Council for Responsible Nutrition
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March 19, 2018

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-0763; Proposed rule to revoke the regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease

The Council for Responsible Nutrition (CRN) respectfully submits these comments to the Food and Drug Administration (FDA) in response to the agency's proposal to revoke its regulation authorizing the use of health claims on the relationship between soy protein and coronary heart disease (CHD) on the label or in the labeling of foods. CRN is the leading trade association for the dietary supplement and functional food industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements.[1]

CRN recognizes that as the body of scientific research in the area of soy protein and cardiovascular health continues to grow, it is important to periodically re-assess the totality of the scientific evidence. As such, CRN supports FDA's efforts to re-evaluate the scientific basis for the soy protein and CHD health claim. However, we are concerned that FDA's proposal to revoke the regulation authorizing the use of the claim is inconsistent with evaluations by other international regulatory bodies, most recently Health Canada. In 2015, Health Canada's Food Directorate concluded that the "evidence consistently supports a direction of effect towards a reduction in total and LDL cholesterol levels when soy protein is consumed."[2] Health Canada also conducted a meta-analysis of the available scientific literature, the results of which showed

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

[2] https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims/assessments/summary-assessment-health-claim-about-protein-cholesterol-lowering.html

"a statistically significant reduction in total and LDL cholesterol levels with soy protein consumption." Based on the evaluation, Health Canada authorized the use of a health claim about soy protein and cholesterol lowering.

CRN recommends that, in evaluating the totality of evidence, FDA should not only consider whether there is a statistically significant difference between the intervention and control group in each individual study, but also the consistency in direction of effect among studies regardless of statistical significance. Further, FDA should utilize quantitative systematic review methodologies such as meta-analysis to assess the relationship between a food substance and disease. Systematic review methodologies are employed by the scientific community, international regulatory bodies including Health Canada (as discussed above), and U.S. scientific groups such as the U.S. Preventive Services Task Force and the 2015 Dietary Guidelines Advisory Committee.[3] Additionally, FDA indicated in its guidance for the scientific evaluation of health claims that it "intends to consider as part of its health claim review process a meta-analysis that reviews all the publicly available studies on the substance/disease relationship."[4] It is unclear why a meta-analysis was not undertaken in the agency's re-evaluation of the soy protein and CHD health claim, particularly when it has been demonstrated by Health Canada that a meta-analysis can be important in assessing the totality of evidence for the relationship between soy protein and CHD. FDA's re-evaluation of the health claim should include an assessment of the direction of effect and a quantitative systematic review.

Thank you for considering our comments.

Sincerely,

Andrea W. Wong, Ph.D.
Vice President, Scientific & Regulatory Affairs

[3] https://health.gov/dietaryguidelines/2015-scientific-report/05-methodology.asp

[4] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm073332.htm