



COPY

January 23, 1998

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

VIA FEDERAL EXPRESS

Telephone: 425-486-8788  
FAX: 425-483-4996

In reply refer to Warning Letter SEA 98-07

Brian Kemmer, President  
Lyle's Seafoods  
227 N. Sandridge Road  
Ocean Park, Washington 98640

WARNING LETTER

Dear Mr. Kemmer:

During an inspection of your firm on September 24-26, 1997, our Investigator collected samples of product identified as tuna, which is manufactured and distributed by your firm. The inspection found that you distribute product both by the case and individual cans. Review of the individual cans and product cases for labeling, reveal that this product is misbranded within the meaning of Section 403 of the Food, Drug, and Cosmetic Act (Act), in that it fails to meet all requirements prescribed by Title 21, Code of Federal Regulations (CFR), Part 101-Food Labeling.

1. This product is misbranded within the meaning of Section 403(e)(1) and (2) of the Act in that it fails to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.
2. This product is misbranded within the meaning of Section 403(i)(2) of the Act in that it is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient in the food [21CFR 101.4(a)(1)].
3. This product is misbranded within the meaning of 403(g)(2) of the Act in that the product purports to be a food for which a definition and standard of identity has been prescribed by regulation, but fails to bear a label that identifies the name of the food specified by the standard and the common names of the optional ingredients present in the food (21 CR 161.190).

Brian Kemmer, President  
Lyle's Seafoods, Ocean Park, WA  
Re: WL SEA 98-07  
Page 2

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. 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.

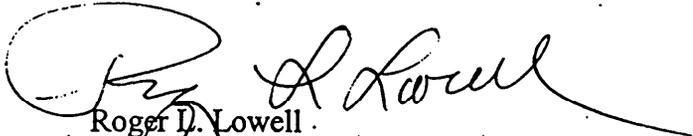
The information provided in the affidavit signed by the manager of your firm indicates that "salt free" canned tuna is also manufactured at your firm. Should your firm decide to sell this product with a salt free claim then the product must be labeled in accordance with the provisions set forth in 21 CFR 101.9 and 101.61 of the regulations. This product would not be exempt from the requirement to bear nutrition labeling if salt free claims are made on the product label.

You should notify this office in writing, within thirty (30) 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 proposed labels. If corrective action cannot be completed within 30 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: Janelle K. Main, Acting 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 preparing a proper label, to include nutritional information.

Sincerely,



Roger D. Lowell  
District Director

Enclosure:  
A Food Labeling Guide

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