



February 7, 2017

**VIA ELECTRONIC SUBMISSION**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. FDA-2013-P-0047. Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease.

Dear Sir or Madam:

The American Frozen Food Institute (AFFI), on behalf of its member companies, respectfully requests a 60-day comment period for the interim final rule on health claims related to risk of Coronary Heart Disease.

As the voice of the U.S. frozen food industry, AFFI is the national trade association that promotes and represents the interests of all segments of the frozen food industry. AFFI fosters industry development and growth, and advocates on behalf of the industry before legislative and regulatory entities. AFFI members appreciate the opportunity to provide comments, and our members want to supply as much information to the agency as possible.

In response to an American Heart Association citizen petition, the U.S. Food and Drug Administration (FDA) has released an interim final rule that allows all fruits and vegetables to bear health claims related to lowering the risk of Coronary Heart Disease (CHD). AFFI appreciates FDA's efforts to respond to the petition and the acknowledgement that it is in the interest of public health to send the educational message that all fruits and vegetables can contribute to lowering the risk of CHD. AFFI is concerned, however, that FDA did incorporate the request of the petitioners that, in addition to fresh, frozen fruits and vegetables without added sugar, salt, and fat should be exempt from the health claim's criteria.

FDA has stated they are unsure that providing an exemption for frozen fruits and vegetables will result in the same positive public health impact that they anticipate providing an exemption for raw fruits and vegetables will. FDA has asked for comment and information on this particular issue. Accordingly, AFFI is collecting information and research from our members to assist FDA in the finalization of the rule. However, AFFI requests additional information about the specific concern that FDA has with frozen fruits and vegetables. FDA states in its conclusion, "it is difficult to know all of the types of products that may become included in an exemption." If only single ingredient or mixtures of frozen fruits and vegetables without added salt, sugar, or fat are exempt, what other ingredients or products is FDA envisioning falling into that category that may not positively contribute to

lowering the risk of CHD? AFFI would appreciate knowing what examples FDA has in mind so that we are given the opportunity to respond accordingly in our comments.

AFFI is also representing our companies in comments in several other FDA comment periods such as the Nutrition Facts Label draft guidance, the Request for Information on "Healthy," several food safety draft guidance, and would appreciate additional time in this comment period so we meaningfully participate in the rulemaking process for all of these issues.

Our members are passionate about their frozen fruits and vegetables positively impacting public health goals. AFFI is excited to provide FDA with more information to assist in responding the American Heart Association's petition.

AFFI hereby requests an extension of 60 days to comment period of this interim final rule. Please do not hesitate to contact us if you have any questions regarding this request. Thank you for your consideration.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Donna M. Garren". The signature is fluid and cursive, with a long horizontal stroke at the beginning.

Dr. Donna Garren  
Senior Vice President of Scientific and Regulatory Affairs  
American Frozen Food Institute