DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute for
Occuptional Safety and Health
Centers for Disease Control
and Prevention (CDC)
200 Independence Avenue, SW
Washington, DC 20201

July 27, 2006

Mr. Patrick J. McConnon, M.P.H.
Executive Director
Council of State and Territorial Epidemiologists
2872 Woodcock Boulevard
Suite 303
Atlanta, Georgia 30341-4015

Dear Mr. McConnon:

Thank you for your recent letter regarding the Council of State and Territorial Epidemiologists (CSTE) position statement on worker lung disease risk from exposures to flavoring chemicals. The National Institute for Occupational Safety and Health (NIOSH) is in the process of planning or implementing the majority of the activities recommended by CSTE, as noted below:

1. NIOSH has already conducted two animal studies on the toxicity of butter flavoring chemicals. Additional studies are scheduled for the coming year.

2. We have developed a draft survey form for physicians to report possible or probable cases of flavoring-related occupational lung disease. We are communicating with state health departments regarding a reporting system and to discuss states' participation and the details of implementing the system. Until the system is fully implemented, physicians can report possible flavoring-related cases through the NIOSH internet website or by e-mail (flavorings@cdc.gov).

3. NIOSH is starting a medical and environmental investigation at a flavoring plant in California in response to a request for technical assistance from the California Department of Health Services' Occupational Health Branch (CDHS-OHB) and the California Department of Industrial Relations' Division of Occupational Safety and Health (Cal/OSHA).

4. NIOSH is planning a new research effort to evaluate exposures and engineering controls in the flavoring industry. The study marks the beginning of an engineering, solution-based approach to reducing occupational exposures in this industry. As part of this effort, we will contact flavoring companies to discuss the possibility of working

with them to accomplish these goals. NIOSH researchers have previously demonstrated that the use of engineering controls, improved work practices, and other workplace solutions can effectively lower exposures in a popcorn plant. We plan to expand this effort to companies in the larger flavoring industry to identify practical solutions for exposure control.

5. NIOSH has produced an *Alert* on preventing lung disease in workers who use or manufacture flavorings. It was previously disseminated to approximately 4,000 companies that might use butter flavorings to produce various food products, as well as to flavoring manufacturing companies. We are reprinting this *Alert* for redistribution and have produced a Spanish translation of a worker information tear-out sheet contained within the *Alert.* We are developing strategies to alert physicians to consider the possibility of occupational lung disease in patients who have a history of working in food production or flavoring manufacturing plants.

6. We have had regular communications with the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA) staff regarding findings from our investigation of lung disease in workers exposed to butter flavorings. We will continue to communicate our findings to both agencies and provide any other information that would be useful in their prevention efforts.

I welcome the recommendations put forth by CSTE on this very important occupational health issue and look forward to continued input from, and collaboration with, your organization to prevent occupational lung disease from exposure to flavoring chemicals.

Sincerely,

John Howard, M.D.
Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 14, 2006

Patrick J. McConnon, MPH
Executive Director
Council of State and Territorial Epidemiologists
2872 Woodcock Boulevard, Suite 303
Atlanta, Georgia 30341-4015

Dear Mr. McConnon:

Thank you for your July 27 letter regarding occupational exposure to diacetyl. You provided the Food and Drug Administration (FDA) with Council of State and Territorial Epidemiologists (CSTE) position statement 06-OH-01 entitled, "Reducing the risk of bronchiolitis obliterans due to diacetyl and other food flavorings" and requested FDA's comments to the position statement.

Under the Federal Food, Drug, and Cosmetic Act, all food offered for sale in the United States must be safe for consumption. Any ingredient added to the food must either be approved as a food additive by FDA or generally recognized as safe (GRAS) for its intended food ingredient use. Diacetyl is affirmed as GRAS in Title 21 of the Code of Federal Regulations, Section 184.1278 (21 CFR 184.1278) for use as a flavoring agent and adjuvant in food in accordance with good manufacturing practice (http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr184_04.html). FDA's food authority encompasses the appropriate labeling and safety of food for the end consumers of that food. The agency is not aware of any information that would lead it to reconsider the GRAS status of diacetyl for end consumers when used in accordance with 21 CFR 184.1278.

FDA recognizes that safety is context-dependent and that the safety of a substance when consumed as a food ingredient may not correlate with its safety in other settings and through other routes of exposure. The agency is willing to work with other agencies as appropriate. However, the agency believes that the occupational safety concerns you describe in your position statement do not fall within the purview of FDA. Occupational exposure during food manufacturing is within the purview of the Occupational Safety and Health Administration (OSHA). FDA's understanding is that OSHA is working to determine whether additional controls on occupational exposure are needed.

FDA continues to monitor the data and information being generated by OSHA, the National Institute of Occupational Safety and Health, and others, and will re-examine its regulations if any evidence suggests that any use under FDA's jurisdiction may be unsafe.

I hope you find this information helpful.

Sincerely,

Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs