DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

July 10, 2012

VIA EXPRESS DELIVERY

Javier Domezain Granados
Production Manager
Piscifactoria de Sierra Nevada SL / Caviar Per Se, SL
Barrio de San Antonio
Pasaje de Las Pasaderas S/N, Loja,
Granada, Spain 18.300

Reference No.: 292157

Dear Mr. Domezain Granados:

This letter is in response to the documentation your firm provided on April 12, 2012, following the request by the U.S. Food and Drug Administration (FDA) for an English version of your firm's most recent HACCP plan and supporting documentation. Our request for the information was the result of an inspection of your firm Piscifactoria de Sierra Nevada SL located at 18313 Riofrio, Loja, Granada, Spain conducted on December 8-12, 2011.

Failure of a processor to have and implement a HACCP plan that complies with 21 CFR 123.6(g), or otherwise in accordance with the requirements of 21 CFR part 123, renders the 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 firm's ready to eat sturgeon and caviar products appear to be adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. In addition, FDA collected product labels for your Caviar Per Sé Black, Almas Ara Caviar, and Caviar Per Sé NiccarII products during the inspection of your facility. Our review of the labels found that these products are misbranded within the meaning of Section 403 of the Act [21 U.S.C. § 343] and regulations at 21 CFR Part 101. You may find the Act and the regulations through links in FDA's home page at www.fda.gov.

We have evaluated the information provided on April 12th and have found concerns with your HACCP program. We acknowledge that you explained that you have sold the facility named Piscifactoria de Sierra Nevada SL in Riofrio, Spain and that you were moving your location to Yesa (Navarra, Spain) and renaming your facility Caviar Per Se S.L.

Your firm's significant deviations from the requirements of the Seafood HACCP regulation are as follows:

1. You must conduct 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." Specifically:
    a. The hazard of *Clostridium botulinum* growth and toxin formation has not been identified as a hazard in your firm's HACCP plans for Sustainable Caviar and Payusnaya Caviar Preparations provided with your April 12th response. Your products are vacuum packed and intended to be distributed frozen. The hazard of *C. botulinum* is reasonably likely to occur during the thawing of the product by the consumer. FDA currently recommends that frozen products with the hazard of *C. botulinum* be labeled with safe handling instructions (e.g. "thaw under refrigeration").
    b. The hazards of undeclared food allergenic substances and aquaculture drugs have not been listed in your firm's HACCP plan for Traditional Caviar, Sustainable Caviar, Payusnaya Caviar Preparation and Sturgeon (fresh and frozen) provided with your April 12th response.

2. 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)(1). "A food safety hazard 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." Specifically:
    a. You have not listed cold storage as a critical control point in your "(b)(4) [redacted]" HACCP plan provided with your April 12th response. Your flow diagram indicates you store product at refrigerated temperatures ((b)(4)) after you package the fresh fish. However your HACCP plan has not identified this refrigerated holding step as a CCP. Since the hazard of *Clostridium botulinum* is reasonably likely to occur in refrigerated vacuum packaged product you must identify
    b. The "Salt and Preservative Addition" critical control point listed in your "(b)(4) [redacted]" HACCP plan provided with your April 12th response appears as "optional." Critical control points to control reasonably likely hazards can not be optional. Salt/preservation at this step in your process appear to be required to protect the product from the hazard of pathogen growth and toxin formation; therefore, it can not be optional. You should also list the salt or preservative levels in your plan as Critical Limits as well as the method for testing within your monitoring activities to ensure the appropriate levels have been achieved.

3. You must have a HACCP plan that, at a minimum, lists a critical limit 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 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 your firms revised HACCP plans for Sustainable Caviar and Payusnaya Caviar Preparations provided with your April 12th response do not list adequate critical limits for the heat treatment to control the growth of pathogenic bacteria. You should list the actual time and temperature values that must be met and monitored in your HACCP plans to control the hazards that are reasonably likely to occur.

Your firm's significant labeling violations are as follows:

1. Your caviar product labels are misbranded within the meaning of section 403(w) of the Act [21 U.S.C. § 343(w)] in that the label fails to declare the major food allergen, fish, as required by section 403(w)(1) of the Act.

   Section 201(qq) of the Act [21 U.S.C. § 321(qq)] defines milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils, as "major food allergens." A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

   - The word "Contains" followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredient, section 403(w)(1)(A) of the Act, [21 U.S.C. § 343(w)(1)(A)], or
   - The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food from which the major food allergen is derived, except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen), section 403(w)(1)(B) of the Act, [21 U.S.C. § 343(w)(1)(B)].

   As defined in Section 403(w)(2), for fish, the "name of the food source from which the major food allergen is derived," requires that the specific species of fish be identified.

2. Your caviar product labels are misbranded within the meaning of section 403(q) of the Act [21 U.S.C. § 343(q)] in that the labels fail to bear nutrition labeling ("Nutrition Facts" panel), which is required under 21 CFR 101.9.

3. Your caviar product labels are misbranded within the meaning of section 403(f) of the Act [21 U.S.C. § 343(f)] because the labels do not bear an ingredient statement in English in accordance with 21 CFR 101.15(c).

4. Your caviar product labels are misbranded within the meaning of section 403(e)(2) of the Act [21 U.S.C. § 343(e)(2)] in that the labels fail to bear a statement of the net quantity of contents on the principal display panel (PDP) in accordance with 21 CFR 101.105.

This letter may not list all the violations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act and the applicable regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Carol D'lima, Compliance Officer, CFSAN Office of Compliance, Division of Enforcement, Food Adulteration Assessment Branch HFS-607, 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding any issue in this letter, you may contact Carol D'lima by email at Carol.Dlima@fda.hhs.gov or by phone at (240) 402-2033.

Sincerely,

Jennifer A. Thomas
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc:
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