



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference Number: 2936438

January 7, 2000

Mr. Stephen G. Norcross, President
Fruit Fillings, Inc.
2531 E. Edgar Ave.,
Fresno, CA 93706

WARNING LETTER

Dear Mr. Norcross:

The Food and Drug has reviewed labels collected during an inspection of Fruit Fillings Inc., 2531 E. Edgar Ave., Fresno, CA, conducted by Food and Drug Administration Investigator Christopher J. Lee on March 25, 26 and April 15, 16, 1999. Our review of the labeling for Orchard Fresh Cubed Apple Net Wt. 35 lbs. and Orchard Fresh Sliced Apple Net Wt. 36 lbs. determined that these products are misbranded under Section 403 of the Food, Drug, and Cosmetic Act (the Act) and Title 21 Code of Federal Regulations (21CFR) as follows:

The Orchard Fresh cubed and sliced apples are misbranded within the meaning of Section 403(a)(1) of the Act, in that the term "Fresh" is used in the statement of identity to describe apples that have been subjected to heat treatment and that contain chemical preservatives potassium sorbate and sodium metabisulfite (21 CFR Part 101.95).

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies found in your food product labels. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

We also have the following additional comments regarding the above referenced products:

- If a food contains a chemical preservative, then the food must bear a label

declaration stating both the common or usual name of the ingredient and a separate description of its function, e.g., Ascorbic Acid (A Chemical Preservative)(21 CFR 101.22(j)).

- The ingredient declared as "Fresh Apples, (Prepared with Sulfur Dioxide)" on both of your labels should be more appropriately declared as "Apples (Sodium Metabisulfite added as a Preservative)".
- The ingredient declared as "Potassium (Preservative)" on both of your labels should be correctly declared as "Potassium Sorbate (Preservative)".

Furthermore, at the conclusion of the inspection, a list of insanitary conditions were listed on Form FDA 483 (Inspectional observations) and discussed with your Director of Operations, Mr. William Barr. Please be aware that a food is considered adulterated within the meaning of Section 402(a)(4) of the Act if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met.

You should notify this office within 15 (working) days of receipt of this letter of the specific steps you have taken to correct the violations, including an explanation of preventive measures taken to preclude recurrence of similar violations. Copies of the proposed or revised labels should be submitted with you response. If corrective action cannot be completed within fifteen working days, cite the reason for the delay and the time by which the corrections will be completed. Your response should be sent to: Russell A. Campbell, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely,



Darrell T. Lee
Acting Director
San Francisco District

Enclosure