



WARNING LETTER

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

AUG 29 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Albert A. Rodriguez
President
Rodriguez Inc.
3541 South 12th Avenue
Tucson, AZ 85713

W/L 73-00

Dear Mr. Rodriguez:

On March 6, 2000, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of your seafood processing and importing operations, located at the above address. At the conclusion of the inspection, you were presented with Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (seafood HACCP) Regulation. By reason of these deficiencies, the fisheries products processed at your facility are adulterated within the meaning of Section 402 (a)(4) of the Food, Drug and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

For your **domestic processing** operations, the deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for products such as fresh tuna and yellowtail to control the hazard of histamine formation.

For your **import** operations, the deviations were as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for yellowtail or Baqueta (grouper) [REDACTED]
2. You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). Your firm has apparently chosen to utilize 21 CFR 123.12(2)(ii)(D) as an affirmative step. This section of the regulation requires that you have a copy in English

of the processor's HACCP plan and a written guarantee. Our inspection found that you obtain written guarantees but that you do not obtain copies in English of the firm's HACCP plan. Thus you cannot assure yourself that the HACCP plan that the processor uses properly addresses food safety hazards that are reasonably likely to occur for the fish or fishery product they process, and that this plan is being properly implemented.

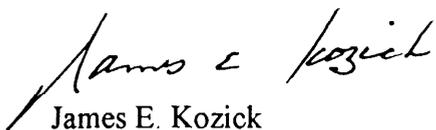
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction. With regard to your importation of fisheries products, failure to correct deficiencies above related to importation may result in refusal of admission pursuant to Section 801(a)(1) of the Act.

Please notify this office in writing, within three (3) weeks from your receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. You may wish to include in your response documentation such as written HACCP plan(s) for your domestic operations, and importer verification steps including product specifications and complete affirmative steps, or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed before you respond, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be directed to:

Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

Sincerely,



James E. Kozick
Acting District Director