



U.S. Food and Drug Administration
Protecting and Promoting Your Health

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Inspections, Compliance, Enforcement, and Criminal Investigations

L.A. Lucky Import & Export 8/16/13



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Import Operations Branch
Los Angeles District
222 W. Sixth Street, Suite 700
San Pedro, CA 90731-3354
Telephone: 310-971-2280
Fax: 310-971-2360

WARNING LETTER

VIA UNITED PARCEL SERVICE SIGNATURE REQUIRED

W/L 34-12

August 16, 2012

Mr. George Anh Nguyen
L.A. Lucky Import & Export Inc.
5699 Rickenbacker Rd
Bell, CA 90201-6413

Dear Mr. Nguyen:

We inspected your seafood importer establishment, located at 5699 Rickenbacker Rd. Bell, CA 90201, between 06/07 – 14/2012. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). The specific requirements for imported fish and fishery products are set out in 21 CFR 123.12.

As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123. In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with 21 CFR Part 123. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under 21 CFR Part 123, the fish or fishery products will appear to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4) and will be denied entry. Because our inspection identifies serious violations for 21 CFR Part 123, your white anchovy, yellow stripe trevally, spiny eel, and cooked snail meat are adulterated under Section 402(a)(4) of the Act (21 U.S.C. § 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov¹.

Your significant violations were as follows:

1. You have not implemented an affirmative step for the fishery products you import in accordance with the seafood HACCP regulation, 21CFR 123.12(a)(2)(ii). For example, you could not provide the affirmative step for the white anchovy, yellow stripe trevally, spiny eel, and cooked snail meat manufactured by **(b)(4)**.
2. You do not have product specifications for the fishery products you import in accordance with the seafood HACCP regulation, 21CFR 123.12(a)(2)(i). For example, you could not provide any product safety specifications for the white anchovy, yellow stripe trevally, spiny eel, and cooked snail meat manufactured by **(b)(4)**.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to refuse admission of your imported fish or fishery products under Section 801(a) of the Act (21 U.S.C. § 381(a)), including placing them on "detention without physical examination," seize your product(s) and/or enjoin your firm from further violating the Act.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation, such as HACCP and importer verification records and records that document the performance and results of your firm's affirmative steps, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your seafood importer establishment operates in compliance with the Act and the seafood HACCP regulation (21 CFR Part 123). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations for the fish or fishery products that you import into the United States.

Please send your reply to:

Food and Drug Administration,
Attention: Daniel Solis
Director, Import Operations Branch
Los Angeles District
222 West 6th Street, Suite 700
San Pedro, CA 90731

If you have questions regarding any issues in this letter, please contact Samuel Rudnitsky, Compliance Officer, at (310) 971-2325.

Sincerely,
/S/
Alonza E. Cruse, Director
Los Angeles District

Cc: Ingeborg Small
Branch Chief
Food and Drug Branch
California Department of Public Health
1500 Capitol Avenue - MS 7602
P.O. Box 997413
Sacramento, California 95899-7435

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