**DEPARTMENT OF HEALTH AND HUMAN SERVICES** Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

December 7, 2011

VIA EXPRESS MAIL

Mr. Gunawan, Director
P.T. Arta Mina Tama
JI. Cumi Raya Blok E No. 1A
Pelabuhan Perikanan Samudera
Jakarta, Indonesia 14440

Dear Mr. Gunawan,

The U.S. Food and Drug Administration inspected your seafood processing facility, located at JI. Cumi Raya Blok E No. IA, Pelabuhan Perikanan Samudera, Indonesia on May 26 and 27, 2011. During that inspection, we found that you had deviations from the Seafood Hazard Analysis and Critical Control Point (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). That inspection resulted in FDA's issuance of an FDA-483, Inspectional Observations, listing the deviations found at your firm at the conclusion of the inspection. We acknowledge receipt of your response to that FDA-483, received via email on June 11, 2011 that included supporting documentation including the Hazard Analyses and revised HACCP plans for your frozen carbon monoxide treated Escolar, tuna loins, steaks, ground tuna, and snapper products, as well as photographs of improvements made to your facility. However, our review revealed that the response was not adequate, as further described in this letter.

In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your frozen carbon monoxide treated Escolar, tuna loins, steaks, ground tuna, and snapper products are adulterated, 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 and Controls Guidance: 4th Edition (the Hazard Guide) through links in FDA's home page at www.fda.gov.

We note the following concerns:

1. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and you must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However your firm does not have a HACCP plan for your frozen carbon monoxide (CO) treated snapper to control the food safety hazards of:
    a. Ciguatera. FDA is aware that the waters surrounding Indonesia are conducive to ciguatera blooms and the hazard should be included in your HACCP plan to ensure that the snapper your firm receives are not captured in waters closed due to ciguatera.
    b. *Clostridium botulinum* (i.e., during the CO treatment). We note that the snapper your firm distributes may receive a CO treatment (i.e., smoking treatment). *Clostridium. botulinum* growth and toxin formation would be a reasonably likely hazard during the treatment process, due to the reduced oxygen conditions conducive to toxin development during the extended CO treatment.
    c. Undeclared allergens. Fish protein poses a hazard for allergenic reactions in sensitive individuals and in order to control the hazard of undeclared allergenic substances FDA recommends that firms monitor labels with inclusion of a "Packing and Labeling" critical control point to ensure that products accurately declare the fish species on the labels.

2. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c) (1). A food safety hazard is defined in 21 CFR 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. However, your firm's HACCP plans entitled "Observation 2: Monitoring Procedures"; "Observation 3: Histamine Control" and "Observation 4: Ground Tuna/Scrape" submitted with your June 11, 2011 response do not identify the food safety hazards of:

    a. Undeclared allergens and *Clostridium botulinum* at the "Packing and Labeling" critical control point. Fish protein poses a hazard for allergenic reactions in sensitive individuals and in order to control the hazard of undeclared allergenic substances FDA recommends that firms monitor labels at the "Packing and Labeling" critical control point to ensure that products accurately declare the fish species on the labels. In addition, frozen vacuum packaged fish products pose a hazard for *Clostridium botulinum* growth and toxin formation because

the packaging conditions can create an anaerobic environment conducive to toxin development during thawing by the end user. FDA recommends that in order to control the hazard of *Clostridium botulinum* growth and toxin formation in frozen vacuum packaged products, firms monitor their labels at the "Packing and Labeling" critical control point to ensure that the labels include handling instructions such as "Keep Frozen, thaw under refrigeration immediately prior to use".

b. *Clostridium botulinum* growth and toxin formation at the "Cooler Storage" critical control point, in your HACCP plans entitled "Observation 3: Histamine Control" and "Observation 4: Ground Tuna/Scrape". The "(b)(4) " critical control point appears to be your (b)(4) step. As noted above in bullet # 1, *Clostridium botulinum* is a reasonably likely hazard during the (b)(4) because the treatment is conducted under (b)(4) that are conducive to *Clostridium* growth and toxin formation. Consequently, your firm needs to identify the hazard of *Clostridium botulinum* toxin formation during your (b)(4) . Moreover, FDA recommends that the treatment be conducted at temperatures below 3.3°C with continuous monitoring and recording of the time and temperatures for the duration of the treatment.

3. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6 (a) and (c) (2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan included in the document entitled "Observation 2: Monitoring Procedures" provided in your response dated June 11, does not list a critical control point for your (b)(4) step to control histamine formation following receipt of fish at your facility, prior to processing. Specifically, our investigator noted that scombroid species of fish are (b)(4) .

4. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However,

   a. your firm's HACCP plans entitled "Observation 2: Monitoring Procedures"; "Observation 3: Histamine Control" and "Observation 4: Ground Tuna/Scrape" (b)(4)

(b)(4) [redacted]" critical control points that are not adequate to control decomposition in order to assess the level of spoilage in the lots. Specifically, your critical limits do not specify a sampling strategy and/or measurable quantity of decomposition, detectable in the incoming lot. FDA recommends that a sensory examination of a representative sample of scombrotoxin-forming fish shows decomposition in less than 2.5% of the fish in the sample. For example, no more than 2 fish in a sample of 118 fish may show signs of decomposition. In addition, we note that your Corrective Action Plans listed at the same critical control points in these plans include (b)(4) [redacted]. Please be advised that without critical limits associated with monitoring a representative sample of fish, your firm will be unable to implement this corrective action. Please refer to Chapter 7, pages 132-136 of the 4th Edition of the Fish and Fishery Products Hazards and Controls Guidance for additional information.

b. your firm's HACCP plan entitled "Observation 4: Ground tuna / Scrape" lists a critical limit of "(b)(4) [redacted]°C" at the "minced ground meat" critical control point that is not adequate to control histamine formation during unrefrigerated processing of the minced ground meat. Specifically, the critical limit does not list time and/or temperature controls for unrefrigerated processing and appears to only address storage conditions which are not associated with the actual processing of the minced ground fish (i.e., when held unrefrigerated).

In addition, your firm's HACCP plans entitled "Observation 2: Monitoring Procedures"; "Observation 3: Histamine Control" and "Observation 4: Ground Tuna/Scrape" do not include any information or critical limits associated with control of histamine formation during transit to your facility. Processors who act as primary processors, (b)(4) [redacted], need to have both primary and secondary processor responsibilities to ensure that the fish were properly handled (b)(4) [redacted] and safely transported to the processing facility.

Additionally, we note that the HACCP plans submitted were untitled and so we have reviewed and commented on the plans based on the "observation number" printed on each plan. Please be certain to include complete, properly titled HACCP plans, listing the products covered by each the plan in any response documents that you provide.

Please respond in writing within thirty (30) working days from your receipt of this letter. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections.

This letter may not list all your deviations from the requirements of the Act or applicable regulations. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation, and the current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please direct your response the Food and Drug Administration, Attention: Mildred Benjamin, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Manufacturing and Storage Adulteration Branch (HFS-607), 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Ms. Benjamin by phone at (320) 402-1424 or via email at Mildred.Benjamin@fda.hhs.gov

Sincerely,

/s/

Kathleen Lewis, J.D.
Acting Division Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition