



Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell WA 98041-3012

Telephone: 206-486-8788  
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COPY

October 8, 1997

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**VIA FEDERAL EXPRESS**

In reply refer to Warning Letter SEA 98-03

Larry F. Fountain, President  
Larry's Smokehouse Inc.  
11324 Mukilteo Speedway  
Mukilteo, Washington 98275

**WARNING LETTER**

Dear Mr. Fountain:

The Food and Drug Administration (FDA) has reviewed your label for "LARRY'S SMOKEHOUSE SMOKED SALMON", which was collected by Investigator Weishaar, during her inspection of your firm on September 19 & 22, 1997. Our review reveals that this label causes the above product to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101-Food Labeling, as follows:

1. This product is misbranded in that it fails to declare the proper labeling for the chemical preservative "Sodium Nitrite", in accordance with the requirements of sections 403(i) and 403(k) of the Act.

These sections require the label to state, (1) the common and usual name of the preservative, and (2) the technical or functional use of the preservative, such as: "Sodium Nitrite added as a preservative", or "Preserved with Sodium Nitrite".

2. This product is also misbranded under section 403(e) of the Act in that it fails to have a net weight statement on the label.

The above violations are not meant to be an all inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

These and other deficiencies have been repeatedly brought to your attention in past correspondence following inspections and review of your labels, without response or corrections. Copies of these letters are enclosed for your review.

Larry F. Fountain, President  
Larry's Smokehouse Inc., Mukilteo, WA  
Re: Warning Letter SEA 98-03  
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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

Notify this office in writing, within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations. Your response should include copies of the revised labels. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your reply should be addressed to: Food and Drug Administration, P.O. Box 3012, Bothell, WA 98041, Attention: Robert L. Wesley, Compliance Officer.

A copy of "A Food Labeling Guide", which contains the applicable sections of the food labeling regulations referred to in this letter, is enclosed for your review and information. The guide should help in correcting the other deviations noted in our review of this label and for the label "LARRY'S SMOKEHOUSE BAR-B-QUE SAUCE". Our analysis of one of the ingredients for this product (red wine vinegar), disclosed that it contains a sulfiting agent, which is a chemical preservative. Additionally, the full list of ingredients for the smoke flavoring must be declared, and the specific type of oil used must be declared.

Sincerely,



Roger L. Lowell  
District Director

Enclosures:

A Food Labeling Guide  
Letters dated 12/16/93, 11/25/91 & 7/30/90

cc: Washington State Department of Agriculture  
Food Safety & Animal Health Division M/S AX-41  
P.O. Box 42560  
Olympia, Washington 98504-2560