

April 21, 2003

Dr. Mark McClellan, Commissioner  
U.S. Food and Drug Administration  
Room 14-71  
5600 Fishers Lane  
Rockville, MD 20857

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

Dear Dr. McClellan:

“First, do not harm,” the dictum attributed to Hippocrates, epitomizes the widely accepted cautionary approach to health care. Unfortunately, in the case of a new food ingredient—mycoprotein—the Food and Drug Administration, on which Americans rely for protection from unsafe labeled foods, is not adhering to that philosophy. The FDA is allowing that novel ingredient to be used, even though the agency knows that many consumers will be harmed.

It took the FDA less than six weeks to accept (January 7, 2002) Marlow Foods’ November 30, 2001, notification that its Quorn mycoprotein ingredient is “Generally Recognized As Safe” (GRAS). Beginning in April 2002, CSPI has provided the FDA with copious information demonstrating that Quorn is causing harm, is not GRAS, and should not be allowed to remain in our food supply either as a GRAS substance or a food additive. The FDA has failed to act. I urge you to show leadership on this issue and protect the public’s health.

Please consider these key facts:

- \* The FDA accepted the GRAS designation for mycoprotein, even though it had in its files a company study demonstrating that the ingredient causes vomiting and other gastrointestinal symptoms in several percent of consumers.
- \* The FDA knew that Marlow Foods had been receiving about 100 adverse-reaction reports per year from consumers in the United Kingdom, but the FDA apparently never asked the company for details of those (and possibly other) adverse reactions.
- \* CSPI has provided the FDA with adverse-reaction reports from most of the 558 consumers who have contacted us. Four people reported anaphylactic reactions, hundreds of people

experienced

vomiting or diarrhea, and dozens suffered hives, Mallory-Weiss syndrome, fainting, or breathing difficulties. Many of the people who contacted us experienced such severe symptoms that they needed medical attention, including treatment by family physicians or at hospital emergency rooms. One can be certain that CSPI has received reports from only a tiny fraction of consumers sickened by Quorn.

\* For the past six months the FDA, I am told, has been investigating the reports we have submitted. The slowness of that inquiry is in stark contrast to the speedy acquiescence to Marlow Foods' GRAS notification. And as the inquiry drags on, more and more people are being sickened by Quorn foods.

\* CSPI commissioned a telephone survey of 1,000 randomly selected British consumers that determined that almost 5% of people who ate Quorn mycoprotein experienced vomiting, hives, or other symptoms. That percentage is *higher* than the percentage of consumers who have allergies to peanuts, dairy, and the other major food allergens. At a time that health officials—including Secretary Thompson and you—have evinced great concern about traditional food allergens, it is astonishing that a government health agency would sanction the introduction into the food supply of a *new* ingredient that causes severe reactions (through allergic and/or other mechanisms) in large numbers of people.

\* Mycoprotein, in the future, could become even more difficult to avoid by sensitive individuals. Quorn foods may soon be marketed without labels in food-service situations, as is the case in the United Kingdom. Also, Marlow Foods has started, at least in the UK, to market mycoprotein as a salt substitute (“Mycoscent”); it would be listed on labels only as a “natural flavoring.” If mycoprotein-containing foods are sold at restaurants, cafeterias, and other food-service venues or if mycoprotein is hidden in foods as a flavoring, many more Americans—including those who are seeking to avoid mycoprotein—will suffer adverse reactions.

The FDA has ample authority to halt the use of this odious ingredient. I urge you, as Commissioner, to protect the public by immediately denying the GRAS status of mycoprotein and ordering Quorn foods off the market.

Sincerely,

Michael F. Jacobson, Ph.D.  
Executive Director