

May 25, 2021 Guy Johnson, Ph.D. 3801 W. 28th Street Minneapolis, MN 55416

Dear Dr. Johnson:

We are requesting an additional 1-year extension from the current due date of May 26, 2021, in order to complete our review of the qualified health claim petition submitted by Danone North America regarding the relationship between consumption of yogurt and reduction in the risk of type 2 diabetes mellitus.

FDA, including the staff in our office, are currently engaged in activities related to addressing the Coronavirus Disease 2019 (COVID-19) outbreak. These high priority activities are requiring a significant amount of our time and resources right now and they are diverting some of our attention from our other regular work. However, we are continuing work on our other food labeling issues, including on our response to your petition.

With this 1-year extension, we would inform you of our decision by May 26, 2022. Unless an extension for reaching a decision about the petition is mutually agreed upon between FDA and the petitioner, the petition would be deemed denied.

Please reply to this letter (email is acceptable) and let me know if Danone North America agrees to the 1-year extension we are requesting.

Please feel free to call me at 240-402-1581 if you have any questions or would like to discuss this matter further.

Thank you for your consideration.

Sincerely,

Cherisa Henderson Nutrition Assessment and Evaluation Team Office of Nutrition and Food Labeling Room 3D-044, HFS-830