

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2773

VIA Federal Express

August 12, 2004

Philip A. Thieneman, President
Paul's Fruit Market, Inc.
4618 Jennings Lane
Louisville, KY 40218

WARNING LETTER CIN-DO 04-21995

Dear Mr. Thieneman:

We inspected your juice processing facility, located at 4618 Jennings Lane, Louisville, Kentucky, 40218, on April 29 and 30, 2004, and found that you have serious deviations from the FDA's juice processing regulations (21 CFR Part 120). In accordance with **21 CFR 120.9**, failure of a processor to have and implement a Hazard Analysis and Critical Control Point (HACCP) system that complies with **21 CFR 120.6, 120.7, and 120.8**, or otherwise to operate in accordance with the requirements of this part, shall render the juice products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your orange juice and grapefruit juice are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act and the juice HACCP regulations through links in FDA's home page at www.fda.gov.

The observations of concern to us are as follows:

1. You must have and implement 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 orange juice and grapefruit juice to control the food safety hazard of pathogens. Your HACCP plan must include control measures that will consistently produce, a minimum 5 log reduction in the pertinent microorganism(s), for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, to comply with **21 CFR 120.24(a)**.
2. 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 for 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 orange juice and grapefruit juice that you process.
3. You must have sanitation control records that document monitoring and corrections, to comply with **21 CFR 120.6(c)**. However, your firm does not maintain sanitation control records for the cleanliness of food contact surfaces and maintenance of toilet facilities.

Paul's Fruit Market, Inc.
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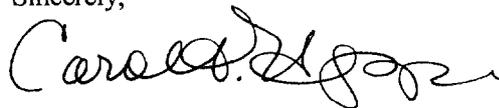
This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the juice HACCP regulation (21 CFR Part 120) and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things that you are doing to correct these deviations. You may wish to include in your response documentation such as your HACCP plan, copies of your Sanitation Standard Operating Procedure, 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.

Your reply should be sent to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 6751 Steger Dr., Cincinnati, OH 45237. If you have questions regarding any issue in this letter, please contact Karen Gale Sego, Compliance Officer, at (513) 679-2700 extension 164.

Sincerely,



Carol A. Hepe
District Director

KGS:kgs

Cc: Guy Delius, Manager
Food Safety Branch
Cabinet for Health Services
275 East Main Street
Frankfort, KY 40621