U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

James Miller
Omeat Inc.
2495 Teller Rd.
Thousand Oaks, CA 91320

Re: GRAS Notice No. GRN 001254

Dear Mr. Miller:

The Food and Drug Administration (FDA, we) is granting the request that we cease our evaluation of GRN 001254. We received this request on September 23, 2025. We received Omeat Inc.'s (Omeat) notice on February 22, 2025 and filed it on June 26, 2025.

The subject of the notice is bovine plasma protein preparation (BPP) for use as a source of protein and as a cell culture aid in the production of cell cultured beef products at a level resulting in up to 90% by weight of the food. The notice informs us of Omeat's view that these uses of BPP are GRAS through scientific procedures.

In an email on September 15, 2025, we communicated additional information needed to support a GRAS conclusion to your agent. The following deficiencies were noted: absence of robust digestibility discussion, including supporting data, and material errors that impacted the readability and clarity of the notice. Given the extent of the changes needed to continue our evaluation, we recommended that Omeat request that we cease our evaluation of the notice.

We have ceased our evaluation of the notice at your request. We remind Omeat of a manufacturer's responsibility to ensure the safety and regulatory status of the substances that it markets for use in food or that it uses in food. We also remind Omeat that the use of a substance in food that is not GRAS (and is not otherwise excluded from the definition of a food additive), must have pre-market approval by FDA for its use in food (21 CFR 170.30(g)). More information about the criteria for GRAS is available in our regulations (21 CFR part 170).

Your request does not preclude Omeat from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that Omeat address these issues to adequately support a GRAS conclusion. Finally, we remind Omeat of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which Omeat agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

U.S. Food and Drug Administration
Human Foods Program
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 001254 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.09.29 16:17:54 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program

cc: Stephanie Hretz, M.P.H., C.P.H.
Director
Risk Management and Innovations Staff
Office of Policy and Program Development