Stuart M. Pape
Polsinelli PC
1401 Eye Street NW, Suite 800
Washington, DC 20005

Re: GRAS Notice No. GRN 000091

Dear Mr. Pape:

The Food and Drug Administration (FDA, we) is providing additional information relevant to the GRAS notice that you submitted on behalf of Marlow Foods Ltd. (Marlow) on December 1, 2001. Specifically, we are providing additional information about a publicly available quality standard for mycoprotein (Mycoprotein from *Fusarium venenatum*). The U.S. Pharmacopeia has developed a monograph for this substance that will serve as a publicly available quality standard (Food Chemicals Codex, 13th edition[1]).

In a letter dated January 7, 2002, we informed you that we had no questions at that time regarding Marlow's conclusion that mycoprotein is GRAS under the intended conditions of use, provided that neither trichothecene mycotoxins (represented by nivalenol, deoxynivalenol, 3-acetyldeoxynivalenol, diacetoxyscirpenol, fusarenone X, and neosolaniol) nor fusarin mycotoxins are detectable in the ingredient.

In addition, in our January 7, 2002, response to GRN 000091, we indicated our intent to complete our evaluation of Food Additive Petition 6A3930, stating that it would be valuable for the procedures that Marlow has developed to ensure the safe manufacture of mycoprotein to be available in a concise and convenient form through incorporation by reference in FDA's regulations.[2] Subsequently, as explained in our letter to you dated February 2, 2022, we concluded that it would not be appropriate to issue a food additive regulation for an intended use of a substance for which we have issued a "no questions" response to a GRAS notice. In response, Marlow withdrew the food additive petition (21 CFR 171.7).[3]

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[1] The monograph for mycoprotein from *Fusarium venenatum* published on September 1, 2022, as part of the Food Chemicals Codex, Thirteenth Edition, First Supplement, having an effective date of December 1, 2022.
[2] FDA notes that procedures for the manufacture of mycoprotein are included in the Food Chemicals Codex monograph. FDA further notes that the monograph includes detection methods for, and specifications limiting, trichothecene mycotoxins and fusarin mycotoxins.
[3] In the *Federal Register* of May 5, 2022 (87 FR 26707), FDA announced the withdrawal, without prejudice to a future filing, of FAP 6A3930.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In issuing this additional correspondence, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing mycoprotein. Accordingly, our additional correspondence should not be construed to be a statement that foods containing mycoprotein, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

In accordance with 21 CFR 170.275(b)(2), the text of this letter providing additional correspondence to GRN 000091 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlso
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Digitally signed by Susan J. Carlson -S
Date: 2023.09.28 15:14:17 -04'00'

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