SimplyThick Announces Voluntary Recall

Important Announcement: June 4, 2011

SIMPLY THICK, LLC ANNOUNCES THE VOLUNTARY RECALL OF PRODUCTS MANUFACTURED BY THERMO PAC, LLC AT THEIR STONE MOUNTAIN, GA FOOD PROCESSING PLANT

St. Louis, MO -- Simply Thick, LLC is announcing a voluntary recall of its SimplyThick® thickening gel products manufactured at a food processing plant located in Stone Mountain, Georgia since June 1, 2009. This plant is currently owned and operated by Thermo Pac, LLC. *This voluntary recall is limited to only those products manufactured at the Stone Mountain, Georgia plant*. Simply Thick products manufactured at two additional food processing plants are *not subject to this voluntary recall*.

Anyone who has purchased or who has **SimplyThick® thickening gel products manufactured at a food processing plant located in Stone Mountain, Georgia** is urged to return the product to the point of purchase for a refund or exchange or contact SimplyThick directly at 1-800-205-7115 for a full refund or an exchange for product(s) unaffected by the recall. Consumers with questions may contact the company at its toll free number 1-800-205-7115 24 hours a day, or by email at <u>latestinfo@simplythick.com</u>.

The SimplyThick® thickening gel products manufactured at the Thermo Pac, LLC Stone Mountain plant are being recalled because the U.S. Food and Drug Administration (FDA) advised the company that Thermo Pac, LLC failed to file with the FDA a scheduled process designed to ensure that vegetative cells (harmful bacteria) of possible public health significance are destroyed during the manufacturing process. This failure was discovered during an FDA inspection of the Thermo Pac, LLC Stone Mountain plant conducted from May 23 through June 3, 2011.

On May 20, 2011, the company notified our customers and medical professionals in Canada and in the United States to follow the FDA's and the Canadian Food Inspection Agency's (CFIA) warning not to give SimplyThick® brand thickener to infants born before 37 weeks gestation who are currently receiving hospital care or have been discharged from the hospital in the past 30 days, pending the results of our, the FDA's and the CFIA's investigations View the FDA press release here..

At this time, Simply Thick has not been advised by the FDA as to whether there is a relationship between the FDA's previous warning and the FDA's recent discovery that Thermo Pac, LLC failed to file a certain process with the agency.

Until the FDA, the CFIA and our company have completed our investigations, we continue to warn against the use of SimplyThick® brand thickener with infants born before 37 weeks gestation who are currently receiving hospital care or have been discharged from the hospital in the past 30 days regardless of whether or not the product is affected by the recall.

For additional information, please call **800-205-7115** or email <u>latestinfo@simplythick.com</u>.