TATE & LYLE

TATE & LYLE
5450 Prairie Stone Parkway
Hoffman Estates
Illinois 60192
USA
Tel +1 847 396 7500
Fax +1 847 396 7600
www.tateandlyle.com

August 7, 2020

Addendum to Docket No. FDA-2019-P-4006-0001

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fisher Lane
Room 1061
Rockville, MD 20852

Dear Commissioner,

This letter and attachment are an addendum to the petition dated August 21, 2019 that was submitted by Tate & Lyle Ingredients Americas LLC (Docket No. FDA-2019-P-4006-0001).

The petition requests the Commissioner of Food and Drugs to amend 21 CFR §101.9(c)(1)(i)(C) to assign a calorie value of 0.2 kcal/ gram of fiber to a sub-type of resistant maltodextrin composed primarily of non-digestible oligosaccharides of glucose molecules (minimum of 70%) that are joined by specified linkages, with a ratio of 1-4 to 1-6 linkages that is less than 2.2. For purposes of the petition, this sub-type of maltodextrin is referred to as "resistant maltodextrin A." Tate & Lyle's PROMITOR® Soluble Fiber is an example of "resistant maltodextrin A."

At the time the petition was submitted, the breath hydrogen clinical study that was discussed in the petition was not yet published. However, as of July 30, 2020 the study was published in the *Journal of the American College of Nutrition*. (Canene-Adams, *et al.*)

It was previously established that PROMITOR® Soluble Fiber is fermented by human microbiota using a Simulator of the Human Intestinal Microbial Ecosystem (SHIME®). (Marzorati, *et al.*) The Marzorati *et al.* abstract is attached.

To further examine this effect in humans Tate & Lyle performed a randomized, double-blind, crossover study to determine the available energy of PROMITOR® Soluble Fiber products by measuring post-consumption breath hydrogen, with inulin as a control. (Canene-Adams, et al.) Breath hydrogen, a marker for fermentation, was quantified following consumption of beverages consisting of water and the following: inulin (control), PROMITOR® Soluble Fiber 70 (SF70) or PROMITOR® Soluble Fiber 85B

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(SF85B) at 5, 10, or 15g (total ingredient weight, "as is"). Subjects were generally healthy men and women (N = 19), age 18 to 34 years, with body mass index (BMI) 19.3 to 24.8 kg/m^2. The available energy (kcal/g ingredient and kcal/g fiber) from SF70 and SF85B at each dose was calculated using inulin as the reference.

Breath hydrogen production was significantly lower following consumption of SF70 and SF85B compared to inulin at all consumption amounts. There were no significant differences in breath hydrogen production following consumption of SF70 compared to SF85B. The available energy per gram of fiber was not significantly different between SF70 and SF85B. The available energy of the fiber portion of PROMITOR® Soluble Fiber products was determined to be 0.2 kcal/gram using a calculation described in the petition.

Based on the results of this breath hydrogen clinical study, we conclude that PROMITOR® SF is a lower calorie sub-type of resistant maltodextrin ((C6H10O5)n), that provides 0.2 kcal per gram of fiber**.**

Sincerely,

Lore W. Kolberg, MS RDN
Director, Regulatory and Scientific Affairs
Tate & Lyle Ingredients Americas LLC

References cited above:

- Marzorati M, et al. Abstract presented at 6th International Dietary Fibre Conference; France, 2015.
- Canene-Adams, K, Spence, L, Kolberg, LW, Karnik, K, Liska, D, Mah, E. 2020. A randomized, double-blind controlled study to determine the available energy from soluble fiber. *JACN* 40: Published online 30 July.