

2002 FEB 28 10:00 AM

February 28, 2002

Mr. Joe Levitt, Director  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5700 Paint Brush Parkway  
College Park, MD 20740-3835

Re: GRAS Notice No. GRN 000091; Food Additive Petition FAP 6A3930

Dear Mr. Levitt:

Marlow Foods Ltd.'s Quorn Foods, Inc., of Riverside, Connecticut, recently began marketing a line of meat-free products containing its mycoprotein ingredient, a substance recently self-designated GRAS by Marlow Foods (a division of AstraZeneca) in a notification to the FDA that the FDA did not question.<sup>1</sup> We applaud the company for developing and marketing nutritious products that have little impact on the environment, especially compared to meat and poultry. However, we urge the Food and Drug Administration (FDA) to take enforcement action regarding the deceptive labeling of those products, to reconsider the GRAS designation, and not to approve mycoprotein as a food additive until certain testing is conducted.

### **I. Labeling**

“**Quorn meat-free patties**” and related products are mislabeled, in violation of section 403(a)(1) of the Food, Drug, and Cosmetic Act. Copies of product labels are attached.

The label states:

- “‘Mycoprotein’ comes from a small, unassuming member of the mushroom family, which we ferment like yogurt.”

In fact, the mycoprotein in this product comes from *Fusarium venenatum* fungus. Though all mushrooms are fungi, not all fungi are mushrooms—and *Fusarium* is not a mushroom. The manufacturer is deceiving consumers by indicating that its product is somehow made from a familiar, natural, rather costly, umbrella-shaped food that people have eaten for a long time. The

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<sup>1</sup> GRAS Notification for Mycoprotein, Marlow Foods Ltd., Nov. 30, 2001; FDA response letter, Jan. 7, 2002.

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mycoprotein in this product has nothing to do with mushrooms. Indeed, two articles, written by Marlow Foods employees, in *Food Technology* about the production and marketing of mycoprotein products never use the word “mushroom” even once.<sup>2</sup> The mycoprotein is produced as a continuous fermentation product and is considered a single-cell protein. It has never been used in the American food supply and has only been used in Europe for the past decade or so. Though it is obvious why the manufacturer does not wish to define mycoprotein as fungal in origin, it should be required to do so and not deceive consumers about the nature of its product.

The manufacturer also compares the production of mycoprotein to the production of yogurt. That, too, is deceptive. Yogurt is basically milk that has been fermented by small amounts of various bacteria (not fungi). Those bacteria moderately alter the characteristics of the basic milk ingredient. In the case of mycoprotein, the fungus *is* the basic ingredient. Fermentation is not modifying other ingredients, but is the means of creating the product itself.

- Common or usual name

The ingredient label identifies Marlow’s new ingredient as “Mycoprotein\* ... \*Mushroom in origin.” “Mycoprotein” is a word not even included in the dictionary (Merriam Webster’s Collegiate Dictionary, 10<sup>th</sup> edition; Webster’s New World, second college edition (1982)). Other than a few mycologists, no consumer would understand what the ingredient is (and we suspect that the manufacturer will not be mounting an educational campaign to explain to consumers what the ingredient really is. Furthermore, “*mycoprotein*” suggests that the ingredient is a particular protein, whereas, in fact, the ingredient is only 50 percent protein.<sup>3</sup> A common or usual name like “fungal extract” would be descriptive. If it allows the unfamiliar technical term “mycoprotein” to be used in the ingredient listing at all, the FDA should stipulate a more explanatory common or usual name, such as “mycoprotein from fungus.”

- “We do not use ingredients that were produced using modern biotechnology.”

Judging from the description of the manufacturing process, it appears that the mycoprotein *is* produced using modern biotechnology. The technology appears to be quite modern or sophisticated, with temperature controls, aeration, and specific nutrients all designed to produce *Fusarium* fungus in a continuous-fermentation process. The fungus is alive (“bio”) and the manufacturing system is certainly a “technology.” Of course, the *Fusarium* fungus is not genetically engineered, but genetic engineering is only one form of biotechnology. It would be accurate for the company to say that its product is not genetically engineered, but that, too, might

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<sup>2</sup> Rodger G. “Production and properties of mycoprotein as a meat alternative.” *Food Technology*, 55, No. 7, 36-41 (July 2001). Wilson D. “Marketing mycoprotein: the Quorn Foods story.” *Food Technology*, 55, No. 7, 48-9 (July 2001).

<sup>3</sup> Miller SA, Dwyer JT. “Evaluating the safety and nutritional value of mycoprotein.” *Food Technology*, 55, No. 7, 42-6 (July 2001).

be misleading, because no mycoprotein is genetically engineered.

- “Made from natural ingredients”

That phrase on the front label suggests that the product is made from familiar ingredients. However, in eight or so products that the company is marketing, mycoprotein is the key ingredient, and it is certainly not a familiar ingredient. We don't deny that it is natural, but we believe that the average consumer would interpret “natural ingredients” as the kind of ingredients that are used to produce competing meatless patties, cutlets, and the like. Those products are usually made of soy protein, wheat protein, comminuted vegetables (including *real* mushrooms), and other natural, familiar ingredients.

- Nutrition claims

“**Quorn meat-free Fettuccine Alfredo**” emphasizes the nutritional value of Quorn, stating that it has “About half the calories and a third less fat than skinless chicken breast.” That statement may be true about mycoprotein itself, but not about the products in which it is used. In this case, the Quorn version of Fettuccine Alfredo provides 16 grams of fat (25% of the Daily Value), 9 grams of saturated fat (45% of the DV), and 920 milligrams of sodium, which is far more than is present in a skinless chicken breast. The back of the package claims that the mycoprotein is “very healthy.” While that may be true of the mycoprotein itself, the product contains too much fat, saturated fat, and sodium to permit such a claim. (see 21 C.F.R. 101.6) We have similar concerns about “**Quorn meat-free lasagna**.” Also, it is worth noting that the mycoprotein being bragged about comprises only 11% and 7%, respectively, of those products.

## II. Safety and GRAS status

We question the Food and Drug Administration's (FDA) acceptance (“...the agency has no questions at this time...”) of a recent GRAS notification by Marlow Foods Ltd. for its mycoprotein product.<sup>4</sup> The mycoprotein in this product comes from *Fusarium venenatum* fungus, a novel food with virtually no history of use. Indeed, the company states that this fungus was obtained only a couple of decades ago in a soil sample obtained from Buckinghamshire, United Kingdom. Commercial-scale production in the United Kingdom only began in 1994.

It is possible that this fungus can cause allergic reactions. Marlow Foods states that in 1999 and 2000 it received only about 90 reports per year of adverse reactions, including several IgE food-allergy reactions, from consumers of its products. That observation provides some assurance that the fungal proteins do not cause many severe reactions, but it is still weak evidence that those proteins do not cause numerous milder reactions or occasional severe reactions.

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<sup>4</sup> Agency Response Letter, GRAS Notice No. GRN 000091, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Jan. 7, 2002.

Assuming that all the reported reactions were actually due to the mycoprotein and not other ingredients of the foods, one should presume that, because no systematic effort was made to encourage reporting, only a small percentage, perhaps one percent, of people who suffered reactions (a) actually figured out that the reaction might have been due to the mycoprotein product and (b) contacted the company. Thus, the true rate of reaction might not be on the order of 1/140,000, as asserted in the GRAS petition, but closer to 1/1,400. Also, the limited consumption, mostly by adults, of mycoprotein in Europe sheds little light on whether the product may sensitize young children and result in allergic reactions at subsequent eating occasions.

The FDA and Environmental Protection Agency (EPA) are gaining greater experience, and evolving policies for, evaluating the potential allergenicity of novel food ingredients introduced into the human food supply through genetically engineered (GE) crops. Typically, the FDA and EPA consider a protein's molecular weight, heat stability, acid stability, and amino acid sequence to determine whether it is likely to pose a risk of allergenicity. In the case of the Bt protein in StarLink corn, the EPA and its Scientific Advisory Panel recognized that that protein's moderate stability in a simulated gastric environment suggests the possibility that the protein could cause allergic reactions. The EPA has ruled that StarLink protein may be allergenic and that even minute amounts should not be allowed in food. That ruling followed from allergists' acknowledgment that thresholds are not known for either sensitizing a person to an allergen or eliciting a reaction.

In contrast to the minute amounts of the individual novel (to the human diet) proteins in current GE foods, (a) mycoprotein is consumed in *multi-gram* quantities in the form of imitation meat products, (b) mycoprotein contains hundreds or even thousands of proteins not normally consumed by humans, and (c) Marlow Foods apparently has not assessed whether *any* of the novel proteins share the characteristics of known allergens.

We recommend that the FDA rescind its acknowledgment of Marlow Foods' GRAS notification and not approve the food additive petition for mycoprotein/*Fusarium venenatum*. Instead, the FDA should require the company to determine whether any of the proteins in the fungus have the characteristics of known allergens (heat stability, simulated gastric stability, and amino acid sequencing of any stable proteins to identify homologies to known allergens) and pose a risk to consumers.

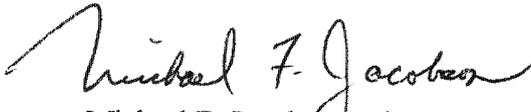
The company's Expert Panel did not express any concerns about possible allergenicity. That may reflect the fact that none of its members was an allergy expert. The absence of such a key expert disqualifies that panel from being considered "expert," and on that ground alone the FDA should have denied GRAS status.

We also note that *Fusarium venenatum* is a member of a group of fungi known to produce toxins. The company says that it ferments the fungus under conditions that preclude the formation of toxins, but the GRAS notification did not specify in any detail the nature and frequency of the company's assays for toxins of concern. The FDA, at the very least, should

specify both manufacturing practices and how often batches must be assayed for mycotoxin content, as well as accepted levels of known mycotoxins. The company should routinely and frequently assay its product, and the FDA should do its own spot-checks.

Thank you for your attention to this matter.

Sincerely,



Michael F. Jacobson, Ph.D.  
Executive Director



Doug Gurtan-Sherman, Ph.D.  
Co-Director, Biotechnology Project

cc: Christine Lewis, Bradford Williams, Alan Rulis

Attached: product labels



**What are you looking for?**

Ask your only source to discover our...  
 • Free choice. A look for a lot longer to find...  
 • Ideal protein source for its key ingredients...  
 • 15 years of searching in many parts of the...  
 • 20-year history. Found what we were looking...  
 • And it was growing naturally in our own...  
 • fields.

• Soy protein comes from a small, unassuming...  
 • member of the mistletoe family, which we...  
 • use for yogurt. Unlike for milk, this...  
 • soy ingredient contains:

- Almost as much protein as an egg
- Twice the fiber of fresh broccoli
- About half the calories of a beef...  
 • And 50% less cholesterol than chicken breast
- Zero cholesterol

That's all very healthy, but we know you're also...  
 • looking for a great taste. Happily, Quorn products...  
 • only contain mycoprotein, but also have that...  
 • taste you're looking for. That's why in...  
 • our, when people first taste Quorn...  
 • all the way through, they say Quorn is the number...  
 • one meat-free brand.

Just Quorn meat-free source sounds like...  
 • if you've been looking for One thing's...  
 • clear: you'll love what's on the package, you'll...  
 • want it all.

Additional ingredients per 25g portion	Quorn Meat-Free Grounds	Lean Ground Beef
Total Fat	1.5g	10.0g
Total Cholesterol	0.5g	25.0g
Total Sodium	0.5g	2.0g
Total Protein	0.5g	1.0g

**Nutrition Facts**

Serving Size 2/3 cup (85g)  
 Servings per Container about 4

Amount Per Serving		Calories from Fat 25	
		%Daily Value*	
<b>Total Fat</b> 2.5g			4%
Saturated Fat 0.5g			3%
Polyunsaturated Fat 1g			
Monounsaturated Fat 0.5g			
<b>Cholesterol</b> 0mg			0%
<b>Sodium</b> 220mg			9%
<b>Total Carbohydrate</b> 5g			2%
Dietary Fiber 4g			16%
Sugars 0.5g			
<b>Protein</b> 13g			26%
Vitamin A	0%	Vitamin C	0%
Calcium	2%	Iron	4%

\* Percent Daily Values are based on a 2000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

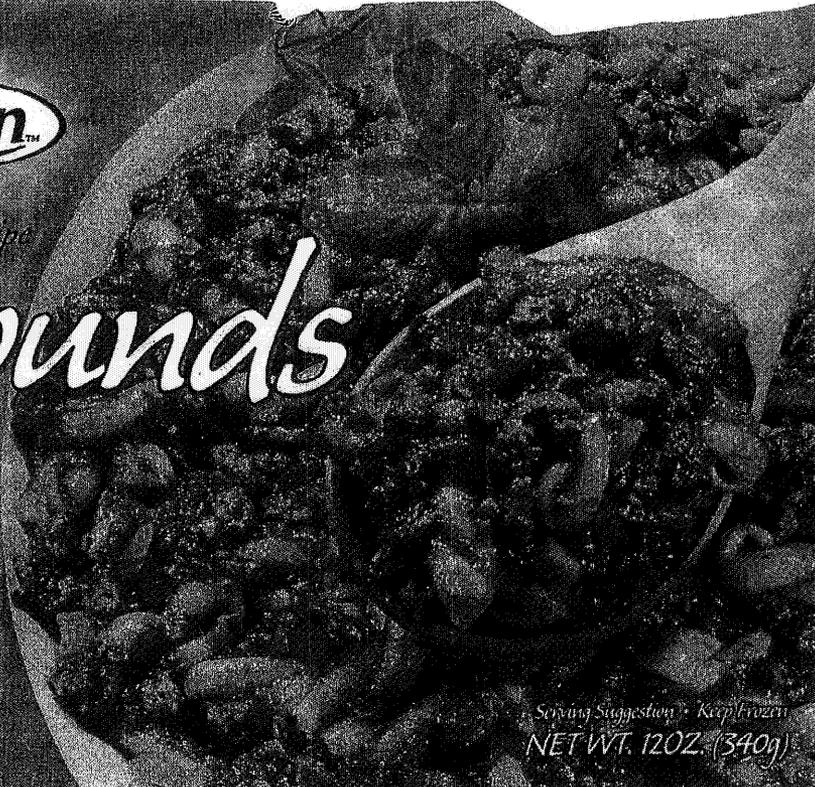
	Calories: 2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2400mg	2400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

Calories per Gram  
 Fat 9 • Carbohydrate 4 • Protein 4



*meat-free recipe*

# Grounds



Serving Suggestion • Keep Frozen  
 NET WT. 12OZ. (340g)



*What are you looking for?*

...of protein in chicken breast...  
 ...of the meat you eat...  
 ...like yogurt...  
 ...Almost as much protein as in pork...  
 ...of your favorite...  
 ...where people are rather cautious...  
 ...the way things taste...  
 ...These Quorn meat-free products...  
 ...you've been looking for...  
 ...it's a work of art...  
 ...what's still...

**Nutrition Facts**  
 Serving Size 1 cup (85g)  
 Servings per Container about 4

Amount Per Serving		Calories from Fat 20	
		%Daily Value*	
<b>Calories</b>	90		
<b>Total Fat</b>	2g	3%	
Saturated Fat	0.5g	3%	
Polyunsaturated Fat	1g		
Monounsaturated Fat	0.5g		
<b>Cholesterol</b>	0mg	0%	
<b>Sodium</b>	350mg	15%	
<b>Total Carbohydrate</b>	8g	3%	
Dietary Fiber	3g	12%	
Sugars	1g		
<b>Protein</b>	12g	24%	
<b>Vitamin A</b>	0%	<b>Vitamin C</b>	0%
<b>Calcium</b>	4%	<b>Iron</b>	2%

\*Percent Daily Values are based on a diet of other people's secrets.  
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 \*Percent Daily Values are based on a diet of other people's secrets.

Calories		2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2400mg	2400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per Gram  
 Fat 9 • Carbohydrate 4 • Protein 4



*meat-free recipe*

# Tenders

*meat-free recipe*

Amount per serving	Quorn Chicken Tenders	Chicken Breast (meat)
Total Fat	2g	2g
Saturated Fat	0.5g	0.5g
Cholesterol	0mg	0mg



- ✓ No cholesterol
- ✓ No trans fats
- ✓ No artificial ingredients
- ✓ No MSG

*Serving Suggestion • Keep Frozen*  
**NET WT. 12OZ. (340g)**



# Fettuccine Alfredo

meat-free



## Quorn Fettuccine Alfredo

## Quorn Fettuccine Alfredo



### COOKING INSTRUCTIONS

#### What are you looking for?

It took you only seconds to discover our wholesome, all-natural line of Quorn™ meat-free cousins. It took us a bit longer to find the ideal protein source for its key ingredient. After 15 years of searching in many parts of the world, we finally found what we were looking for. And it was growing literally in our own backyard.

\*Mycoprotein\* comes from a small, unassuming member of the mushroom family, which we ferment like yogurt. Ounce for ounce, this unique ingredient contains:

- Almost as much protein as an egg
- Twice the fiber of fresh broccoli
- About half the calories and a third less fat than skinless chicken breast
- Zero cholesterol

That's all very healthy, but we know you're also looking for great taste. Happy, Quorn products not only contain mycoprotein, but also have that great taste you're looking for. That's why in Europe, where people are rather particular about the way things taste, Quorn is the number one selling meat-free brand.

We hope Quorn meat-free cuisine sounds like what you've been looking for. One thing's certain: if you like what's on our package, you'll love what's in it.

### Nutrition Facts

Serving Size 1 package (300g)  
Servings per Container 1

Amount Per Serving		%Daily Value*	
<b>Calories</b>	360	Calories from Fat 150	
<b>Total Fat</b> 16g		25%	
Saturated Fat 9g		45%	
Cholesterol 45mg		15%	
Sodium 920mg		38%	
<b>Total Carbohydrate</b> 40g		13%	
Dietary Fiber 4g		16%	
Sugars 5g			
<b>Protein</b> 17g		34%	
Vitamin A	25%	Vitamin C	35%
Calcium	20%	Iron	10%

\*Percent Daily Values are based on a 2000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2400mg	2400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per Gram  
Fat 9 • Carbohydrate 4 • Protein 4

**COOKING INSTRUCTIONS**

**Quorn**  
*Lasagna*

*What are you looking for?*

It took you only seconds to discover our delicious, substantial line of Quorn® meat-free options. It took a bit longer to find the ideal protein source for us here in the States. After 15 years of searching in many parts of the world, we're finally proud to have found what we were looking for. And it's growing steadily on our own backyard!

"Mycoprotein" comes from a small, unassuming member of the mushroom family, which we ferment like yogurt. Once it's done, this unique ingredient contains:

- Almost as much protein as an egg
- More than 10 times the fiber of beef
- About half the calories and a third less fat than chicken breast
- No cholesterol

That's all very healthy, but we know you're also looking for great taste. Happily, Quorn products fit our criteria for great taste. They're made from a special blend of rather plain, 100% mycoprotein, which people are finding delicious in a wide variety of recipes. Quorn is the number one selling meat-free brand.

It's hard to believe, but Quorn meat-free products like this one have been tested for 18 months to ensure that you'll love what's in it.

**Quorn** *Lasagna*

**Nutrition Facts**

Serving Size 1 package (300g)  
Servings per Container 1

**Amount Per Serving**

**Calories 360** Calories from Fat 110

	%Daily Value*
<b>Total Fat</b> 12g	19%
Saturated Fat 4g	20%
<b>Cholesterol</b> 15mg	5%
<b>Sodium</b> 910mg	36%
<b>Total Carbohydrate</b> 43g	14%
Dietary Fiber 4g	16%
Sugars 13g	
<b>Protein</b> 23g	46%

Vitamin A	15%	Vitamin C	15%
Calcium	20%	Iron	10%

\* Percent Daily Values are based on a 2000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2400mg	2400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

Calories per Gram  
Fat 9 • Carbohydrate 4 • Protein 4

**Quorn**

*meat-free*

*Lasagna*

Serving Suggestion • Keep Frozen  
NET WT. 10.6 OZ. (300g)

**Quorn** *Lasagna*

1-0314  
CTP

MICHAEL JACOBSON

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