



DEPARTMENT OF HEALTH AND HUMAN SERVICES

84924d

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

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

August 4, 2004

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-42

Mr. John R. Scherer, President
Sun Valley Juice Company
101 North Clear Creek Road
P.O. Box 2127
Ketchum, Idaho 83340

WARNING LETTER

Dear Mr. Scherer:

We inspected your firm, located at 101 North Clear Creek Road, Ketchum, Idaho, on April 14 and 16, 2004, and found that you have serious deviations from the Juice Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR Part 120). These deviations cause your 100% unpasteurized orange juice and your 100% unpasteurized grapefruit juice to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the juice HACCP regulations through links in FDA's home page at www.fda.gov. Your firm is classified as a very small business and therefore you were to be in compliance with this regulation by January 20, 2004, as set out in 21 C.F.R. § 120.1.

The serious deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 120.8(a). However, your firm does not have a HACCP plan for your 100% unpasteurized, orange juice and your 100% unpasteurized, grapefruit juice to control the food safety hazard of pathogens, or any other hazards that are reasonably likely to occur. Furthermore, you must develop, or have developed for you, a written hazard analysis to determine whether there are any food safety hazards that are reasonably likely to occur from each type of juice that you process and to identify control measures that you can take to control those hazards, to comply with 21 CFR 120.7(a). Your firm does not have a written Hazard Analysis to determine whether there are food safety hazards that are reasonably likely to occur, and to identify control measures that you can apply to control those hazards, for the

Mr. John R. Scherer, President
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100% unpasteurized, orange juice and the 100% unpasteurized, grapefruit juice that you process.

2. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 120.6(c). However, your firm did not maintain sanitation control records for the following:
 - (a) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;
 - (b) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
 - (c) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;
 - (d) Maintenance of hand washing, hand sanitizing, and toilet facilities;
 - (e) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
 - (f) Proper labeling, storage, and use of toxic compounds;
 - (g) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
 - (h) Exclusion of pests from the food plant.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

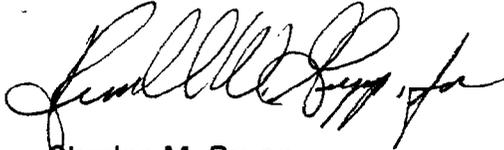
Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plans for your 100% juice products, copies of Sanitation Standard Operating Procedure records, or other useful information that would assist us in evaluating your corrections. 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.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations. Please send your reply to the Food and Drug Administration,

Mr. John R. Scherer, President
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Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, WA
98021-4421. If you have questions regarding any issue in this letter, please contact
Michael J. Donovan at (425) 483-4906.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen". The signature is written in a cursive style with a large, prominent initial "C".

Charles M. Breen
District Director

Enclosure:
Form FDA 483

cc: IDHW, with disclosure statement