DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3178n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

OCT 1 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jeurgen C. Lotter, President
Royal Crown Enterprises, Inc.
780 Epperson Drive
City of Industry, CA 91748

W/L 46-9

Dear Mr. Lotter:

Based on our review of the label for "Royal Crown Foods Abalone Type Shellfish (*Caliptraea trochiformis*)" distributed by your firm, we find this product to be misbranded within the meaning of section 403 (i)(1) of the Federal Food, Drug and Cosmetic Act (the Act) in that it does not bear a common or usual name. The product is also misbranded within the meaning of section 403 (a)(1) of the Act in that it is labeled both as *Caliptraea trochiformis*, the scientific name but not the common name for cap shells, and as "Abalone Type Shellfish" which is not the common or usual name of cap shells or any other seafood, but, which is likely to be taken by consumers as abalone. The Food & Drug Administration (FDA) restricts the use of the name "abalone type shellfish" or "abalone style shellfish" to *Concholepus concholepus*. The product is further misbranded within the meaning of section 403(q) of the Act in that the label fails to bear nutrition labeling as required under 21 CFR 101.9. We note that your firm does not have a small business exemption from nutrition labeling currently filed for this product.

The above referenced product should be marketed with the common or usual name for the species. Members of the family Calyptraeidae for which "*Caliptraea trochiformis*" is found taxonomically, have the common names: cap shells, cup-and-saucer shells, half slippers and trochitas.

We do not object to the use of the scientific name of the product in conjunction with the common or usual name.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other labeling violations may subject a food to legal action. It is your

responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should take prompt action to correct the aforementioned violations. Failure to promptly do so may result in regulatory action without further notice, such as a seizure.

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

Other Canned Seafood Labels:

Recent inspections and other information indicate that your firm continues to distribute canned seafood products which are currently or may have recently been labeled as "Abalone Type Shellfish," including "Royal Crown Foods Abalone Type Shellfish (Odontocynbiola Magellanica)", "Royal Crown Foods Abalone Type Shellfish (Fissurella)", and "Royal Crown Foods Abalone Type Shellfish (Dosidiscus Spp.)". FDA would like to point out that any of these products labeled as "Abalone Type Shellfish" would not be the common or usual name of that item, and would be considered misbranded.

HACCP Concerns:

During our 3/9-10/99 inspection of your distribution facility, we noted several deficiencies relating to your firm's compliance with FDA's seafood processing regulations (21 CFR 123). These regulations require that importers of fish & fishery products have and implement written procedures to verify that your foreign suppliers have implemented a preventative food safety system known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements. These procedures must include product specifications to preclude safety hazards (for each product) and at least one of the affirmative steps as defined in 21 CFR 123.12 (a)(2)(ii).

During our inspection, the FDA investigator observed shortcomings in your verification procedures that, upon our preliminary review, appear to be deviations from the requirements of the HACCP regulations. The FDA investigator also provided you with a copy of the Import Seafood HACCP Report (form FDA 3502), which presents the investigator's evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

Your firm did not have product specifications for the product reviewed during the inspection, canned baby clams from [redacted] As an importer, you are required to have product specifications for each type of fish & fishery product you import, per 21 CFR 123.12 (a)(2)(i).

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's assessment, you should explain how your system is complying with the Seafood HACCP regulations.

In either case, you should respond to this office on this HACCP matter within 30 working days of the receipt of this letter. Upon receipt of your response, we will work with you to resolve any outstanding issues associated with your verification plan. If we do not hear from you, or if your response is inadequate, we will assume that our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

We look forward to working with you to achieve a successful HACCP program.

Your written reply(s) to the labeling matter and the HACCP matter should be directed to:

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

Sincerely,

Acting District Director

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