



Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
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April 12, 2004

Warning Letter No. 2004-NOL-23

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Jerry L. Knott
CEO and President
Knott Wholesale Foods
125 N. Blakemore Street
Paris, Tennessee 38242-4283

Dear Mr. Knott:

On January 12-13, 2004, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 125 N. Blakemore Street, Paris, Tennessee. Our investigators documented several deviations from regulatory requirements, which were listed on an FDA 483 Form, issued to Greg Dawson on January 13, 2004. A copy of this document is included for your review. We found that you have a serious deviation from the seafood Hazard Analysis Critical Control Points (HACCP) regulation, Title 21 *Code of Federal Regulations*, Part 123 (21 CFR 123).

In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of this Part, renders the seafood products adulterated with the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, this causes your tuna salad and tuna salad sandwich products to be adulterated within the meaning of Section 402(a)(4) of the Act. You may find the Act and the seafood HACCP regulation through links in FDA's homepage at <http://www.fda.gov>.

The seafood HACCP deviation was as follows:

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (b). However, your firm does not have a HACCP plan for tuna salad and tuna salad sandwiches to control the food safety hazards of pathogen growth and scombrototoxin formation.

Furthermore, a review of some of your product labels reveals deviations from food labeling requirements. These deviations cause your products to be misbranded within the meaning of 403(i)(2), in that the labels on your salads and sandwiches fail to list all of their ingredients. For example, the bread, cheese, salad dressing, cole slaw dressing, mustard, and pickle relish are all ingredients that are, themselves, composed of two or more ingredients which, unless exempt (e.g. see 21 CFR 101.100), must be declared on the label (21 CFR 101.4(b)).

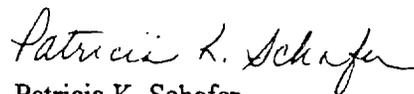
Some of the ingredients that are not listed on your labels may be allergens or cause reactions in individuals who are sensitive to the ingredients. FDA has received increasing numbers of reports concerning consumers who have experienced adverse reactions following exposure to allergenic substances in food. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic response are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans and derivatives of these products.

The above noted observations are not intended to be an all-inclusive list of existing deficiencies. It is your responsibility to assure compliance with all requirements of the Act and regulations, including the violations that are listed above. You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice; such action may include seizure and/or injunction.

We are concerned that your Knott's brand Pickled Eggs product may be an acidified food subject to 21 CFR Parts 108 (Emergency Permit Control) and 114 (Acidified Foods Regulation). If determined to be an acidified food, and you decide to distribute your products into interstate commerce (to locations outside the state of Tennessee), the regulations for Emergency Permit Control under 21 CFR Part 108 will apply to your firm. This regulation includes a requirement for you to register with the Food and Drug Administration and file scheduled process information for any products determined to be acidified foods. Accordingly, we recommend that you contact a processing authority or consultant who is familiar with acidification of foods to assist you in making this determination. More information on whether a food is covered by the acidified food regulations can be found in the "Guide to Inspections of Acidified Food Manufacturers" beginning on page 3 under the heading "Is it an acidified food?" A copy of this guide is enclosed for your use and reference.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Please respond directly to Kari L. Batey, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217 or telephone (65) 781-5380, extension 112.

Sincerely,



Patricia K. Schafer
Acting Director, New Orleans District

Enclosures:

- Form FDA 483
- Guide to Inspections of Acidified Food Manufacturers

cc: Mr. Greg Dawson
V.P. of Operations
Knott Wholesale Foods
125 N. Blakemore Street
Paris, TN 38242-4283