

CERTIFIED
RETURN RECEIPT REQUESTEDFood and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260
FAX: 313-226-3076**WARNING LETTER**
97-DT-10

May 29, 1997

Mr. Philip J. Ricossa, President
Giovanni's Appetizing Food Products, Inc.
37775 Division Road
Richmond, MI 48062

Dear Mr. Ricossa:

An inspection was made of your low acid canned food manufacturing plant on April 22 to May 6, 1997 by Investigators Michael V. Owens and Roger A. Hartman. At the conclusion of the inspection, you were issued an Inspectional Observations list (FDA-483) which delineated a number of gross insanitary conditions present in your firm at the time of that inspection. These conditions cause the anchovy paste manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

The following is a list of the insanitary conditions observed by our investigators during the inspection.

1. On 4/22/97, approximately 208 opened, heavily rusted cans of anchovies were observed stacked directly on top of each other with the open cans in contact with the rust on the bottom of the cans above. The rusted, cut metal lids were inside the cans, partly submerged in the anchovies, and rust was observed in the product. These cans were seized by the Michigan Department of Agriculture to prevent their use in making anchovy paste until they are adequately reconditioned.
2. On 4/28/97, anchovy cans with a gritty, oily residue on the lid were being opened by an air powered opener which submerged the lids in the product. Your firm's attempt to clean the lids with a wire brush prior to opening appeared to be inadequate.
3. On 4/28/97, your employee was observed placing the rusted bottoms of anchovy cans directly on top of anchovies in plastic totes.
4. On 4/28/97, your employee was observed placing cleaned plastic totes used in anchovy paste manufacturing on the floor and then nesting them for storage. The bottoms which were on the floor were observed to be in contact with the food contact surface of the nested tote.

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Richmond, MI

5. Margarine intended for use in anchovy paste production was observed to be stored overnight outside the cooler so that the product was not kept at or below the labeled storage temperature.

These violations were listed on a FDA-483 which was issued to you at the conclusion of the inspection. The FDA-483 is not intended to be an all inclusive list of violations at your firm. It is your responsibility to assure that all of your firm's products comply with the requirements of the Act and the regulations.

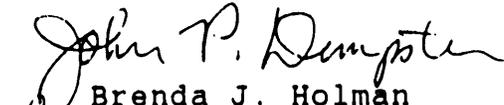
You should take prompt action to correct these violations. Failure to promptly correct them may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

We would also like to call your attention to several apparent label deviations for your anchovy paste product. The ingredient listing for Giovanni's Anchovy Paste does not list either the margarine ingredient, or the ingredients of the margarine. In addition, the specific vegetable oil (canola) is not named in the ingredient listing and the sodium benzoate ingredient is not identified as a preservative. Finally, the [REDACTED] Anchovy Paste label has these same label deviations as well as a nutrition label which declares the product contains no fat, no saturated fat and no cholesterol. However, the Giovanni's nutrition label for anchovy paste in tubes declares 3g of fat, 0.5g of saturated fat and 5mg of cholesterol.

Please notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken or intend to take to correct these violations. If corrective action cannot be completed within the 15 working days, please state the reason for the delay and time within which corrections will be implemented. Please include in your response any plans for correcting the apparent label deviations noted above.

Please direct your response to this office to the attention of Mr. John E. Klemmer, Compliance Officer.

Sincerely yours,


for Brenda J. Holman
District Director
Detroit District