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March 19, 2018

Ms. Crystal Rivers  
Center for Food Safety and Applied Nutrition (HFS-830)  
Food and Drug Administration  
5001 Campus Drive  
College Park, MD 20740

**Re: Docket No. FDA-2017-N-0763 Food Labeling: Health Claims; Soy Protein and  
Coronary Heart Disease**

Dear Ms. Rivers:

On behalf of the American Soybean Association (ASA), I am writing about the Food and Drug Administration (FDA) proposal to revoke its regulation authorizing the use of an unqualified health claim on the relationship between soy protein and coronary heart disease on the label or in the labeling of foods. The American Soybean Association (ASA) represents all U.S. soybean farmers on domestic and international policy issues important to the soybean industry. ASA has 26 affiliated state associations representing 30 soybean producing states and more than 300,000 soybean farmers.

Numerous scientific studies published before and after the soy protein health claim was approved in 1999 show that soy protein lowers LDL-cholesterol and the totality of the evidence supports continued approval of an unqualified health claim. We do not support revoking the authorized claim and do not believe the studies cited by the FDA validate a conclusion to do so.

Given that the FDA has no history of revoking an approved health claim, this unprecedented action puts the Agency on a "slippery slope" regarding such decisions in the future. We strongly suggest that FDA withdraw its proposed rule and then develop and lay out a process for when a claim could be revoked and for what reasons. We believe that overwhelming data must be present to revoke a claim, which is not the case with the soy protein claim.

We appreciate the Agency's clear statement in the record that soy protein has been demonstrated to be safe and lawful. Unfortunately, this proposed rule has unfairly contributed to negative perceptions surrounding soy protein. As part of the final rule, we respectfully ask that the FDA make a public statement to correct any negative impression that has been created due to this rulemaking.

We hope that the FDA will reconsider its proposal. Thank you for your consideration of our concerns.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Heisdorffer", written in a cursive style.

John Heisdorffer  
President