Jo Anne Shatkin, Ph.D.
Vireo Advisors, LLC.
111 Perkins St.
Apt 223
Boston, MA 02130

Re: GRAS Notice No. GRN 000954

Dear Dr. Shatkin:

The Food and Drug Administration (FDA, we) is granting the request from Vireo Advisors, LLC.'s (Vireo), on behalf of Borregaard AS, Evergreen Packaging, LLC., Fiberlean Technologies Limited, Sappi North America Inc., Sappi Papier Holding GmbH, Sappi Southern Africa Limited, Stora Enso Oyj, and Weidmann Fiber Technology by Weidmann Electrical Technology AG, to cease our evaluation of GRN 000954, which we filed on November 23, 2020. We received this request on May 25, 2021.

The subject of the notice is fibrillated cellulose for use as a rheology modifier, stabilizer, low calorie fat substitute and bulking agent, source of fiber, component to improve food quality (e.g. humectant and texturizer), and processing aid in baked goods and baking mixes (at levels of 0.5-5.0%), puffed snacks (at levels of 2-5%), alcoholic beverages (at levels of 0.3-0.5%), non-alcoholic beverages (at levels of 0.28-1.0%), cheeses (at levels of 0.1-1.25%), confections and frostings (at levels of 0.2-5.0%), salad dressings (at levels of 1.0-3.0%), fruit juices and drinks (at levels of 0.5-2.0%), frozen dairy desserts and mixes (at levels of 0.1-1.0%), gelatins, puddings and fillings (at levels of 1.4-4.8%), gravies and sauces (at levels of 0.25-1.3%), milk and milk products (at levels of 0.25-0.7%) (all calculated as a weight/weight percentage). Additionally, it is intended for use as a protective coating for fresh fruits and vegetables at levels up to 10 g per square meter of produce.

The notice informs us of Vireo's view that these uses of fibrillated cellulose are GRAS through scientific procedures.

On March 24, 2021, in a telephone conversation with you, we discussed the issues we identified during our evaluation of GRN 000954. In general, our comments related to the lack of adequate physiochemical characterizations of the notified substances (six fibrillated celluloses) and a robust comparison among them and the reference fibrillated cellulose substance; the need for more data to complete and strengthen the toxicological read-across between these substances; and a lack of evidence to demonstrate consensus among experts in the scientific community that the intended uses are GRAS.

Additionally, we suggested that Vireo request that we cease our evaluation of the notice. In a follow-up email on May 12, 2021, we provided a detailed list of the issues we identified in the notice and suggested that a food additive petition may be the appropriate regulatory pathway for the intended uses described in the notice. In an email dated May 25, 2021, you requested on behalf of the notifiers that we cease our evaluation of GRN 000954.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000954 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2021.06.10 15:55:02 -04'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition