



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

g/1982d

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

02-PHI-02

November 16, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rajavel Jagadesan, Owner
Palace Foods, Inc.
100 Cleveland Avenue
Reading, PA 19605

Dear Mr. Jagadesan:

On August 30, 2001 the Food and Drug Administration (FDA) conducted an inspection of your food processing plant located at 100 Cleveland Avenue, Reading, PA. This inspection identified deviations from federal regulations relating to processing of acidified food products. These regulations are described in Title 21 of the Code of Federal Regulations (21 CFR) in Part 108, Emergency Permit Control, and in Part 114, Acidified Foods. Your failure to comply with these regulations causes your acidified foods to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act). These products include, but are not limited to, Coriander Chutney, Mint Chutney, Green Chile Chutney, Ginger Paste, and Garlic, in glass jars.

Specifically, your acidified food products are considered adulterated under section 402(a)(4) of the Act. A food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. The following are the reasons your products are adulterated under the Act:

- ☐ Failure to provide the Food & Drug Administration with information on the scheduled processes for all acidified foods (21 CFR 108.25(c)(2))
- ☐ Failure to retain copies of processing and production records at the processing plant or other reasonably accessible location (21 CFR 114.100(e))

You are reminded that these same deficiencies have been reported to you during prior FDA inspections dating back to 1993 and were formally identified on the Inspectional Observations, form FDA 483, that was issued to you at the conclusion of several of these inspections.

We are aware that you submitted process information to FDA on or about August 15, 2000 for five of your acidified products. However, FDA determined this information was not complete and returned your documents November 2, 2000. The letter that FDA sent to you at that time, which you acknowledged receiving during the August 30, 2001 inspection, identified specific

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Rajavel Jagadesan

information FDA needs in order to evaluate the safety of your processes. As of the date of this letter to you, FDA has not received this information.

You informed our investigator that you had not refiled because you were thinking of changing the processes. You must have on file with us the processes you are currently using. If you decide to change them in the future, there are procedures to follow for submitting a replacement form with the new processing information.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure, injunction and/or issuance of an order requiring an emergency permit prior to future interstate distribution.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. Any corrective action taken should apply to all acidified products you manufacture.

Your reply should be sent to Ann L. deMarco, Compliance Officer, at the address provided in the letterhead.



Thomas D. Gardine
District Director

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cc:

