

Brandon Walters Intertek 2233 Argentia Rd. Suite 201 Mississauga, ON Canada L5N 2X7

Re: GRAS Notice No. GRN 000941

Dear Mr. Walters:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Swedish Oat Fiber to cease our evaluation of GRN 000941, which we filed on August 28, 2020. We received this request on May 12, 2021.

The subject of the notice is oat polar lipid extract for use as a source of oat phospholipids, an emulsifier, or as a partial substitute for other fats and oils in baby food, pan or flat bread products, beverages and beverage bases, breakfast cereals, specialty coffee drinks and combined coffee and whitener, dairy product analogues, fats and oils, frozen dairy desserts, grain products and pastas, milk products, plant protein products, snack foods, chocolate, nougat, and toffee at levels up to 2.0 g/100 g, in flavored or carbonated waters at levels up to 0.8 g/100 g, and in sport or electrolyte drinks and fluid replacement drinks at levels up to 0.2 g/100 g.

The notice informs FDA of Swedish Oat Fiber's view that oat polar lipid extract is GRAS through scientific procedures.

In a March 31, 2021 telephone conversation, we discussed the issues we identified during our evaluation of GRN 000941. In general, our comments related to insufficiencies of the safety narrative supporting the ingredient's GRAS status through a compositional approach or through toxicology studies conducted with the notified substance. We recommended that Swedish Oat Fiber request that we cease our evaluation of the notice. In a follow-up email on May 5, 2021, we provided an additional detailed list of minor issues with the notice and suggested that Swedish Oat Fiber request a pre-submission meeting with us to discuss oat polar lipid extract, prior to submitting a new notice. In an email dated May 12, 2021, you requested on behalf of Swedish Oat Fiber that we cease our evaluation of GRN 000941.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000941 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.

Carlson -S

Digitally signed by Susan J. Carlson -S

Date: 2021.06.11 14:20:40

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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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