

Congress of the United States
Washington, DC 20510

June 26, 2017

Mr. Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We write to request the status of a “Qualified Health Claim” petition; specifically, the “Petition for the Authorization of a Qualified Health Claim for Macadamia Nuts and Reduced Risk of Coronary Heart Disease,” Docket FDA-2015-Q-4850.

As specified in 21 CFR 101.70 the process for a “Qualified Health Claim” petition within the U.S. Food and Drug Administration (FDA) takes no more than 270 days. If the FDA needs additional time to process the petition, no more than two extensions of 90 days each may be requested by the FDA to the petitioner.

Royal Hawaiian Macadamia Nut, Inc. submitted Docket FDA-2015-Q-4850 on September 4, 2015. Assuming that the petition review had been conducted on-time without a request for an extension, a decision by FDA would have been reached in June of 2016. However, as of late April 2017 Royal Hawaiian has received four separate requests for 90-day extensions from the FDA, double the allowable number of extensions as cited in 21 CFR 101.70. This means that if another request for an extension is not made, FDA has through July 2017 to issue a decision to Royal Hawaiian. This is more than a full year after the initial petition process would have been completed in accordance with 21 CFR 101.70.

As you can imagine, this level of uncertainty has left Hawaii’s macadamia nut industry frustrated and concerned with the status of the petition. Macadamia nuts are a very important commodity for Hawaii, with a farm value of \$46 million during the 2015-2016 season. Being able to label macadamia nuts as “healthy,” like that afforded to other tree nuts following FDA’s approval of that health claim in 2003, would help the industry communicate to consumers that macadamia nuts are not just an indulgent product, but can be considered as part of a healthy diet.

Issuing a decision for the Royal Hawaiian petition that was submitted nearly two years ago would provide needed certainty to our macadamia nut industry on the labeling of their product. As such, we request information on the status of the petition as well as a timeline for which Royal Hawaiian can expect the petition process to be finalized.

Thank you for your consideration of this request.

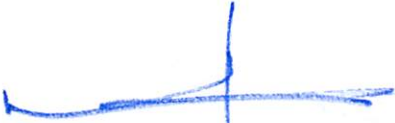
Sincerely,



MAZIE H. HIRONO
United States Senator



BRIAN SCHATZ
United States Senator



COLLEEN HANABUSA
Member of Congress



TULSI GABBARD
Member of Congress