



Severin Mueller
Naturex
Givaudan International SA
Kemtpark 50
8310 Kempththal
SWITZERLAND

Re: GRAS Notice No. GRN 001077

Dear Mr. Mueller:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001077, which we filed on November 17, 2022. We received this request on June 6, 2023.

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 cakes, muffins and biscuits, margarine and margarine-like spreads, and chocolate at levels up to 1.0 g/100 g; white chocolate at levels up to 1.5 g/100 g; nut spreads and non-milk-based meal replacement beverages at levels up to 2.0 g/100 g; and coffee and tea whiteners at levels up to 3.0 g/100 g of finished food. The notice informs us of Naturex's (you, your) view that these uses of oat polar lipid extract are GRAS through scientific procedures.

In a March 15, 2023 telephone conversation, we discussed issues we identified during our evaluation of GRN 001077 and suggested that you request that we cease to evaluate this notice. In general, our comments related to an insufficient safety narrative supporting your GRAS conclusion, and deficiencies in the 28-day feeding study used to establish a no observed adverse effect level (NOAEL). Additionally, this study, which we considered pivotal to your safety decision, is unpublished.


In a follow-up email on June 1, 2023, we provided a detailed list of deficiencies in the notice and suggested that you request a pre-submission meeting with us prior to submitting a new notice for oat polar lipid extract.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001077 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S



Digitally signed by
Susan J. Carlson -S
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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