

NEWS RELEASE

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New Analysis Supports Health Claims for Soy Protein and Heart Disease *NPA Provides Details of New Meta-Analysis to Food and Drug Administration in Comment Letter*

WASHINGTON, DC – The Natural Products Association in an official comment letter to the Food and Drug Administration (FDA) today provided the details of its new analysis supporting health claims for soy protein and coronary heart disease. The FDA is proposing to revoke its regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease on the label or in the labeling of foods but has failed to perform its own meta-analysis.

“The FDA has failed to offer any compelling evidence in its proposal to eliminate the soy heart health claim” said Daniel Fabricant, Ph.D., President and CEO of NPA. “We are strongly urging the FDA to take into account the overwhelming amount of evidence included in NPA’s meta-analysis indicating a clear benefit in soy protein consumption and lower cholesterol. The FDA’s proposal to revoke its health claim for soy protein is not only bad public health policy but it will harm small business manufacturers, distributors, re-packers, and retailers who would be affected by this proposal. We are hopeful the FDA will take into account our new meta-analysis and conduct its own economic analysis on this proposal.”

Read NPA’s full comment letter to the FDA [here](#).

Executive Summary

- The totality of evidence indicates a clear benefit in heart health as a result of the positive association between soy protein consumption and LDL cholesterol reduction.
- FDA should not eliminate the soy protein heart health claim or convert it to a qualified health claim.
- FDA does not have any material fact to compel industry to change labeling by eliminating the soy protein heart health claim or converting it to a qualified health claim. All material facts support keeping the heart health claim and lowering the threshold to 15 g soy protein.
- NPA has performed its own meta-analysis, reporting an overall effect size reduction in LDL cholesterol of $0.221 \pm .024$ mmol/L
- NPA’s meta-analysis demonstrating a positive association between soy protein consumption and lowering of LDL cholesterol is similar in magnitude to others performed after 1996.
- NPA encourages FDA to replace 25 g in the current heart health claim with 15 g as the new threshold in soy protein a newer meta-analysis from 2011 supports this serving level to consistently lower LDL cholesterol and therefore benefit heart health.
- Soy protein lowers LDL cholesterol through an intrinsic or direct effect and an extrinsic effect by consumers replacing animal protein sources with plant-based soy protein sources. The



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combined intrinsic and extrinsic effect of soy to lower LDL cholesterol is 10.3%, which is on par with the heart health claim for plant sterols and stanol esters to reduce LDL cholesterol by 10%.

- FDA has failed to perform its own meta-analysis and Forest plot out of government transparency on the totality of study evidence to make a determination on the overall effect of soy protein on LDL cholesterol. Without such data, it is unclear how FDA, a data-driven public health agency, can propose to eliminate the health claim.
- FDA fails to meet the four-part Central Hudson test to compel a labeling change in its proposal to eliminate the soy heart health claim in the absence of any scientific justification; FDA's proposal to do so is misleading on its face.

Natural Products Association

The **Natural Products Association (NPA)** is *the* trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA represents approximately 1,000 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements and health/beauty aids. Visit www.NPAinfo.org. Follow NPA on social media:

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