



Ashish Talati
Amin Talati Wasserman, LLP
100 S. Wacker Drive
Suite 2000
Chicago, IL 60606

Re: GRAS Notice No. GRN 001042

Dear Mr. Talati:

The Food and Drug Administration (FDA, we) is granting the request on behalf of GF Fermentech, Inc. (GF Fermentech) to cease our evaluation of GRN 001042, which we filed on May 4, 2022. We received this request on March 15, 2023.

The subject of the notice is menaquinone-7 (MK-7) derived from a strain of *Bacillus subtilis natto* for use as an ingredient at a maximum level of 10 µg per serving in beverages and beverage bases, breakfast cereals, cheeses, fats and oils, frozen dairy desserts, grain products and pastas, milk, milk products, processed fruits and fruit juices, and processed vegetables and vegetable juices. The notice informs us of GF Fermentech's view that these uses of MK-7 are GRAS through scientific procedures.

In a teleconference on November 3, 2022, we informed you that we had concerns regarding the dietary exposure for MK-7 in patients who are on anticoagulant therapies such as warfarin and noted that the safety assessment of MK-7 should be based on the data for adults on warfarin and not on the data for healthy individuals. We further noted that the clinical studies on MK-7 discussed in the GRAS notice considered the use of anticoagulants as an exclusion criterion when recruiting individuals for the study.


In your emails dated January 4, 2023 and February 16, 2023, you proposed to decrease the use level and remove some food categories from the intended uses. We found your responses to be inadequate to address our concerns. During a telephone call on March 8, 2023, you proposed to amend GRN 001042 to the same intended conditions of use as GRN 000887¹. In an email dated March 13, 2023, we recommended that GF Fermentech request that we cease our evaluation of GRN 001042 and submit the revised dossier as a new notice. We further suggested that you request a pre-submission meeting with us prior to making a new submission. In an email dated March 15, 2023, you requested on behalf of GF Fermentech that we cease our evaluation of GRN 001042.

¹ MK-7 was the subject of GRN 000887. We evaluated GRN 000887 and responded in a letter dated June 12, 2020, stating that we had no questions at the time regarding the notifier's GRAS conclusion.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001042 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

 Digitally signed by Susan J.
Carlson -S
Date: 2023.04.03 11:40:40
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition