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#1 respiratory hospital in the U.S.
US News & World Report

July 18, 2007

Mr. Michael Landa
Deputy Commissioner for Regulatory Affairs
Office of the Center Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-2
5100 Paint Branch Parkway (4B-071)
College Park, Maryland 20740

Dear Mr. Landa:

We are aware that the Centers for Disease Control, the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Food and Drug Administration are addressing different aspects of risks associated with inhalation of chemicals used in butter flavorings, including diacetyl. Publications in the CDC's Morbidity and Mortality Weekly Report describe lung disease in both microwave popcorn factory workers and flavor production factory workers who are occupationally exposed to butter flavorings. We have recently identified a patient with significant lung disease whose clinical findings are similar to those described in affected workers, but whose only inhalational exposure is as a heavy, daily consumer of butter flavored microwave popcorn.

We considered the possibility that this patient developed butter flavoring-related lung disease based on several features of his clinical presentation, diagnostic findings, and disease course, as follows:

1. The patient described progressively worsening respiratory symptoms of cough and shortness of breath. Extensive medical, occupational and environmental history taking did not reveal a known cause for these symptoms. The patient did report daily consumption of several bags of extra butter flavored microwave popcorn for several years.
2. Serial pulmonary function testing revealed progressively worsening fixed airflow limitation without a bronchodilator response and with a normal diffusion capacity for carbon monoxide. This is the pattern of lung physiologic abnormalities described in affected workers.
3. High resolution chest CT scan showed bronchial wall thickening, bronchiectasis, mosaic attenuation and expiratory air trapping. This appearance is similar to the imaging abnormalities reported in affected microwave popcorn factory workers.
4. Lung biopsy showed diffuse hyperinflation, a relative absence of small airways, and bronchioles in various stages of obliteration, findings of bronchiolitis obliterans (BO).

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5. The patient's clinical course has been consistent with that described in microwave popcorn factory workers with BO, with a progressive decline in FEV₁ (Forced Expiratory Volume in the first second, a marker of airflow obstruction) despite treatment with oral corticosteroids. His lung function appears to have stabilized recently with cessation of exposure to butter flavored microwave popcorn.
6. We measured airborne levels of diacetyl during microwave popcorn preparation in the patient's home and found levels similar to those reported in the microwave oven exhaust area in the quality assurance unit of the microwave popcorn manufacturing plant where affected workers were initially described.

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. Given the public health implications of this possibility, we wanted to alert you to our concerns. We have sent similar letters to the Centers for Disease Control, the Environmental Protection Agency, and the Occupational Safety and Health Administration.

Please let me know if you need additional information or detail.

Sincerely,



Cecile Rose, M.D., M.P.H.
Acting Head, Division of Environmental and Occupational Health Sciences
National Jewish Medical and Research Center
Associate Professor of Medicine and Preventive Medicine and Biometrics
Division of Pulmonary Medicine
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Arent Fox

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August 20, 2007

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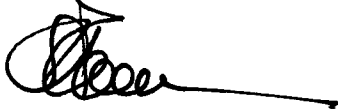
Division of Dockets Management
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

Re: Docket 2006P-0379

Dear Sir/Madam:

We are submitting the attached letter, which our client sent to the Center for Food Safety and Applied Nutrition on July 18, 2007. Please add this submission to Docket 2006P-0379.

Sincerely,



Stanley H. Abramson

Attachment

cc: Ellen Stewart, Esq.

Stanley H. Abramson

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