



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

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

March 14, 2001

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-31

Anthony M. Freytag, General Manager  
Fresh Products Northwest LLC  
#2 Barnett Road  
Medford, Oregon 97501

WARNING LETTER

Dear Mr. Freytag:

On November 9, 2000, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 3907-10 Chelan Highway, Wenatchee, Washington. During the inspection, our investigator collected sample 115909, Crunch Pak Fresh Apple Slices. Our analysis of product labels found the product to have serious deviations from Title 21 of the Code of Federal Regulations 21 CFR Part 101- Food Labeling and to be in violation of Section 403(k) and 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Food Labeling regulations through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

1. Crunch Pak Fresh Apple Slices are misbranded within the meaning of Section 403(k) of the Act in that the labels fail to bear the common or usual name of the chemical preservative, calcium ascorbate, and a separate description of its function. Your labels fail to list calcium ascorbate on the principal display panel or information panel for your product in accordance with 21 CFR 101.4(b)(1). [REDACTED] (calcium ascorbate) is used on your products to prevent browning. In accordance with 21 CFR 170.3(o)(3), this material is an antioxidant and not a processing aid. Furthermore, 21 CFR 182.3189 defines calcium ascorbate as a chemical preservative. Pursuant to 21 CFR 101.22(j), a food to which a chemical preservative is added shall bear a label declaration stating both the common or usual name of the ingredient and a separate description of its function, e. g., "preservative" or "to promote color retention".
2. Crunch Pak Fresh Apple Slices are also misbranded within the meaning of Section 403(i)(2) of the Act, because the food consists of two or more ingredients, but the labels fail to bear an ingredient statement that lists the common or usual name of each ingredient in the food. In accordance with 21 CFR 101.4(a)(1), all ingredients shall be listed by common or usual name in descending order of predominance by weight.

Anthony M. Freytag, General Manager  
Fresh Products Northwest LLC, Medford, Oregon  
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The above violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

For your information, since calcium ascorbate is added to your apple slice products, the products cannot be labeled as "Fresh". In accordance with 21 CFR 101.95(a), the use of the term "fresh" on a food label or labeling implies that the food is unprocessed and that it has not been subjected to any form of preservation. In addition, the FDA also recommends that the bar code on your labels be removed from the "Nutrition Facts" box. In accordance with 21 CFR 101.9(c), only those nutrients listed in FDA's nutrition regulations, as mandatory or voluntary components of the nutrition label, may be included in the "Nutrition Facts" label box.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

Sincerely,



Charles M. Breen  
District Director

cc: WSDA with disclosure statement

Randell E. Wakefield, Plant Manager  
3907-10 Chelan Highway  
Wenatchee, Washington 98801