



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1509d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: 2914820

July 13, 2001

Burt T. Okura, President
Hawaiian Sun Products, Inc.
259 Sand Island Access Road
Honolulu, HI 96819-2227

Dear Mr. Okura:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1614 Republican Street, Honolulu, HI on May 9 and 10, 2001.

The inspection found significant insanitary practices and conditions which cause your food products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they have been prepared, packed and held under insanitary conditions whereby they may have been contaminated with filth.

During the inspection, copies of your labeling of frozen juice concentrates were collected. Review of your labels found serious violations of the Act and Title 21, Code of Federal Regulations Part 101—Food Labeling (21 CFR 101). The frozen juice concentrates are misbranded within the meaning of Sections 403(a)(1) and 201(n) of the Act because they do not comply with the labeling requirement that juices not specifically processed to prevent, reduce, or eliminate the presence of pathogens bear the required warning statement set forth in 21 CFR 101.17(g).

The following is a list of the insanitary practices, conditions, and findings observed by FDA:

1. You do not take necessary measures to protect against contamination of food with microorganisms and foreign substances:
 - Peeling paint, mold, and condensation were observed over open beverage vats.
 - Condensation was observed constantly dripping from the moldy ceiling directly into the open beverage vats containing in-process product and into the formulation tank, which also contained in-process product.
 - A water drain line from the second floor processing area is located directly over an open beverage vat.

- The open beverage vats and formulation tank were left uncovered and unattended for at least 15 minutes while they contained in-process product.
 - An employee rinsed off his arm and a scoop, both of which were covered with pineapple puree, with water so that the rinse water drained into the formulation tank.
 - A kettle cover was observed in direct contact with the floor in the chocolate processing area.
2. Not all employees wear hair restraints.
 3. You do not take effective measures to exclude pests from the processing areas:
 - A roll-up door leading from the outside to the beverage processing area, as well as other processing areas of the facility, was observed open throughout the entire inspection.
 - Signs of bird activity were observed inside the facility, specifically, findings of four bird feathers on the floor adjacent to the jam/jelly processing vats.
 4. You do not clean and sanitize non-food-contact surfaces of equipment as frequently as necessary to protect against contamination. Specifically, the interior surface of one of the jam cooling tanks had a buildup of a dark residue around the sides.

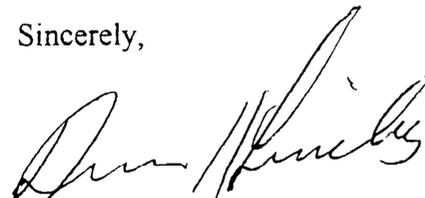
At the conclusion of the inspection, the insanitary practices and conditions were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations.

You should take prompt action to correct the violations. As a manufacturer of FDA-regulated products, it is your responsibility to comply with all provisions of the Act.

Please advise FDA in writing, within thirty (30) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 30 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

Enclosure: Form FDA 483

cc: Rick Sugimoto, Plant Manager
Hawaiian Sun Products, Inc.
1614 Republican Street
Honolulu, Hawaii 96819