THERMO PAC..
1609 Stone Ridge Dr. Stone Mountain, GA 30083 Tel. (770) 934-3200 Fax (770) 939-6199

June 23, 2011

Mr. John Gridley
District Director
Food and Drug Administration
60 Eighth Street NE
Atlanta, GA 30309

SUBJECT: Response of Corrective Actions regarding notification of FDA Simply Thick finished product results received on June 22, 2011

Dear Mr. Gridley:

I am writing in response to the notification from the FDA on June 22, 2011, that 11 samples of finished product (Simply Thick) and one raw material sample of xanthan gum has tested positive for the organism *Bacillus cereus*. TPL takes these findings very seriously and we continue to devote significant resources to implement corrective measures to address FDA's observations made during the investigation conducted at TPL the dates of May 23 through June 3, 2011. This letter supplements our response to the Form FDA 483 dated June 11, 2011.

In our June 11, 2011, response, we described numerous corrective actions that had been implemented for various products. As it relates to the Simply Thick product, TPL believes that the corrective measures now in place and communicated in our response letter dated June 10, 2011 to Form FDA 483 are effective to address the concerns of the recently communicated test results.

TPL, in conjunction with its customer, Simply Thick, LLC, previously initiated a voluntary recall on June 4, 2011 of the Simply Thick thickening gel as it was unable to provide scientific documentation excluding this product from receiving a thermal process. TPL had been following process parameters that were established and in place for the Simply Thick product prior to TPL's acquisition of the business in July, 2008. Per collaboration with Simply Thick and the FDA, all lots of Simply Thick product produced in the time period of June 1, 2009 to the close out of the investigation June 3, 2011 are under recall. As of June 23, 2011, the recall is still on-going.

Prior to resuming production of the Simply Thick product, processing parameters were established by a competent processing authority. All of the Simply Thick products produced by TPL following the date of June 4, 2011 have been produced following a

filed process established by a competent processing authority and have been reviewed and accepted by the FDA, LACF division. The acidified filed processes were designed utilizing industry-accepted scientific research that assures no public health risk (including the organism *Bacillus cereus*) is present when following the defined and detailed control parameters. The current measures and controls in place to monitor, maintain and document key operating parameters within the production process assure the packaged finished product is commercially sterile and is fully compliant with all federal, state and local regulations.

Upon notification of the FDA finished product results, TPL again consulted with a competent processing authority and was assured the existing thermal process parameters address any concerns for public health risk as it relates specifically to *Bacillus cereus* in the Simply Thick finished product.

Thermo Pac remains strongly committed to supplying the highest quality products to our customers and to the consuming public in compliance with all applicable legal and regulatory requirements. Thermo Pac is of the opinion the above implemented corrective measures address any concerns as it relates to the finished product test results. If you have any questions about our response or the adequacy of the corrective actions, we would be pleased to meet with you to address those questions or concerns.

Thank you in advance for your prompt review and response to this matter. Please contact the undersigned with any questions or clarifications you have concerning this communication of corrective measures identified above.

Sincerely,

Shane Chancellor
Senior Vice President of Operations
Thermo Pac, LLC