



December 3, 2009

Margaret Hamburg, MD  
Commissioner  
US Food and Drug Administration  
5630 Fishers Lane  
Rockville, Maryland 20852

Dear Dr. Hamburg:

In September 2006, the Project on Scientific Knowledge and Public Policy at the George Washington University School of Public Health and Health Services submitted a petition to the U.S. Food and Drug Administration (FDA) requesting that the agency cancel the “generally recognized as safe” (GRAS) designation for the food-flavoring agent diacetyl. We submitted our petition (copy attached) pursuant to section 409(b)(1) of the *Federal Food, Drug and Cosmetic Act*, 21 *Code of Federal Regulations (CFR)* 171.130 and as provided in 21 *CFR* 10.30. In March 2007, we received a response to our petition from the Director of the Office of Food Additive Safety, indicating that the agency had not reached a decision on our petition.

More than three years have passed since we filed that petition. We respectfully request information on the status of your scientific review and a timeline for next steps. We note that the docket containing our petition<sup>1</sup> includes a letter from Cecile Rose, MD, MPH reporting the case of an individual with significant lung disease whose only inhalational exposure was heavy, daily consumption of butter-flavored microwave popcorn. Exposure levels in the individual's home were similar to those documented in the quality assurance areas of microwave-popcorn manufacturing plants where workers with lung disease were identified.<sup>2</sup>

Three years have passed since we filed our petition calling on FDA to cancel the GRAS designation for diacetyl. The evidence remains strong: breathing diacetyl vapors causes lung disease, and there is no evidence of a safe exposure level. The FDA's current GRAS

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<sup>1</sup> <http://www.fda.gov/ohrms/dockets/dockets/06p0379/06p0379.htm>

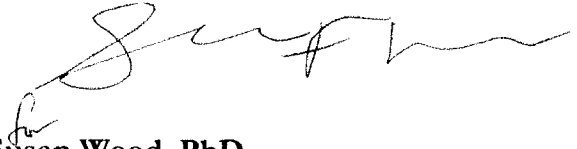
<sup>2</sup> Kanwal R et al. (2006). Evaluation of flavorings-related lung disease risk at six microwave popcorn plants. *J Occup Environ Med* 48(2): 149-57.

designation for diacetyl is not supported by scientific evidence. We again urge the FDA's prompt action to cancel the GRAS designation for diacetyl until proper testing is completed and the results are independently evaluated.

Sincerely,



**Celeste Monforton, DrPH, MPH**  
Assistant Research Professor  
Environmental & Occupational Health



**Susan Wood, PhD**  
Associate Professor of Health Policy and  
Environmental & Occupational Health

Enclosures

cc: Dockets Management Branch  
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