

## Sources: Lawmakers Eye Dietary Supplement Legislation For 2022

By Kelly Lienhard / January 26, 2022 at 6:56 PM

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The dietary supplement industry could see a mandatory product listing requirement for its products take another step closer to reality in 2022 as lawmakers, FDA and some industry stakeholders back the idea as a way to instill more trust in dietary supplements, policy experts say.

However, not all industry members agree with the proposed step, arguing it would be a detriment to industry and keep important products off the shelves.

**Peter Lurie, president of the Center for Science in the Public Interest, told *Inside Health Policy* that he expects to see congressional movement this year to create a mandatory product listing requirement for dietary supplements.** He predicts there is a real chance of mandatory product listings becoming a reality as some lawmakers are beginning to address weaknesses in the Dietary Supplement Health and Education Act.

Sens. Richard Durbin (D-IL) and Richard Blumenthal (D-CT) have both shown interest in enacting the reform, Lurie said, and both FDA and major industry players have supported having a product list in place.

"This is not the most enlightened industry in the world and so to have a segment of them that are actually asking for this listing requirement is really striking and suggests that there's opportunity," Lurie said.

FDA has asked Congress for mandatory product listing in several budget justifications. The listings would allow the agency to know when new products are introduced so it could take action against dangerous supplements.

If mandatory product listing were put into place, companies wanting to market dietary supplements would need to submit the product label to an FDA database. If a company failed to do so, its product would be considered misbranded.

**The product list idea would not give FDA any premarket authority to tell companies they can't bring products to market -- it would only allow the agency to know what products are out there so it could pursue bad actors.**

Durbin and Blumenthal introduced the "Dietary Supplement Labeling Act" in 2013, which would have required manufacturers register products with the agency and hand over a copy of the label. However, the bill never moved forward.

**The president and CEO of the Council for Responsible Nutrition, Steve Mister, said he would like to see legislation setting up a mandatory product listing introduced and added that CRN has spoken with lawmakers, including Durbin, who are interested in sponsoring legislation.**

When asked by *IHP* whether such legislation was in the works, Durbin's office noted Durbin worked on dietary supplement legislation in the past but offered no further comment.

A spokesperson for Blumenthal stated that the senator remains concerned with the lack of oversight and labeling requirements for dietary supplements and supports reforms like the mandatory product listing but stopped short of saying there was active legislation in the works.

If a bill introducing a mandatory product listing does come into play in 2022, Mister said it would be beneficial to both industry and consumers, as long as it doesn't go too far on imposing requirements for manufacturers.

**"Our mantra on this has been that a mandatory listing should be a birth certificate, not a driver's license," Mister said.** "That highlights the difference between simply giving [FDA] your information and having premarket approval where [FDA] could slow you down."

Duffy MacKay, senior vice president of the Consumer Healthcare Products Association's dietary supplement division, echoed CRN's sentiment and said FDA should only be able to use the database as a tool to help prioritize enforcement and catch bad actors.

"We think this is a really important part of transparency, not only transparency for the industry but to be transparent to the agency with products that is makes."

According to MacKay, the mandatory product listing would allow the agency to know how many products are on the market and what ingredients they are using. FDA could install a web crawler that flags the agency anytime a company tried to register a product with illegal ingredients or with high levels of certain, unsafe nutrients.

**However, not all dietary supplement groups agree that mandatory product listing would be in the industry's best interest.**

Daniel Fabricant, CEO of the Natural Products Associations, told *IHP* that mandating dietary supplement manufacturers list their products in a database would have unintended consequences, including creating premarket approval for an industry that doesn't need it.

For example, Fabricant argued that mandatory product listing could kill the marketplace for certain products, like CBD. According to Fabricant, the FDA has said CBD is not a dietary supplement while also not pursuing enforcement of the ingredients. If mandatory listing were in place, CBD products would not be included, and retailers might not want to stock items not on the listing.

"How does a listing protect consumers? We don't know all the brands of spinach out there, we do know all the brands of cookies out there," Fabricant said. "I think there are other organizations that are wedded to their own ideas and a lot of their members are drugmakers who are in a premarket approval system and favor a premarket approval system."

Fabricant argued that the industry is already sufficiently regulated and there are bad actors sitting in jail cells that have violated the Food, Drug and Cosmetic Act. He said it was strange that some members of the dietary supplement industry want their products to be regulated "like a drug," when supplements are just made up of natural ingredients, similar to food.

**However, both CHPA and CRN said product listing is not akin to premarket approval.** They made it clear their members also don't want additional regulation, just more tools to increase transparency.

"What mandatory product listing would answer is not premarket approval and we are really clear about that," Mister said. "It is not premarket approval. It is a step that a company takes when it brings new products to the market."

MacKay added that there will always be "freedom-fighting" companies that push against any type of accountability, but in this instance a mandatory product registry would be beneficial to the industry, as proved in countries like Canada and Australia that already have one in place.

**However, while CHPA and NPA butt heads over the mandatory product listing, both agree more inspections are needed.**

CHPA told *IHP* that during 2021, only one out of every 20 dietary supplement facilities was inspected. While some of this was admittedly due to COVID-19 restrictions, MacKay added that even before the pandemic, only one in 10 facilities was inspected per year.

MacKay said CHPA is proposing that the agency enlist more qualified third parties to inspect facilities on behalf of FDA so that facilities could be inspected once per year.

"We think that there needs to be a mechanism so that all facilities can be inspected at least annually," MacKay said. "FDA just doesn't have the manpower and resources to get into every facility every year. We need a solution."

NPA added that the lack of inspections during the pandemic has been one of the industry's biggest problems. In addition to not inspecting facilities as often as it should, NPA's Fabricant said that FDA isn't even taking as much action at the import level as he would like to see.

"We've really pushed FDA to take more action at the import level to check more products ... They haven't done that during a pandemic when there's supply chain issues and everything else," Fabricant said. "It doesn't seem like a commonsense thing." -- *Kelly Lienhard* ([klienhard@wpnews.com](mailto:klienhard@wpnews.com))

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