



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g1850d

Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2771

October 12, 2001

**WARNING LETTER**  
**WL-CIN-9118-0**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Michael F. Harter, President  
Frank L. Harter & Sons, Inc.  
3778 Frondorf Avenue  
Cincinnati, OH 45211

Dear Mr. Harter:

On July 13, 16 & 18, 2001, the U.S. Food and Drug Administration (FDA) conducted an inspection of your salad manufacturing operation located at the above address. During the inspection, labeling for your "Hawaiian Delight" fruit salad was collected.

Review of this label reveals your product to be in violation of federal law and regulations. The product is misbranded under Sections 403(a)(1), 201(n) and 403(i)(2) of the Federal Food, Drug, and Cosmetic Act by failing to appropriately list the ingredients of the salad, some of which are known allergens.

Specifically, this product contains an ingredient, "sour dressing", which is composed of several other ingredients which are not included in your products ingredient statement. The requirements for and alternative methods of listing ingredients are described in the Code of Federal Regulations (21 CFR) part 101.4.

This is of particular concern because several of these undeclared ingredients are allergenic substances. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life-threatening. Currently, there is no cure for food allergy. The only successful method to manage food allergy is avoidance of foods containing the allergen. These exposures have occurred because the presence of the allergenic substance in the food was not declared on the food label. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustacean, tree nuts, wheat, peanuts, soybeans and derivatives of these products.

The above cited violation is not intended to be an all-inclusive statement of the deficiencies which may exist in your product labeling. 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, such as seizure and/or injunction, without further notice.

Please advise us within fifteen (15) working days of receipt of this letter of the specific actions you have taken to correct these violations. Include copies of your revised labels.

If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

We understand you have initiated a voluntary recall of this product. You should coordinate your recall activities with Wayne Edward, Recall Coordinator, at this office. His telephone number is (513) 679-2700, extension 125.

Your written reply to this letter should be sent to the U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237, to the attention of Charles S. Price, Compliance Officer.. If you have any questions regarding this letter, you may contact Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,



Henry L. Fielden,  
District Director  
Cincinnati District