

JHeimbach LLC

July 1, 2008

RE: GRAS Status of Lauric Arginate

To Whom It May Concern:

In 2003 an Expert Panel determined that lauramide arginine ethyl ester, an antimicrobial product containing as its active ingredient ethyl-N^α-lauroyl-L-arginate hydrochloride and being known by the common and usual name lauric arginate, is generally recognized as safe (GRAS) for addition to a variety of foods. The GRAS conditions of use allow for addition of lauric arginate to permitted foods at a concentration not to exceed 200 mg/kg of the active ingredient.

The Expert Panel included:

- Joseph F. Borzelleca, Ph.D., Professor Emeritus of Toxicology and Pharmacology, Virginia Commonwealth University Medical School;
- Robert J. Nicolosi, Ph.D., Director, Center for Health and Disease Research, University of Massachusetts at Lowell;
- Michael W. Pariza, Ph.D., Director, Food Research Institute, University of Wisconsin; and
- John A. Thomas, Professor Emeritus of Toxicology and Pharmacology, University of Texas Health Sciences Center

The GRAS determination was submitted to the U.S. Food and Drug Administration (FDA) as GRAS Notice No. GNR164. The Agency accepted this GRAS notice with no questions.

At a later time, this same Expert Panel determined that lauric arginate is also GRAS for addition to carbonated beverages at up to 100 mg/kg of the active ingredient; FDA was also notified of this addition.

Still later, this same Expert Panel determined that lauric arginate is also GRAS for addition to chewing gum at up to 5000 mg/kg of the active ingredient, and FDA was notified of this addition.

FDA has not raised any questions regarding these expansions of the original GRAS conditions of use.

Sincerely,



James T. Heimbach, Ph.D., F.A.C.N.
President