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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 11, 1998

Mr. Hee Kook Park
Owner
Doo Rae Trading Corporation
1121 East Ash Avenue
Fullerton, CA 92631

W/L 40-8

Dear Mr. Park:

A review of the labeling of fishcake products being manufactured by your firm, including "PLAIN FISHCAKE WITH VEGETABLE", finds that these products are misbranded within the meaning of 403 (a) of the Act. The labels falsely list "Pollack" as the predominate ingredient in these products and our investigator determined that the actual ingredient was whiting surimi, a multi component food. These products are further misbranded within the meaning of 403 (i) (2) of the Act in that the labels fail to declare the common or usual name of each ingredient in the whiting surimi. You may list the ingredients of the whiting surimi according to Title 21, *Code of Federal Regulations* (CFR) 101.4 (b) (2) (i) by using its common or usual name, followed by a parenthetical listing of all ingredients contained therein in descending order of predominance by weight; or according to 21 CFR 101.4 (b) (2) (ii) by incorporating in the ingredient list, the common or usual name of every ingredient in the whiting surimi.

The product is further misbranded in that it fails to bear a label with nutritional labeling as required under Section 403 (q) (1) of the Act, and 21 CFR 101.9. Some small businesses are exempt from the nutritional labeling requirements; however, it is your responsibility to determine if your firm meets exemption requirements and file an exemption notice.

Adulterated and/or misbranded foods are subject to seizure as authorized by Section 304 of the Act. Section 301 (a) prohibits the introduction, or delivery for introduction, into interstate commerce of any adulterated and/or misbranded food. This adulteration and/or misbranding of food after receipt interstate commerce is prohibited by Section 301 (k). Section 302 authorizes the government to seek injunctive relief to restrain violations of Section 301 of the Act.

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 LABELING DEVIATIONS:

The product label bears required information in a foreign language. Therefore, all required information, including the nutrition information, must appear on the label that foreign language. An example of the bilingual format is included in the August 1993 *Federal Register* document.

HACCP DEVIATIONS:

On May 12-15, 1998, Investigator Eric S. Myskowski conducted an inspection of your seafood processing facility located in Fullerton, CA. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and Good Manufacturing Practices (GMP) requirements for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the FDA 483 which presents his evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

1. Your firm has failed to meet the requirements of 21 CFR 123.6 in that it does not have and has not implemented a HACCP plan for hazards which have been identified for your products. Among the potential associated with your product are inclusion of metal fragments and survival and growth of pathogens.

In addition, since some of your product is refrigerated and vacuum-packaged, we are especially concerned about the potential for the formation of botulism toxin. If your firm is controlling this hazard, it is not apparent how this is being accomplished. Unless the product is maintained in a frozen condition until immediately before use by the consumer or you can demonstrate that the frying step destroys both the vegetative and spore states of *Clostridium botulinum*, the only control to prevent toxin production by *C. botulinum* for this product is storage below 38° F. Such a control requires constant monitoring of refrigeration during processor storage, distribution, and at the wholesale and retail level. Beyond this, we are not aware of any adequate controls for this type of product once the product leaves the hands of the processor. Therefore, you must demonstrate how you are controlling this hazard. This includes once the product leaves your hands and reaches the final user.

21 CFR 123.6 (a) requires that you perform a hazard analysis for each seafood product that you manufacture. When you identify one or more safety hazards associated with a product, 21 CFR 123.6 (b) requires that you have and implement a HACCP plan. 21 CFR 123.6 (c) details what a HACCP plan shall include.

You may want to consult the *Fish & Fishery Products Hazards & Controls Guide: Second Edition* for information related to conducting a hazard analysis and identifying potential hazards associated with your products and processes.

2. Failure to monitor sanitation conditions and practices specified in 21 CFR 123.11 (b) and maintain sanitation control records as specified in 21 CFR 123.11 (c). The need for such monitoring and documentation is underscored by the numerous Good Manufacturing Practices (GMP) deviations found during the inspection of your firm. Among the more serious deviations were the following:

- Processing machinery, food contact surfaces, walls, and utensils were not cleaned with any sanitizers or cleaners except for hot water. After cleaning procedures and processes were completed at the end of the day, machinery, food contact surfaces, walls, and utensils were observed with remanent materials and dirt. Also, non-food contact surfaces of equipment were observed with accumulated rust and dirt material.

- Failure to provide employees with adequate and convenient hand-washing facilities. Specifically, the firm had no soap hand cleaners, or hand towels in any of the firm's bathrooms or at the production area sinks.

- Employees involved in the direct handling of in-process/exposed products were observed without hair restraints; not to wash their hands between breaks in production or after handling dirty hoses and raw materials; and drinking canned soda in the processing area where

production was simultaneously occurring. One employee was observed dropping his gloves on the floor, spraying them off with a hose, putting them back on, and then handling exposed products during production.

- Failure to manufacture foods under conditions and controls to minimize the potential the contamination of food. Conditions in your plant included: loose nuts, bolts, and machine parts were found scattered over counter tops and shelves in close proximity to food processing and storage areas; no safety-type light bulbs were provided in fixtures suspended over exposed food; storage of food ingredients on the processing area floor less then a foot away from waste bins before introduction into production; and condensate from the freezer ceiling accumulating directly over exposed cooked product while cooling in the freezer.

- A large door on the side of the production area wall open during production for ventilation purposes with no barriers against insect or vermin entry into the plant. Furthermore, this door was noted directly adjacent to the outside trash dumpster location. Both live and dead flies and other insects were observed in several locations in your firm's processing area.

- Instruments used for measuring conditions that control or prevent the growth of undesirable microorganisms were not being adequately maintained. The freezer and refrigeration unit thermometers differed by more then five degrees from the calibrated thermometer used by the investigator. For example, the refrigerator thermometer in place at the firm showed a reading of 38° F, as compared to the FDA reading of 44° F.

- No back flow devices on processing hoses observed lying directly on the processing floor in standing water.

You must take appropriate steps to correct these violations on a permanent bases. Failure to do so could lead to the adulteration of foods, processed and stored in your facility, within the meaning of 402 (a) (3) and/or 402 (a) (4) of the Act.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment, you should explain how your system identifies hazards and implements controls in a manner that the agency should regard as complying with the regulation. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. 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.

Your reply relating to these concerns should be directed to the Food & Drug Administration, Los Angeles District, Attention: Robert B. McNab, Consumer Safety Officer, 19900 MacArthur Blvd, Ste. 300, Irvine, CA 92612-2445. If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific product, please contact Mr. McNab at (949) 798-7709 for answers and/or direction towards guidance and sources of training in achieving compliance. We look forward to working with you to achieve a successful HACCP program in your plant.

Sincerely,

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Stuart P. Richardson Jr.
Chief Food and Drug Branch
714 "P" Street, Room 400
Sacramento, CA 95814