
By Ruth Kava — October 31, 2017

You can hardly buy a food product these days without seeing a claim that some food or ingredient in the product somehow benefits health. One of these has been that consuming soy protein could help decrease the risk of heart disease. Before a manufacturer can make such a claim, the FDA has to approve it, based on scientific evidence.

But now, the FDA is considering revoking the rule that allows manufacturers to make that claim. Writing for the agency [1], Dr. Susan Mayne, director of the FDA’s Center for Food Safety and Applied Nutrition, explained:

"[S]ome studies, published after the FDA authorized the health claim, show inconsistent findings concerning the ability of soy protein to lower heart-damaging low-density lipoprotein (LDL) cholesterol. Our review of that evidence has led us to conclude that the relationship between soy protein and heart disease does not meet the rigorous standard for an FDA-authorized health claim."

A health claim [2] — approved by the FDA — is one that connects a substance and a disease or health-related condition, but is limited to disease risk reduction - it can’t say there’s a possible link to a cure or that it will treat a condition or disease. An authorized health claim is one that the FDA has approved based on significant scientific evidence. On the other hand, a qualified health claim is one for which there is not the same level of proof. So the FDA isn't planning to totally eliminate health claims related to soy protein, they're proposing that qualified claims be used rather than
authorized claims. And the consumer will have to be told that there's a difference.

Now, anyone who's interested has 75 days to comment on this proposed move. The agency will then consider those comments before proposing a final rule. It's noteworthy that this is the first time that FDA has considered revising an authorized health claim. We're not totally surprised by this move on the FDA's part because six years ago we reviewed a study that questioned the supposed link between soy protein and a reduced risk of heart disease. You can read that entry here [3].

So tune in again after mid-January 2018 to see what the agency decides to do.

Links
[1] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm582744.htm