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