



**Alcoa**

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July 2, 2002

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

**RE: Docket 02P-0013**

Dear Hearing Clerk:

This document responds to the petition of 12/03/01 by Dr. Colin Meyer to rescind the FDA's Generally Recognized As Safe (GRAS) status for food additives that contain aluminum. In support of his petition, Dr. Meyer asserts several points based on the scientific literature.

In a letter to the Docket dated April 11, Dr. Theodore I. Lidsky refuted the claims by Dr. Meyer and concluded that there is a "large body of solid scientific investigation that simply does not support the hypothesis" that aluminum has a role in the etiology of Alzheimer's disease.

The United Nations World Health Organization (*Environmental Health Criteria* 194; p202) states, "There is no evidence to support a primary causative role of aluminium in Alzheimer's disease (AD). Aluminium does not induce AD pathology *in vivo* in any species, including humans."

Dr. Oyebode Taiwo of the Yale Occupational and Educational Medicine Group concluded in a private correspondence to Alcoa, "I agree that the body of evidence in the literature indicates that aluminum from drinking water or dietary source is unlikely to have a direct toxic effect..."

Alcoa is the world's largest producer of aluminum and a leader in the production of aluminum sheet for food-packaging including can body stock, end stock, formed containers and closure sheet. We also produce household aluminum foil as well as other food, drug and medical device packaging materials. Alcoa has monitored and reviewed the literature regarding the association between aluminum and Alzheimer's disease. Alcoa agrees with Dr. Lidsky's conclusion and has independently concluded that the preponderance of evidence does not support a cause and effect association.

Alcoa is concerned that opening rulemaking on the GRAS status of the salts listed by Dr. Meyer might also raise public concern about the safety of aluminum metal used in packaging or the use of various forms of aluminum hydroxide in packaging. Aluminum has a long-standing role in providing the public with safely packaged foods and pharmaceuticals. Aluminum cans and foil serve as complete barriers to air and light, enabling a longer stable shelf life than many other forms of packaging. Use of aluminum pots and pans in cooking has been recognized as safe for years. Aluminum hydroxide, listed as GRAS under 21 CFR §182.90 and other aluminum salts have FDA clearance for use in food packaging. Proceeding with rulemaking on the selected salts could jeopardize these safe products as well.

02P-0013

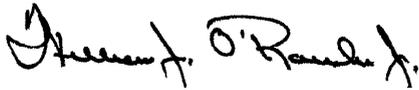
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FDA has a history of utilizing a sound scientific approach in the regulation of chemicals. As stated by Dr. Lidsky, the science supporting Dr. Meyer's claim is simply not there. He poses a theory based on speculation and faulty conclusions based on select, but out-of-date literature. He does not offer up-to-date credible scientific evidence of his claim, and he does not consider evidence that does not support his claim. We urge the FDA to continue to require sound scientific evidence before opening a rulemaking which, apart from casting unsupportable doubt on useful and safe food additives, could also falsely and unnecessarily damage the perception of aluminum's usefulness as a packaging material and therefore have a potentially adverse effect on the overall safety of food.

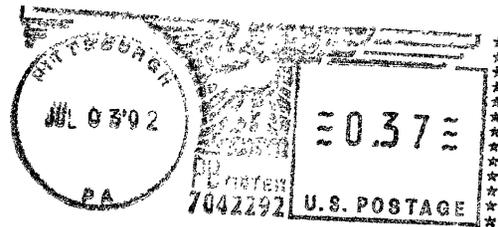
Sincerely,

A handwritten signature in black ink, appearing to read "William J. O'Rourke, Jr.", written in a cursive style.

William J. O'Rourke, Jr.  
Vice President  
Environment, Health & Safety and Audit

2J11  
Alcoa

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