From: Guy Johnson
To: Smith, Lillian

Cc: Kevala, Jillonne; BLECHMAN Amanda; Miguel.FREITAS@Dannon.com

Subject: [EXTERNAL] RE: Extension Request for Danone North America: Yogurt and reduced risk of Diabetes

Date: Wednesday, May 25, 2022 11:20:01 AM

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Dear Drs. Smith and Kevala,

Thank you for alerting us to the need for another extension for our petition entitled, "Petition for the Authorization of a Qualified Health Claim for Yogurt and Reduced Risk of Diabetes" originally submitted to your office on December 18, 2018. While we were hoping to receive your response during the previous extension period, we formally grant your request for an additional year until May 26, 2023.

We understand that FDA has been dealing with many competing priorities, which have undoubtedly been compounded by the pandemic. However we're hoping you can give us some sense of a realistic timeframe for the agency's response. I'm sure you can appreciate the fact that it is becoming increasingly difficult to explain these delays to senior management and other stakeholders within the Company -- especially as the science supporting the association between yogurt and type-2 diabetes continues to accumulate as shown, for example, by a recent meta-analysis (Zhang et al., Can J Diabetes 2022;46:307). Any insights you can share as to the current status of the petition, and its priority within CFSAN would be very much appreciated.

We would be happy to meet with you if that approach would be helpful.

Sincerely,

From: Smith, Lillian [mailto:Lillian.Smith@fda.hhs.gov]

Sent: Monday, May 23, 2022 11:19 AM

To: guy@nutritionsolutions.net

Cc: Kevala, Jillonne

Subject: Extension Request for Danone North America: Yogurt and reduced risk of Diabetes

Hello Dr. Guy Johnson,

This is Lillian Smith and Jill Kevala from FDA and we are contacting you regarding a qualified health claim petition you submitted on behalf of Danone North America for a claim about Yogurt and reduced risk of Diabetes. We tried calling your number 612-926-8208, but got a message that the number had been disconnected. Regardless due to limited staff and other competing priorities, such as other health claim and qualified health claim petitions, FDA would like to request a 1-year extension to complete our review and have a final response.

A 1-year extension would be until May 26, 2023 and of course we would get a final response to you if it is possible before that date.

Respectfully,

Lillian Smith, Ph.D., MS
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Nutrition Assessment and Evaluation Branch
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