



**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.

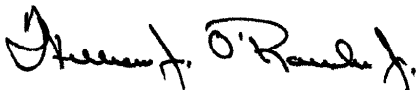
Alcoa is concerned that opening rulemaking on the GRAS status of the salts listed by Dr. Meyer might also raise public concern about the safety of aluminum metal used in packaging or the use of various forms of aluminum hydroxide in packaging. Aluminum has a long-standing role in providing the public 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.

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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.

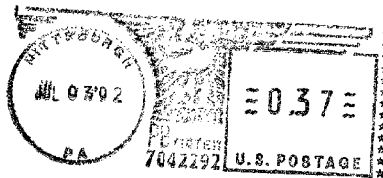
Sincerely,



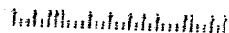
William J. O'Rourke, Jr.  
Vice President  
Environment, Health & Safety and Audit

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# The Aluminum Association

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June 12, 2002

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

**RE: 02P-0013**

To Whom It May Concern:

It has come to our attention that a petition was submitted by Dr. Colin Meyer requesting that FDA rescind its "Generally Recognized AS Safe" (GRAS) status for aluminum-containing food additives. This is in response to that petition.

The Aluminum Association, a non-profit organization that represents the leading producers of aluminum and aluminum products in the U.S. and abroad, has long been involved in the subject of aluminum and health. For more than twenty years we have closely followed the developing studies of Alzheimer's disease and its cause. We have been funding research on the role of aluminum, if any, in this disease at various university and governmental laboratories. In addition, we fund ongoing surveillance of the world's literature on the health effects of aluminum and its compounds.

The Aluminum Association fully supports the document submitted to FDA on April 11, 2002 by Dr. Theodore I. Lidsky of the New York State Institute for Basic Research in Developmental Disabilities and Director of the Center for Trace Element Studies and Environmental Neurotoxicology .

Published studies by Dr. Janet Greger of the University of Wisconsin and Dr. Jean Pennington of FDA indicate that the intake of dietary aluminum is quite small, even with aluminum-containing food additives, and should have no adverse health effects. A human balance study by Dr. Greger showed that dietary levels of aluminum are not retained by the body, but quickly pass through. This was confirmed in later human studies by Priest, et al at the Harwell Laboratories in the U.K.

In a 1986 review article on Alzheimer's disease, Dr. Robert Katzman of the University of California, a noted authority on this condition, concluded that there is no

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evidence that exposure to sources of exogenous aluminum increases the risk of Alzheimer's disease.

In September 1986, the National Institute on Aging and the American Association of Retired Persons jointly sponsored a two-day conference on trace metals, aging, and Alzheimer's disease. The participants could not agree as to whether or not aluminum played a role in Alzheimer's disease, but none advocated it as a causative agent. Subsequent conferences held in Europe also yielded no conclusions.

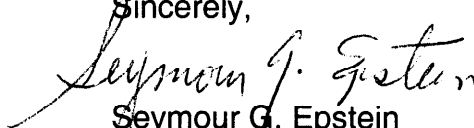
Starting in 1989, The Aluminum Association sponsored several international conferences on aluminum and health to bring together the world's leading scientific and medical authorities to discuss their research findings. The most recent conference was held in May 2001, and it was clear from the discussions that the issues remain controversial and that no definitive link has been established between aluminum and Alzheimer's disease.

In its final rule on air contaminants, published in the Federal Register on January 19, 1989, the Occupational Safety and Health Administration stated that aluminum metal dust has been shown to present a minimal health hazard based on studies and company reports. The Environmental Protection Agency, proposing to delist aluminum oxide from the list of toxic substances under Section 13 of SARA, stated in the April 24, 1989 Federal Register that there is no clear evidence that aluminum has a role in the observed pathological changes, signs, and symptoms of Alzheimer's disease or other neurological diseases in which it has been implicated. The Agency added that aluminum has not been found to be a risk factor for Alzheimer's disease in several case-control studies. Other government agencies and the World Health Organization have reached similar conclusions.

The Aluminum Association continues to fund research on the role of aluminum in the human body. From these efforts, from continuing surveillance of the world's literature, and from personal contacts with leading researchers in the field, we have drawn two basic conclusions: (1) aluminum does not cause Alzheimer's disease and (2) use of aluminum products should not harm health.

For your convenience, copies of the papers referenced in this letter are enclosed. Please feel free to contact me should you need additional information.

Sincerely,

  
Seymour G. Epstein  
Technical Consultant