



JAN 28 2010

Celeste Monforton, DrPH, MPH
Susan Wood, PhD
The Project on Scientific Knowledge and Public Policy
2100 M Street, NW
Suite 203
Washington, DC 20037

Dear Drs. Monforton and Wood:

Thank you for your letter of December 3, 2009. You inquired about the status of a petition submitted in September 2006 by Dr. David Michaels, formerly head of the Project on Scientific Knowledge and Public Policy at the George Washington University School of Public Health and Health Services. The petition requests that FDA cancel the "generally recognized as safe" (GRAS) designation for the food flavoring agent diacetyl until testing is completed and the results are independently evaluated. The petition asserts, and your letter reiterates, that the available scientific evidence no longer supports GRAS status for food uses of diacetyl. In your letter, you also requested a timeline for next steps with respect to your petition.

Your original petition was based largely upon epidemiological studies involving inhalation exposure to butter flavoring (which includes diacetyl) in an occupational setting. As you noted in your letter, additional information about the potential consequences of exposure to butter flavoring or diacetyl has subsequently accumulated from a number of sources. These sources include published scientific studies from scientists at the National Institute of Environmental Health Sciences and the National Institute for Occupational Safety and Health, other published studies, published occupational case reports, and a case report by Dr. Rose that involved a consumer and that was filed in the docket for your petition. We are aware of other consumers who have filed lawsuits involving butter flavoring. Unfortunately, to date no physician with knowledge of such a case (other than Dr. Rose) has provided information to the agency or published their findings in the medical literature. We are contacting certain physicians to encourage them to submit any potentially relevant information to MedWatch, an FDA program for monitoring safety of agency-regulated products that is used by the medical community. We encourage you to share this suggestion with any physicians known to you that may have information relevant to consumer exposure.

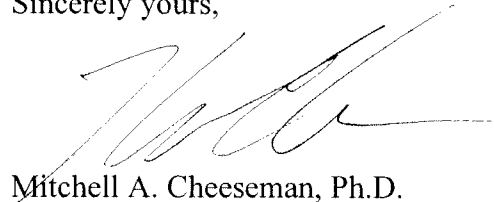
Your petition is under active review at this time. This review will incorporate all the scientific evidence available to the agency and our assessment of its significance for the public health of consumers. The agency intends to issue a substantive response to your petition as soon as our review is completed. We also intend to address the issue of diacetyl-containing substitutes in our response. Although it is highly unusual for FDA to contemplate food ingredient regulation

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on the basis of inhalation, we have not ruled out any regulatory option. Regardless of what regulatory action we might take, we will also need to consider that many diacetyl food ingredient uses involve *de minimis* consumer inhalation exposure (e.g., butterscotch candy) and that diacetyl occurs naturally in many foods including butter. If our review leads us to conclude that additional action is necessary to adequately protect public health, we will take whatever steps are within our legal authority towards that end.

Thank you for sharing your questions with us. If you have additional questions, please feel free to contact us again.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'M. Cheeseman', written over a horizontal line.

Mitchell A. Cheeseman, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition