

From: [Guy Johnson](#)
To: [Smith, Lillian](#)
Cc: [Kevala, Jillonne](#); [Amanda Blechman](#); [FREITAS Miguel](#)
Subject: [EXTERNAL] RE: Extension Request for Danone North America: Yogurt and reduced risk of Diabetes
Date: Tuesday, May 23, 2023 9:17:14 AM

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Dear Dr. Smith.

The six month extension you requested is granted.

Would it be possible for you to send us citations of the new studies you have identified?

Thank you.

From: Smith, Lillian [mailto:Lillian.Smith@fda.hhs.gov]
Sent: Monday, May 22, 2023 3:53 PM
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 we are contacting you regarding a qualified health claim petition you submitted on behalf of Danone North America for Yogurt and Diabetes. It is a priority for our Office to provide a response to your qualified health claim petition for Yogurt and Diabetes and we appreciate your patience. As you may know there are about 30 (27) newer studies that have been recently conducted on yogurt and diabetes between 2019 and 2023. We need to consider those additional studies in our review of the publicly available evidence.

In addition, due to limited resources, everyone involved with the response is juggling multiple projects and priorities which require several layers of review. Some of those layers are outside of our office and once it leaves our office, we have very little control over timing of the response. Since receiving your QHC petition the agency has undergone some major challenges such as COVID-19 and the Infant Formula shortage. Those challenges coupled with our limited resources have delayed our response. That is why we are requesting a 6-month extension for FDA's response to the petition.

A 6-month extension would put the due date of November 22, 2023, which falls on a Wednesday. Our goal is to complete the petition in a timely manner, and we will keep you informed.

If you and the petitioner agree you can send me an email stating that they have granted the request.

Respectfully,

Lillian Smith, Ph.D., MS

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