March 8, 2018

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2017-N-0763

Dear Sir or Madam:

The American Heart Association (AHA), including the American Stroke Association and over 30 million volunteers and supporters, appreciates the opportunity to submit comments on the Food and Drug Administration’s (FDA) proposal to revoke the soy protein and coronary heart disease (CHD) health claim. We agree with the Agency’s tentative conclusion: the health claim does not meet the significant scientific agreement (SSA) standard and should be revoked.

**Soy Protein and Coronary Heart Disease**

AHA applauds the FDA’s decision to reevaluate the soy protein and CHD health claim. As the science supporting health claims is often evolutionary, periodic review is necessary to ensure that health claims continue to be based on strong, sound evidence. Since the soy protein and CHD health claim was first approved in 1999, new data have become available which warrant this reevaluation.

As AHA described in our previous 2008 correspondence to the Agency on this topic,¹ we too have conducted multiple reviews of the evidence describing the relationship between soy protein and CHD; and like the FDA, we too have found that the evidence no longer supports a SSA level health claim. In 2000, just one year after the FDA approved the health claim, an AHA Nutrition Committee Scientific Advisory concluded that “it is prudent to recommend including soy protein foods in a diet low in saturated fat and cholesterol.”² However, given the volume of well-
controlled studies on soy protein and soy-derived isoflavones that were released over the
next several years, the AHA Nutrition Committee decided to reevaluate the evidence on soy
protein and cardiovascular disease (CVD) in 2006 to update its scientific advisory. Like the
FDA, AHA reviewed the literature and considered the effects of soy protein and isoflavones
on several other CVD risk factors, including HDL cholesterol, triglycerides, lipoproteins, and
blood pressure. In 2006, AHA published an updated Scientific Advisory titled “Soy Protein,
Isoflavones, and Cardiovascular Health”\(^3\) as well as our Scientific Statement “Diet and
Lifestyle Recommendations Revision 2006.”\(^4\)

Both statements acknowledged that earlier research indicated that soy protein, as compared
to animal protein, potentially had clinically important favorable effects on LDL cholesterol
and other CVD risk factors. However, that research was not confirmed by later studies. The
majority of that research suggested that a very large amount of soy protein, more than half
the daily protein intake, may lower LDL cholesterol by a few percentage points when it
replaces dairy protein or a mixture of animal proteins. That reduction, however, was thought
to be very small relative to the large amount of soy protein tested in those studies and those
data were mainly from hypercholesterolemic individuals. In addition, the possibility cannot
be ruled out that the small benefit was due to an unaccounted-for difference in fatty acid
profile of the diets, with soy rich in polyunsaturated fatty acids and animal fats rich in
saturated fatty acids. Based on that evidence, AHA strongly recommended that FDA revoke
the soy protein and CHD health claim in 2008.

As the FDA notes in the Federal Register notice, the science remains somewhat inconsistent
and support for the claim weak. The majority of new studies show no significant relationship
between soy protein and a reduced risk of CHD, while some indicate varying degrees of
benefit or inconclusive results. This inconsistency does not meet the standard for a SSA level
health claim. Only health claims that are based on strong, sound evidence that indicates an
unambiguous relationship between the substance and the health benefit should be
authorized as an SSA health claim. Additionally, there is a particular concern because the
current claim has a modest minimum serving size of 6.25 g soy protein and an assumption
that soy containing foods will be consumed on at least four eating occasions per day.

For these reasons, we believe the FDA has reached the correct conclusion: the soy protein
and CHD health claim no longer meets the SSA standard and should be revoked. Continuing
to allow the use of the claim could do a disservice to consumers; only clear, scientifically valid
information should be disseminated to the public.

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If the Agency moves forward with its proposal and revokes the claim, however, we believe it will be equally important for the FDA to clearly explain to the public why the claim is being revoked. We know that replacing foods high in animal protein that contain saturated fat with plant protein such as soy is beneficial, and we do not want to unintentionally discourage consumers from doing so. Therefore, it will be important for the FDA to explain that the claim is being revoked because the evidence linking soy protein consumption and reduced risk of CHD is inclusive and is not sufficient to meet the standards of a SSA claim, not that eating soy protein is bad for your heart or does not have any benefit. We are concerned that some media stories did not make that distinction clear when the FDA’s proposed rule was released last fall.

In closing, AHA reiterates our strong support for the FDA’s proposal to revoke the soy protein and CHD health claim. While the science originally appeared to support a strong link between soy protein and a reduced risk for CHD, more recent studies no longer support a SSA level health claim.

If you have any questions or need additional information, please contact Susan K. Bishop of AHA staff at 202-785-7908 or susan.k.bishop@heart.org.

Sincerely,

John J. Warner, MD, FAHA
President
American Heart Association