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June 10, 2011

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

SUBJECT: Response to Observations documented on form FDA 483 during date of inspection 5/23/2011 to 6/3/2011, FEI # 1031630

Dear Mr. Gridley:

I am writing in response to the Form FDA 483 issued on June 3, 2011 at the conclusion of FDA's inspection of the Thermo Pac LLC ("TPL") Stone Mountain, Georgia facility, conducted May 23, through June 3, 2011. TPL takes these findings very seriously, and we have and continue to devote significant resources in implementing corrective actions to address FDA's concerns. TPL has carefully reviewed the Form FDA 483 observations, and, as your investigators can attest, we began to aggressively address those concerns while the investigators were still in our facility. We continue to implement appropriate corrective actions to address those concerns with the goal of ensuring that TPL is in compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, ("FDC Act") and regulations adopted to implement the Act.

This letter contains trade secrets and confidential commercial information (collectively "Protected Information"). We request that the Protected Information not be disclosed outside of the government pursuant to exemption 4 under the Freedom of Information Act (5 U.S.C. (b)(4) and 18 U.S.C. 1905.

As our responses demonstrate, we reviewed the investigator's observations from a broad quality system-based perspective. Our corrective actions apply not only to the specific concerns raised by the investigator, but also to the underlying systemic causes of those concerns. We have taken this approach to ensure that our corrective actions are effective and that issues raised in the Form FDA 483 do not recur.

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.

Corrective Measures

Upon notification of this concern during the investigation, TPL voluntarily ceased producing and shipping any acidified food until completion of the investigation. TPL completed an overall

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evaluation of all food items produced at the facility to determine each item that is considered an acidified food. Each scheduled process with the processing parameters was reviewed by a recognized processing authority ("PA") and then filed with the FDA, LACF division, for each of the acidified items identified including Simply Thick thickening gel. As of the date of this letter all acidified filings have been accepted by the FDA. For any future new acidified food TPL will ensure that a competent PA has established the processing parameters and the process is filed and accepted by the LACF branch prior to releasing into commerce. For convenience, please refer to Attachment 1 for copies of the recently approved filings for the acidified foods.

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.

Corrective Measures

Upon notification of this concern during the investigation, TPL voluntarily ceased producing and shipping any low-acid food until completion of the investigation. TPL completed an overall evaluation of all food items produced at the facility to determine each item that is considered a low-acid food. Each scheduled process with the processing parameters was reviewed by a recognized PA and then filed with the FDA, LACF division, for each of the low-acid items identified. As of the date of this letter all new low-acid food filings have been accepted by the FDA. For any future new low-acid food TPL will ensure that a competent PA has established the processing parameters and the process is filed and accepted by the LACF branch prior to releasing into commerce. For convenience, please see Attachment 1 for copies of the recently approved filings for the low-acid foods.

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.

Corrective Measures

TPL, in conjunction with its customer, Simply Thick, LLC, initiated a voluntary recall 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 its 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 were recalled. As of the date of this response, the recall is still on-going. Future lots of Simply Thick product will be produced following filed and accepted process parameters as established by a competent PA. Contained within Attachment 1 are the accepted filed process parameters for the Simply Thick product. Production of this product has not yet resumed; any future production will be in accordance with the properly filed process parameters established by a competent PA.

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)(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)(b) (4) powdered starch (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 1 partial box under lot # (b) (4) were being stored directly behind (b) (4) Peanuts (b) (4) lb 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.

Corrective Measures

Prior to the recent FDA investigation, TPL had invested in building an isolated section of the plant solely for the manufacturing of all products containing peanuts or tree nuts as an ingredient. All products containing peanut and tree nuts as ingredients will be produced on isolated and dedicated equipment, eliminating the potential for peanut or tree nut cross contact via equipment. The peanut / tree nut room is isolated from the remainder of the facility, and that area is separately ventilated to avoid contamination through airborne particles. The area will be staffed with dedicated employees and has isolated and separate break rooms, restrooms and entry ways for employee access. As of the dates of the investigation the complete isolation of any and all peanuts and tree nuts had not been fully implemented. By June 13, 2011, all incoming raw materials containing peanuts or tree nuts will be stored and staged in the isolated room or at an off-site location to eliminate the potential for allergen cross contact.

In addition to isolating all peanut and tree nut containing products, TPL is in the process of re-assessing, comprehensively, its Allergen Control Program. It is already in the process of modifying the Allergen Control Program to include testing for all recognized allergens that are used in the facility as ingredients. The Allergen Control Program will also be modified to include, at a minimum, the annual validation of the sanitation controls and allergen program by testing finished product or surrogate product for presence of allergens. Sanitation procedures will be re-assessed and revised as necessary to detail corrective measures to be followed and documented in the event equipment tests positive for an allergen during routine monitoring. TPL anticipates the review and implementation of the revised Allergen Control Program will be completed by August 1, 2011.

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)(b) (4)(b) (4) - an indication of (b) (4)(b) (4) 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.

Corrective Measures

TPL will evaluate and reassess the Standard Sanitation Operating Procedures to ensure all equipment and utensils are maintained in acceptable condition through appropriate cleaning and sanitizing. TPL currently has a very aggressive daily monitoring pre-operational inspection program. TPL currently considers any (b) (4) swab result greater than (b) (4) as a failure which results in equipment being re-cleaned. In the past, the TPL standard operating procedure has been to delay production until an (b) (4) reading of 0% is obtained. Papers and studies on acceptable (b) (4) limits indicate that a more reasonable accept / reject limit is between (b) (4)(b) (4)(b) (4). In addition, we believe that TPL employees may occasionally perform swabbing immediately following the application of a sanitizer which could produce false positive (b) (4) results. TPL will conduct an audit of the Sanitation program to insure that the cleaning / sanitizing procedures are sufficient. TPL will also conduct side by side (b) (4) analyses to determine a more relevant (b) (4) accept / reject limit. Expected completion date of the review of the SSOP program is September 1, 2011.

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.

Corrective Measures

All quality and processing records will be reviewed within (b) (4)(b) (4) after production by a qualified and Better Process Control School ("BPCS") trained individual. TPL will ensure any future process deviations are brought to the attention of and evaluated by a competent PA in accordance with procedures recognized by competent PAs as being adequate to detect any potential hazard to public health.

TPL conducted an exhaustive record review of the acidified items produced by it since its acquisition of the business in 2008. Each batch of each acidified item was reviewed and evaluated by a competent PA. A comprehensive letter was provided by a competent PA concluding that past production of each acidified food was deemed adequate to prevent any potential hazard to public health with the exception of two items, which were voluntarily recalled by TPL. The specific items recalled were Simply Thick, as previously stated, and a (b) (4)(b) (4). As of the date of this response, the FDA has concurred that the acidified items reviewed and documented in writing by a competent PA are acceptable for release into commerce. For your convenience, Attachment 2 contains copies of the letters provided by a PA stating past production lots are acceptable for release and do not present a potential hazard to public health.

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.

Corrective Measures

Prior to the FDA investigation, TPL had recently recognized that supervisors had not satisfactorily completed training in a school approved by the Commissioner for areas under their responsibility. Specifically, TPL recognized no direct line supervisors had attended a BPCS for manufacturing acidified and low acid canned foods. TPL's Manager of Research and Development was the lone member of management who had attended an accredited BPCS training. Prior to the FDA investigation, a BPCS for acidified foods had already been scheduled. A total of 88 employees of TPL consisting of supervisors, production personnel, quality personnel and management completed BPCS training on 6/3/2011 and 6/4/2011. TPL is currently attempting to schedule BPCS for low-acid canned foods for the same cross functional team. TPL anticipates BPCS for low-acid canned foods will be completed by August 1, 2011. Attachment 3 is a list of attendees for the BPCS held 6/3/2011 and 6/4/2011.

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.

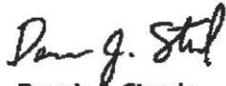
Corrective Measures

Prior to the FDA investigation, TPL had recently recognized that processing and packaging systems were not under the operating supervision of a person who has attended and satisfactorily completed training in a school approved by the Commissioner. TPL's Manager of Research and Development was the lone member of management who had attended an accredited BPCS training. Specifically, TPL recently recognized none of the production personnel directly involved in manufacturing of acidified and low-acid canned foods had attended BPCS. Prior to the FDA investigation, a BPCS for acidified foods had already been scheduled. A total of 88 employees of TPL consisting of supervisors, production personnel, quality personnel and management completed BPCS training on 6/3/2011 and 6/4/2011. TPL is currently attempting to schedule BPCS for low-acid canned foods for the same cross functional team. TPL anticipates BPCS for low-acid canned foods will be completed by August 1, 2011. Attachment 3 is a list of attendees for the BPCS held 6/3/2011 and 6/4/2011.

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 implemented corrective measures or planned corrective measures described above address all observations made by the investigators. 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 in this matter. Please contact Shane Chancellor or the undersigned with any questions or clarifications you have concerning the corrective and preventative measures identified in the response above.

Sincerely,



Dennis J. Straub
Chief Operating Officer
Thermo Pac, LLC

Attachments: #1 Listing of Recently Filed Approvals for Acidified and Low-Acid Foods
#2 Process Authorities Letters
#3 List of Attendees at the Recent TPL Better Process Control School