significantly reduces any new technical hurdles when creating a new system with a new back-end technology, and creates a bit of a more seamless transition for FDA," Michelson added.

He also noted that mandatory registration would add leverage to the FDA's enforcement.

"I think that this will be a great first step in separating the good, reputable players from the unwilling players in the industry. With participation and education on the role of this FDA database, it will become clear that there is a level of trustworthiness for any product listed in this database and a level of distrust for products knowingly abstaining from participation," he said.

"It is also being discussed as to what level of authority FDA would have to enforce against repeat offenders, and whether this could lead to true enforcement of brands unwilling to meet basic regulatory requirements. But I do see it, at the very least, as a representation of well-intentioned and trustworthy brands doing the right thing not just for industry or FDA's sake, but for the end consumer's sake. This could be accomplished through the voluntary [Supplement] OWL as well, but as we all know 'voluntary' can leave out a lot of stragglers where 'mandatory' sets a clear bar."