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September 19, 2007

Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

Dear Dr. Von Eschenbach:

Diacetyl is an artificial butter flavoring used in microwave popcorn and other foods that can cause a rare, severe lung disease in workers who are regularly exposed. A new case of the disease suggests that consumers also may face an increased risk through preparation of foods containing diacetyl, such as microwave popcorn. We are writing to request a briefing on what the Food and Drug Administration (FDA) is doing to evaluate the risks posed by diacetyl to consumers.

The risks of diacetyl exposure are increasingly clear and can be extremely dire. Evidence has linked the inhalation of diacetyl to *bronchiolitis obliterans*, a permanent, debilitating condition that can destroy the lungs and ultimately lead to death.¹ Most of the evidence of diacetyl's health effects involves occupational exposures, such as among workers in flavoring and microwave popcorn factories.² A recent case, however, suggests that consumers also may face an increased risk from inhalation of the chemical during food preparation.³ That case, reported to FDA and other federal agencies in July 2007 by Dr. Cecile Rose of the National Jewish Medical and Research Center, does not establish a causal relationship between inhalation

¹ CDC, *Fixed Obstructive Lung Disease in Workers at a Microwave Popcorn Factory --- Missouri, 2000—2002*, Morbidity and Mortality Weekly, v. 51(16) (April 26, 2002) (online at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5116a2.htm>); Kreiss et. al, *Chronic Bronchiolitis Obliterans in Workers at a Microwave-Popcorn Plant*, New England Journal of Medicine, v.347(5) (Aug. 1, 2002); Kanwal et. al, *Evaluation of Flavorings-Related Lung Disease Risk at Six Microwave-Popcorn Plants*, Journal of Occupational and Environmental Medicine, v.48(2) (Feb. 2006).

² *Id.*

³ *That Buttery Aroma May Be Toxic, Too*, Seattle Post-Intelligencer (Aug. 30, 2007).

of diacetyl during food preparation and *bronchiolitis obliterans*, but it does suggest a link.⁴ Given the popularity and widespread consumption of microwave popcorn and other foods containing diacetyl, such a potential connection raises a significant public health concern.

The evidence that diacetyl may be dangerous to consumers is particularly alarming given that FDA has designated the chemical as “Generally Recognized as Safe,” or GRAS. Under the Federal Food, Drug, and Cosmetic Act, FDA allows the use of added ingredients in food only if the additives have been specifically approved as safe.⁵ In the case of added ingredients that are deemed to be GRAS, FDA does not require any pre-market review or approval.⁶ Because FDA has designated diacetyl as GRAS, food producers are free to use the chemical in any amount without proving its safety for consumers.

Diacetyl’s GRAS status was last affirmed by FDA in 1982, many years before the arrival of microwave popcorn as a popular component of the American diet. At the time, an FDA panel found no indication that the chemical posed a hazard to consumers.⁷ Now, 25 years later, medical evidence suggests that diacetyl may pose serious risks not just to workers but also to consumers.

Despite this emerging evidence, FDA has not acted on public calls to reconsider diacetyl’s GRAS status. In a letter responding to one such request, FDA noted that it had not decided on the petition within the 180-day deadline “because of the limited availability of resources and other agency priorities.”⁸ Recently, however, an FDA spokesperson has said that

⁴ Letter from Cecile Rose, Acting Head, Division of Environmental and Occupational Health Sciences, National Jewish Medical and Research Center, to Michael Landa, Deputy Commissioner for Regulatory Affairs, Office of the Center Director, Center for Food Safety and Applied Nutrition, FDA (July 18, 2007) (“It is difficult to make a causal connection based on a single case report. We cannot be sure that this patient’s exposure to butter flavored microwave popcorn from daily heavy preparation has caused his lung disease. However, we have no other plausible explanation.”)

⁵ 21 U.S.C. § 348.

⁶ U.S.C § 321(s) (defining “food additive” to exclude any substance that is “generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures [or, for substances used in food before 1958, experience based on common use] to be safe under the conditions of its intended use.”)

⁷ 47 F.R. 34155 (Aug. 6, 1982).

⁸ Letter from Laura Tarantino, Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, to David Michaels, Director, Project on Scientific Knowledge and Public Policy, George Washington University (Mar. 6, 2007) (online at: http://defendingscience.org/case_studies/upload/FDA_Response_March_2007.pdf); Letter from David Michaels to Andrew Von Eschenbach, Commissioner, FDA (Sept. 8, 2006) (online at: http://www.defendingscience.org/newsroom/upload/Petition_to_FDA_on_Diacetyl.pdf).

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FDA is “carefully considering the safety and regulatory issues” raised by the evidence of potential risks to consumers.⁹

We request a briefing on FDA’s handling of this matter, including its consideration of the GRAS status of diacetyl. We would appreciate your prompt attention to this request. Please contact Robin Appleberry of the Committee staff at (202) 225-5056 or Ken Jacobson of the Science and Technology Committee, Investigations and Oversight Subcommittee staff at (202) 226-3096 no later than Friday, September 21, to schedule a briefing.

Sincerely,



Henry A. Waxman
Chairman
Committee on Oversight and
Government Reform



Brad Miller
Chairman
Subcommittee on Investigations
and Oversight, Committee on
Science and Technology

cc: Tom Davis
Ranking Minority Member

⁹ *FDA Probes Risks of Popcorn Additive*, Wall Street Journal (Sept. 6, 2007).