

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 05/23/2011 - 06/03/2011*
	FEI NUMBER 1031630

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Dennis J. Straub, Chief Operating Officer**

FIRM NAME Thermo Pac LLC	STREET ADDRESS 1609 Stone Ridge Dr
CITY, STATE, ZIP CODE, COUNTRY Stone Mountain, GA 30083-1109	TYPE ESTABLISHMENT INSPECTED Acidified and Low Acid Canned Food Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

Failure to provide the FDA, before packing any new product, information on the scheduled processes for each acidified food in each container size.

Specifically, this firm has not filed any scheduled processes for any acidified food products manufactured. Furthermore, there is no documentation or evidence to show that the operating processes used in manufacturing these acidified foods were established by a competent Processing Authority. This would include the processing parameters used for the Simply Thick thickening gel.

**OBSERVATION 2**

Failure to provide FDA, before packing any new product, information as to the scheduled process for each low-acid canned food in each container.

Specifically, this firm has not filed any scheduled processes for any of the low acid cheese products.

**OBSERVATION 3**

Acidified foods are not thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of nonhealth significance capable of growing in the food.

Specifically, it was found the Simply Thick thickening gel is being cold-filled as an acidified food. The target pH range for this product is (b) (4) pH. There is no scientific documentation available excluding this product from receiving a thermal process.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE T. Linda Stewart, Investigator <i>Linda Stewart</i> Robert P. Neligan, Investigator <i>Robert Neligan</i> Nelson A. Rodriguez, Investigator <i>Nelson Rodriguez</i> Rory C. Burton, Investigator <i>Rory Burton</i> Arlyss M. Jones, Investigator <i>Arlyss M. Jones</i>	DATE ISSUED 06/03/2011
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**OBSERVATION 4**

Failure to perform chemical testing where necessary to identify sanitation failures and possible food contamination.

The firm's allergen monitoring program is not sufficient to assure complete cleaning is accomplished when positive (b) (4) (b) (4) swab tests are found. Specifically, on 4/10/11 a positive result was found on the sweep (paddle) in a (b) (4) kettle and only the sweep was cleaned, not the entire kettle. Four more positives were found on this sweep (paddle) and it took five cleanings of the sweep before a (b) (4) test was negative. There is no indication to show that the rest of the kettle was cleaned or tested with a (b) (4) allergen detection test. Additionally, this firm uses ingredients containing several recognized allergens but they only are testing for peanut proteins.

Secondly, it was observed that the firm continues to store peanuts and peanut products directly next to non-allergenic products. For example, in warehouse slot #1619601 (b) (4) powdered starch (lot (b) (4)) is stored directly behind (b) (4) Peanuts (b) (4) lb cardboard boxes under lot (b) (4). Also, in warehouse slot #1619602 it was observed that (b) (4) xanthan gum (b) (4) cardboard boxes and (b) (4) partial box under lot # (b) (4) were being stored directly behind (b) (4) Peanuts (b) (4) cardboard cases under lot (b) (4).

Lastly, no finished products are analyzed for allergens to validate the allergen program. This would include finished product testing of the Simply Thick thickening gel for allergens.

**OBSERVATION 5**

Failure to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing.

Specifically, during the months of August thru November of 2010, the (b) (4) testing results (b) (4) - an indication of protein residuals detected after cleaning is completed) indicated a failure rate of 64.28% for August, 80.77% for September, 72.0% for October and 75.0% for November. Corrective actions taken did not result in a decrease in sanitation failure rates as evidenced by continued high rates of (b) (4) testing failures.

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**OBSERVATION 6**

Process deviations are not evaluated by a competent processing authority in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health.

Specifically, due to no scheduled processes being filed for any acidified foods, every batch of every acidified food manufactured by this firm would be considered a deviation. However, the firm continued to manufacture and ship finished product without an evaluation.

**OBSERVATION 7**

Supervisors have not satisfactorily completed training in a school approved by the Commissioner for areas under their responsibility.

Specifically, there are no direct line supervisors that have attended a Better Process Control School for manufacturing acidified and low acid canned foods.

**OBSERVATION 8**

Operators of processing and packaging systems are not under the operating supervision of a person who has attended and satisfactorily completed a school approved by the Commissioner.

Specifically, none of the production personnel directly involved in manufacturing of Acidified Foods and Low Acid Canned Foods have attended a Better Process Control School.

**\* DATES OF INSPECTION:**

05/23/2011(Mon), 05/24/2011(Tue), 05/25/2011(Wed), 05/26/2011(Thu), 05/27/2011(Fri), 05/31/2011(Tue), 06/01/2011(Wed), 06/02/2011(Thu), 06/03/2011(Fri)

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