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60 8th Street, N.E.  
Atlanta, Georgia 30309

November 18, 2003

**VIA FEDERAL EXPRESS**

Winston C. Kutte, President  
Palmetto Food Packaging, LLC  
1218C Donaldson Road  
Greenville, SC 29605

**Warning Letter**  
04-ATL-03

Dear Mr. Kutte:

On August 4-15, 2003, we inspected your Low-acid Canned Food (LACF) processing facility located at Greenville, South Carolina. We found that you have serious deviations from the LACF regulations (21 CFR Parts 108 and 113). Failure to comply with all the requirements of 21 CFR 108.35 and the mandatory portions of Part 113 constitutes a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the Federal Food, Drug and Cosmetic Act (the Act). In addition, such failure renders your low-acid canned food adulterated within the meaning of Section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)). Accordingly your boiled peanuts packed in flexible pouches are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the Low-acid Canned Food regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations of concern are as follows:

1. Your firm has failed to determine and record the initial temperature of the contents of the containers (pouches) to be processed to ensure the temperature was not lower than the minimum initial temperature stated in the scheduled process (21 CFR 113.83(c)). In fact, you have not measured and/or recorded the initial temperature for any of the batches of boiled peanuts processed since your firm began operations.
2. Your firm has not conducted, and maintained records of, any visual and/or destructive seam integrity examinations to assure a consistently reliable hermetic seal on the product pouches (21 CFR 113.60(a)(3)). These examinations and tests must be carried out by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance.

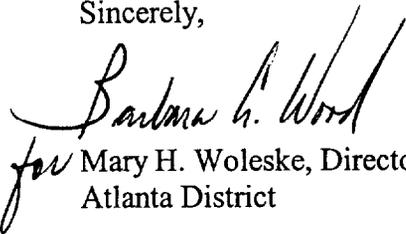
3. Your firm did not maintain complete records of processing and production information (21 CFR 113.100(a)). Specifically, your firm's *DAILY PRODUCTION RECORD* was missing critical factors specified in the formulation of the product or in the scheduled process such as size of container, initial temperature, and actual processing time. Prior to the end of our inspection, you provided our investigator with a new retort operator's log (*DAILY PROCESS RECORD FORM*) which appears to incorporate the necessary elements for proper documentation of the thermal process.
4. Your firm has failed to record fill weights, a critical factor specified in the scheduled process, taken prior to retorting the boiled peanut pouches (21 CFR 113.100(a)). Fill weights and other processing/production information must be recorded at the time it is observed by the retort or processing system operator, or other designated person, on forms designated for this purpose.
5. Your firm has not establish a system for product traffic control in the retort room to prevent unretorted product from bypassing the retort process. In addition, you are not using heat sensitive indicators or alternate means to mark the crates and/or containers therein to indicate visually, to thermal processing personnel, that those units have been retorted (21 CFR 113.87(b)).
6. Your firm has failed to chlorinate or otherwise sanitize the container cooling water as necessary for cooling canals and for recirculated water supplies (21 CFR 113.60(b)).

The above violations are not meant to be an all-inclusive list of deficiencies at your facility. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes and regulations enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure, injunction, and/or issuance of an Order of Need to obtain and hold a Temporary Emergency Permit.

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and a reasonable time within which the corrections will be completed.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

  
for Mary H. Woleske, Director  
Atlanta District