



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  
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March 9, 2012

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Jimmie L. Davis, President  
Snokist Growers  
P.O. Box 1587  
Yakima, Washington 98907

Dear Mr. Davis:

This letter responds to your letter dated November 9, 2011, written in response to Warning Letter SEA 12-02, dated October 20, 2011. FDA issued that letter to you following an inspection of your food processing facility located at 2506 Terrace Heights Drive, Yakima, Washington, from May 3, 2011, through June 2, 2011.

We find your response to Warning Letter Item No. 1, which addressed your firm's practice of reprocessing moldy applesauce contained in compromised aseptically-packaged flexible laminated bags, to be inadequate. Applesauce that has become visibly moldy during storage exhibits decomposition of the food product and thus is considered adulterated within the meaning of Section 402(a)(3) of the FD&C Act in that it consists in whole or in part of a decomposed substance, namely moldy applesauce. Decomposed product is not acceptable for human food use and is not suitable for reconditioning for human food.

We acknowledge that your response included your process authority's analysis. It was not clear from this analysis what samples were utilized and when they were collected, nor were any analytical records included with your response. However, based on our assessment of your Root Cause & Mycotoxin Analysis Report, and Snokist Growers Rework Policy, we remain concerned that other toxic fungal metabolites could be present in the applesauce product that were not identified in the analysis you provided. If other toxic fungal metabolites are present in the applesauce product this would also cause the applesauce product to be adulterated within the meaning of Section 402(a)(1) of the FD&C Act in that it would bear or contain a poisonous or deleterious substance which may render it injurious to health. Testing for patulin alone would not be sufficient to ensure that decomposed - in whole or in part - applesauce does not contain any of the other possible toxic fungal metabolites.

Regarding your response to the remaining violations, as we stated in the Warning Letter, the adequacy of these corrective actions and their implementation will be evaluated during our next inspection.

We remind you that you are responsible for ensuring that your processing facility operates in compliance with the Act and its implementing regulations. As stated above, we object to your firm's practice of reprocessing moldy applesauce product contained in compromised, aseptically-packaged flexible laminated bags. We further remind you that failure to implement corrective action for this violation may result in regulatory action being initiated by FDA without further notice.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen  
District Director

cc: Washington State Department of Agriculture  
Food Safety Program  
P.O. Box 42560  
Olympia, Washington 98504-2560