



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of Policy Program
and Development

Washington, D.C.
20250/3700

December 10, 2007

James T. Heimbach, Ph.D.
JHeimbach LLC
923 Water Street
P.O. Box 66
Port Royal, VA 22535

Dear Dr. Heimbach:

I am responding to your e-mail of October 26, 2007, submitted on behalf of your client, Lamirsa, requesting an acceptability determination regarding the use of lauric arginate (LAE), as an antimicrobial agent on fresh cuts of meat and poultry. Specifically, you are requesting that LAE, when used on fresh cuts of meat and poultry, be considered a processing aid and not subject to labeling. LAE is currently approved for application to the surface of fresh cuts of meat and poultry at a level not to exceed 200 ppm LAE by weight of the finished product.

Lamirsa has conducted tests on fresh cuts of beef, pork, and poultry as well as ground beef. In the studies that were done on ground beef the LAE solution was applied to the cuts of beef prior to grinding. The results of the studies showed that the LAE does not have a continuing antimicrobial effect and that it is enzymatically degraded such that 72 hours after application its concentration is greatly reduced and its antimicrobial efficacy is completely lost.

Processing aids are substances that are added to a food for their technical or functional effect during the processing of the food. Because they are not expected to be part of the product, or to provide a lasting technical or functional effect in or on the finished product, processing aids do not have to be declared on a product's label. The data you submitted show that this preparation does not provide a continuing lasting technical or functional effect when applied to fresh cuts of meat and poultry. Thus, we would consider the use of this preparation to be consistent with FDA's definition of a processing aid that is listed in 21 CFR, Section 101.100(a)(3)(ii). There is no lasting functional effect and there is an

insignificant amount present in the finished product under the proposed conditions of use. As such, there are no labeling issues in regard to application to the surface of fresh cuts of meat and poultry.

If we can be of further assistance, please contact me at Area Code (202) 205-0279.

Sincerely,

A handwritten signature in cursive script that reads "Bill Jones".

Bill Jones, Chemist
Labeling and Program Delivery Division