



DEPARTMENT OF THE ARMY
UNITED STATES ARMY VETERINARY COMMAND
FOOD ANALYSIS AND DIAGNOSTIC LABORATORY
2472 SCHOFIELD ROAD, BLDG 2632
FORT SAM HOUSTON, TEXAS 78234-6232

REPLY TO:
ATTENTION OF:

MCVS-LAB

January 10, 2003

Dr. Alan M. Rulis
Director, Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
College Park, MD 20740

JAN 17 2003

AP


Dear Dr. Rulis:

In response to your correspondence of December 9th (encl 1) regarding Docket No. 02P-0013/CP 1, I am forwarding additional information in support of my petition to rescind the GRAS status of several aluminum-containing food additives. The primary contention of my petition was that there is compelling epidemiological evidence that dietary aluminum is a causal or contributory factor in the pathogenesis of Alzheimer's disease. I also asserted that there are also logical explanations for aluminum-Alzheimer's studies that have failed to demonstrate a positive association, e.g. the presence of silicon in antacid formulations.

There is now additional evidence to support this thesis. The enclosed abstracts of studies of Gauthier et al (encl 2) and Newman (encl 3) indicate that the bioavailability and neuroavailability of aluminum is dependent upon the chemical species of the metal, anions with which it is compounded and dietary co-factors. None of this is at all surprising. Such variables influence the uptake and metabolism of virtually all substances.

While that role that aluminum plays in the pathogenesis of Alzheimer's disease cannot yet be defined it is obviously in the best interest of the public's health to minimize dietary aluminum, particularly in consideration that dietary levels can be reduced by over 50% simply by using alternate leavening agents. If these agents were introduced today rather than having been "grandfathered" as GRAS many years ago, it's a virtual certainty that the FDA would not ignore the current body of scientific evidence that incriminates dietary aluminum and declare them to be GRAS. It requires no more than a superficial risk-benefit analysis of current findings to declare that the inclusion of these agents into the food supply is not a reasonably safe practice.

Sincerely,


Colin G. Meyer, DVM, PhD
Colonel, US Army
Director

02P-0013

supl