

FDA may strip soy protein of its 'heart-healthy' claim

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Dive Brief:

- The Food and Drug Administration [announced Monday](#) that it may end permission for manufacturers to make heart-healthy label claims on soy protein products. "While some evidence continues to suggest a relationship between soy protein and a reduced risk of heart disease — including evidence reviewed by the FDA when the claim was authorized — the totality of currently available scientific evidence calls into question the certainty of this relationship," Susan Mayne, Ph.D., director of FDA's Center for Food Safety and Applied Nutrition, [said in a statement](#).
- If the agency does decide to take the claim away, it would still allow a qualified health claim on soy protein products. A qualified health claim requires a lower scientific standard of evidence and permits label claims based on limited evidence linking consumption of soy protein with heart disease risk reduction.
- FDA will accept comments on the proposed withdrawal of the label claim for 75 days, then consider the comments received, along with existing information, and decide whether to proceed with final rulemaking. Meanwhile, manufacturers will be allowed to keep the current authorized claims on their products. The agency has authorized health claims on packaged foods 12 times since initiating such evaluations in 1990, but this would be the first time it has taken steps to revoke one of them.

Story continues below

Dive Insight:

Heart health is the [No. 1 claim consumers look for](#) when grocery shopping, according to the Hartman Group. The research firm's findings show that 55% of U.S. consumers try to avoid or reduce saturated fat in their diets, and almost 40% try to consume healthier fats like polyunsaturated and monounsaturated fats instead of saturated fats.

Manufacturers and industry groups had mixed reactions to FDA's proposal to nix the claim. The Soyfoods Association of North America (SANA) [responded with concern Monday](#). The group supports keeping the current claim with this wording: "25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease."

"Numerous scientific studies published before and since the soy protein health claim was approved in 1999 consistently show that soy protein lowers LDL-cholesterol and that the totality of the evidence supports continued approval of an unqualified claim," [SANA said in a statement](#). "FDA's decision is inconsistent with 12 other countries that have authorized health claims on soy protein and heart disease, including Health Canada's most recent approval of such a claim in 2015."

Also questioning the development was the Natural Products Association. CEO Daniel Fabricant called FDA's move "somewhat unexpected," since the agency didn't explain what suddenly caused it to take action. Before joining NPA in 2014, Fabricant was head of FDA's Division of Dietary Supplement Programs, so he likely has a decent understanding about how federal regulatory agencies work.

The American Heart Association has supported revoking the claim about soy protein and has questioned whether there are any direct health benefits, [according to Reuters](#). When FDA was reevaluating the health evidence in 2008, the association noted, "Direct cardiovascular health benefit of soy protein or isoflavone supplements is minimal at best."

If FDA does revoke use of the unlimited health claim on soy protein products, it's difficult to predict how customers will respond and whether it might influence their buying decisions. The American Heart Association objects to the agency adopting qualified language on affected products. The group says research shows consumers don't understand qualified health claims, and they're based on limited and varying degrees of evidence.

Once it has set in motion the proposed rule to revoke soybean protein's health claim, it's not likely that FDA will shift its course — unless an overwhelming number of comments are against the move. Those may include DuPont, which produces isolated soy protein, and Gardein, which makes soy-based protein products.

It's also not likely that the agency will start reevaluating its [11 other approved health claims](#) allowed on food products unless there is significant pressure. Only one of the claims involves soybean protein, and that's the one now under review for possible revocation. However, [FDA recently approved the labeling of soybean oil](#) as heart healthy because the agency found that its use can reduce risk of coronary heart disease and lower LDL cholesterol.