

August 23, 2002

Dr. Alan Rulis
U.S. Food and Drug Administration
1110 Vermont Ave. NW 12th floor
Washington, DC

by messenger

Dear Dr. Rulis:

I greatly appreciate the FDA's interest in understanding the problems associated with Quorn mycoprotein. To date, CSPI has received well over 200 reports, about 80 percent from the United Kingdom, where Quorn products have been widely sold for almost ten years. Most of those reports were stimulated by media publicity, one small advertisement in a British newspaper, and individuals' Internet searches and obtained through CSPI's web site, www.quorncomplaints.com. We presume (because of the limited publicity that our web site has received, many people do not use the Internet, individuals' failure to associate symptoms with the cause, some individuals' disinterest in reporting problems, and other reasons) that the reports we received represent just a small percentage of the problems that actually occurred.

I have enclosed all the reports (with personal information redacted) we received via the Internet as of 9:15 a.m. on August 23. We have received (but not enclosed) about 25 additional, but less detailed, reports through the mail or as e-mails sent to a British newspaper. Attached to some of the reports is additional explanatory information received as a result of further e-mail correspondence.

Several points are worth noting:

* At least 9 people reported anaphylaxis, difficulty breathing, or swelling of tissues. That is the first evidence that mycoprotein can cause life-threatening reactions. Considering the difficulty in identifying cases and causes of deaths due to anaphylaxis, it is possible that mycoprotein might already have caused deaths.

* 6 people went or were taken to hospital emergency rooms because of the severity of symptoms

* Numerous people said they vomited so hard that blood vessels broke: bloody vomit: 7; blood vessels in eyes burst: 1; blood vessels in the skin below the eyes visibly burst: 1; nose bleed: 1.

* 8 people reported hives or rashes.

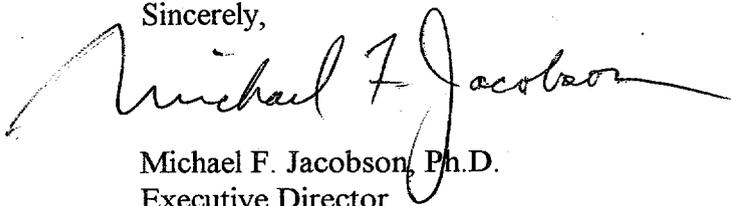
* 6 people fainted and an additional 8 felt on the verge of fainting.

* Labeling is not sufficient to protect people who are sensitive to mycoprotein. Many people got sick after eating Quorn at restaurants/foodservice (some servers said the foods were made with soya). Others who were trying to avoid Quorn foods got sick when they unwittingly ate such foods at friends' homes, at parties, or on airplanes. It is noteworthy that Marlow Foods has been trying to get school systems in the U.S. to use Quorn foods in their foodservice (Palo Alto, California, has considered, but rejected, using those foods).

* Marlow Foods grossly understates the fraction of consumers sensitive to mycoprotein. The company claims that 20 million people (presumably mostly in the UK) have eaten its products since they were introduced. CSPI has received more than 200 adverse reaction reports from the United Kingdom. Thus, just in the past few weeks we have received complaints from 1/100,000 people who have ever consumed Quorn foods. Moreover, surely only a tiny percentage of people who have been affected have contacted CSPI. The new data disprove Marlow Foods' contention that only 1/146,000 consumers is sensitive.

I urge the FDA to investigate this matter and act swiftly. Every day that the FDA fails to deny the GRAS status of mycoprotein and get this flawed product off the market, additional people will be harmed by it. I will be glad to provide whatever information CSPI has that would assist the FDA's inquiry.

Sincerely,

A handwritten signature in black ink that reads "Michael F. Jacobson". The signature is written in a cursive style with a long, sweeping underline.

Michael F. Jacobson, Ph.D.
Executive Director

Enclosures

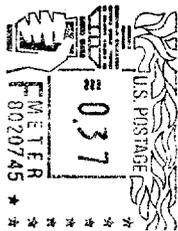
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Interest

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