

*simply*thick®

The Thickening Gel You Can't Taste®

June 29, 2011

VIA FAX AND U.S. MAIL

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

**RE: SimplyThick's Distribution of Product Manufactured After
Implementation of Corrective Actions and Processing Measures
Established By a Competent Processing Authority**

Dear Mr. Gridley:

As you know, on June 4, 2011 SimplyThick, LLC initiated a voluntary recall of SimplyThick® gel thickener manufactured by Thermo Pac, LLC (TPL) at its Atlanta facility. Since that date, TPL has implemented corrective measures and controls to assure that the product is commercially sterile and is fully compliant with all federal, state and local regulations. Those measures and controls are described in Attachment A (TPL's June 23, 2011 letter to FDA).

Before resuming production of SimplyThick gel thickener products, TPL ensured that thermal processing parameters were established by a competent processing authority. After June 4, 2011, all SimplyThick gel thickener production has followed filed processes established by a competent processing authority and reviewed and accepted by the FDA, LACF division. Those 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 control parameters.

When TPL learned of FDA test results on finished product manufactured before June 4, 2011, TPL again consulted with a competent processing authority and was

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assured that the thermal process parameters address any concerns for public health risk as it relates to organisms generally and *Bacillus cereus* specifically in the SimplyThick finished product.

Based on TPL's current measures and controls, SimplyThick LLC believes that the product manufactured after June 4, 2011 presents no public health risk. For this reason, on Friday July 1, 2011. SimplyThick intends to resume shipping and distribution of product manufactured at the Atlanta TPL facility after June 4, 2011, except for product manufactured from the one lot of xanthan gum that tested positive for *Bacillus cereus*.

Please let me know if you have any questions or concerns or would like to discuss SimplyThick's resumption of distribution of product.

Sincerely,

A handwritten signature in black ink, appearing to read "John L. Holahan". The signature is fluid and cursive, with a stylized "J" and "H".

John L. Holahan
SimplyThick, LLC

Encl.

cc: Michelle Thompson (via email)
Rich Pendleton (via email)
Derek Price (via email)