



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93006

WARNING LETTER

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 27, 2001

WL-22-02

Michael Marker, Co-owner
Angelo Minardi, Co-owner
Premium Fresh Juice and Food Company, Inc.
1961 East Vernon Avenue
Vernon, CA 90058

Dear Messrs. Marker and Minardi:

We inspected your juice manufacturing facility located at 1961 East Vernon Avenue, Vernon, CA 90058 between November 13 and 14, 2001, and found that you manufacture and distribute pasteurized orange and grapefruit juice products and unpasteurized lemon juice products under conditions whereby they may have become contaminated with filth or rendered injurious to health, in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). The orange and grapefruit products are distributed under the "PREMIUM Juice Co." label, and the lemon juice products are distributed under the "Paramount Premium Juice Co." label.

During this inspection, insanitary practices were observed which are in conflict with the Good Manufacturing Practices for foods (Title 21 Code of Federal Regulations, Part 110). These insanitary practices include:

- a thick layer of what appears to be slime mold on the ground directly beneath the hose connection of the pump through which bulk juice enters your facility,
- condensate dripping from overhead pipes onto empty product bottles,
- caked residue from previous uses observed on the exterior portions of multi-use containers,
- a broken drain pipe from the hand washing sink discharging water directly onto the filling room floor,
- insufficient frequency for cleaning the CIP piping system (only monthly),
- poor maintenance of the receiving area where a connection from the bulk transport tanker to the pump moving juice into your facility is located, including garbage (such as plastic bags and food debris),

- bird nests observed in the wall directly above the receiving hose connection point.

Our inspection further revealed repeat violations from the previous inspection of June, 2000, for which you had promised corrections at the time and did not follow through with those corrections. Specifically, you are not following the current SOP when mixing the sanitizer solution, you fail to measure the sanitizer concentration after mixing, and you have not established and followed a calibration plan for equipment such as thermometers.

The gross violations of the GMP's observed at your facility effectively negate the intent of the prior pasteurization process, since once in your plant, the juice products are re-exposed to potential contaminants, and you take no further steps to control or reduce the microbiological load of the products.

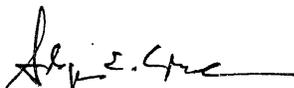
The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

We acknowledge that you corrected the broken drainpipe in the filling suite during the inspection. You should take prompt action to correct the remaining violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction. You should also ensure that all insanitary conditions that we observed during our inspection are also corrected. We provided you a list of these problems on the FDA-483 at the close of the inspection.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and prevent their recurrence. If you cannot complete corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed. Your written reply should be directed to:

Thomas L. Sawyer, Director, Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612

Sincerely


Alonza E. Cruse
District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief