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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

San Juan District
Compliance Branch
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February 5, 2007

WARNING LETTER
SJN-07-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David Vergel Miranda
President
La Coruña Foods, Inc.
36 Diana Street, Amelia Industrial Park
Guaynabo, P.R. 00968-8002

Dear Mr. Vergel:

This letter is in reference to the inspection of your facility located at number 36 Diana Street, Amelia Industrial Park, Guaynabo, Puerto Rico from August 22 to 30, 2006, by an investigator from the U.S. Food and Drug Administration (FDA). During the inspection, labels of some of your seafood products were collected. Our review of your labeling and other evidence collected by the investigator shows violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR). You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

Your Lisboa Bacalao Pollock Baby Fillets (12oz.), Lisboa Filete de Bacalao Desalado Ready to Eat (12oz.), Lisboa Bacalao Select White Fillets (12oz.), Lisboa Bacalao Desmenuzado (12oz.), Lisboa Filete de Bacalao Salted Pollock Fillets (16oz.), and Lisboa Filete de Bacalao Salted Pollock Fillets (80oz.) products make claims on the information panel of their labels that cause these products to violate the Act as follows:

1. The labels of these products claim that pollock "ayuda a evitar los ataques al corazón," which means "helps to prevent heart attacks," and "evita las cavidades dentales," which means "prevents dental cavities." Under section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)], articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs. Based on the quoted claims from the product labels, we have determined that your products are drugs under section 201(g)(1)(B) because they are intended for use in the prevention of heart disease and dental caries. Because your products are not generally recognized as safe and effective when used as labeled for these conditions, they are also new drugs as defined in section 201(p) of the Act [21 U.S.C. 321(p)]. Under section 505(a) of the Act (21 U.S.C. 355(a)), new drugs may not be legally marketed in the United States without an approved New Drug Application (NDA).

2. Furthermore, these products are misbranded under section 403(r)(1)(B) [21 U.S.C. 343(r)(1)(B)] because they bear unauthorized health claims. In particular, the product labels make the claim "[Contiene proteínas y calcio que ayudan en el crecimiento de huesos fuertes y evitan la osteoporosis." This claim translates to:"Contains protein and calcium which help in the growth of strong bones and prevent osteoporosis." The claim is an unauthorized health claim because it fails to meet the requirements of 21 CFR 101.72(c), the regulation governing health claims about calcium and reduced risk of osteoporosis. For example, your products contain levels of sodium that disqualify them from bearing any health claim [see 21 CFR 101.14(a)(4) and 101.72(c)(1)]. In addition, in order to make a health claim regarding calcium and osteoporosis, the product must meet or exceed the requirement for a "high" level of calcium, i.e., 20% or more of the Reference Daily Intake (RDI), as defined in §101.54(b); however, according to the Nutrition Facts panels on the product labels, these products contain only 6% of the RDI for calcium and, therefore, do not meet the requirement for calcium content in 21 CFR 101.72(c)(2)(ii)(A). Also, the foods appear to contain more phosphorus than calcium on a weight basis [see 21 CFR 101.72(c)(2)(ii)(D)]. Furthermore, there is no authorized health claim for protein and osteoporosis.

3. Your Lisboa Bacalao Pollock Baby Fillets (12oz.), Lisboa Filete de Bacalao Desalado Ready to Eat (12oz.), Lisboa Bacalao Select White Fillets (12oz.), Lisboa Bacalao Desmenuzado (12oz.), Lisboa Filete de Bacalao Salted Pollock Fillets (16oz.), Lisboa Filete de Bacalao Salted Pollock Fillets (80oz) and King Crab Imitation (16oz.) products are misbranded under section 403(q) of the Act [21 U.S.C. 343(q)] for the following Nutrition Facts panel deviations:

   - The serving sizes on your products (except for the Lisboa Filete de Bacalao Salted Pollock Fillets (80oz)) are not based on the correct Reference Amount Customarily Consumed (RACC) (i.e., 110 grams uncooked for your raw products; 85 grams for cooked products) [21 CFR 101.12 (Table 2, Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes, Entrees without sauce)] in accordance with the requirements of 21 CFR 101.9(b).
   - Your products bear the claim "Es rico en iodo," which means "rich in iodine," but fail to declare the amount per serving of iodine calculated as a percent of the Reference Daily Intake [21 CFR 101.9(c)(8)(iv)], as required by 21 CFR 101.9(c)(8)(ii).
   - These products (except for your Filete de Bacalao Desalado Ready to Eat (12 oz) product) fail to declare trans fat [21 CFR 101.9(c)(2)(ii)]. Regulations requiring the declaration of trans fat went into effect on January 1, 2006 (see 21 CFR 101.9(c)(2)(ii); 68 FR 41433). You should review all of your product labels to ensure they comply with these regulations. For additional information on trans fat labeling, go to http://www.cfsan.fda.gov/~dms/lab-cat.html#transfat.
   - The King Crab Imitation product fails to declare vitamin C and iron as required by 21 CFR 101.9(c)(8)(ii).
   - The Filete de Bacalao Desalado product declares "Allergens 0%" below the declaration of Cholesterol. No nutrients or food components other than those listed in 101.9(c) as either mandatory or voluntary may be included within the Nutrition Facts panel on the food label. Furthermore, pollock is one of the

allergens identified in the Food Allergen Labeling and Consumer Protection Act (FALCPA), and therefore, the statement "Allergens 0%" is false and misbrands this product under section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)].

- These products fail to bear the complete Daily Value footnote at the bottom of the Nutrition Facts panel in that they fail to display the table providing Daily Value information as specified in 21 CFR 101.9(d)(9). We note that the King Crab Imitation product contains some of the Daily Value table information, but the information is incomplete.

4. Your King Crab Imitation (16oz.) product is misbranded under section 403(i)(2) of the Act [21 U.S.C. 343(i)(2)] for failing to declare the common or usual name of each ingredient. For example, "Natural Pigments" and "Protein" are not declared by their common or usual names. Under 21 CFR 101.4(b), the name of an ingredient must be a specific name and not a collective (generic) name. Therefore, the protein ingredient in your product may not be declared under the generic name "Protein"; you must specify the source of the protein (e.g., "soy protein"). Also, under 21 CFR 101.4(b)(1), ingredients used to color a food, such as the "Natural Pigments" listed in the ingredient statement of your King Crab Imitation (16oz.) product, must be declared according to the requirements for color additives in 21 CFR 101.22(k).

In addition to the violations described above, we have several comments concerning the labeling of your products. First, we note that your salted Pollock fillets declare the term "Bacalao" as part of the statement of identity. The word "Bacalao" translates to "cod," and does not accurately identify the contents of the packaged food [see 21 CFR 101.3 and 102.5].

Also, in the statement of identity on the label of your King Crab Imitation (16oz.) product, in the word "Imitation" is declared in a smaller type size than "King Crab." Under 21 CFR 101.3(e), the statement of identity for a food that is an imitation of another food must bear, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated. Therefore, your product should be named "Imitation King Crab," and all three words should appear in the same type size and with the same prominence.

Also, the nutrition information for your 5 lb (80 oz.) bag of Filete de Bacalao Salted Pollock Fillets is based on a 110 gram (g) serving size; however, the nutrient values appear to be the same as the values declared on the 16 oz. package of this product, where the nutrition information is based on a 56 g serving size. Note that you are responsible for accurately declaring nutrient values as specified by 21 CFR 101.9.

Furthermore, we note that the labels for your products (except for the King Crab Imitation product) bear the claim "tiene pocas calorías," which means "contains few calories." FDA has authorized a nutrient content claim for "few calories" under 21 CFR 101.60(b)(2). For foods such as the fish products discussed in this letter, a "few calories" claim is permitted only if the food does not provide more than 40 calories per RACC [21 CFR 101.60(b)(2)(i)(A)]. According to the calorie information declared on your labels, your products do not appear to meet the calorie limit in 21 CFR 101.60(b)(2)(i)(A) based on a RACC of either 85 grams or 110 grams.

For your information when revising your product labels, please note that product labels that use both English and Spanish must include all required information in both languages. Your labels bear information both in English and Spanish, but not all information required to be on the label appears in both languages. For example, your products' Nutrition Facts panel information appears only in English, and the statement of identity for your Bacalao Desmenuzado (12oz.) product appears only in Spanish. Products intended to be distributed in the Commonwealth of Puerto Rico may be labeled solely in Spanish [21 CFR 101.15(c)(1)]. However, if the product label contains any representations in English, then all information required to appear on the label must appear in both Spanish and English [21 CFR 101.15(c)(2)].

The declaration of trans fat on the Filete de Bacalao Desalado Ready to Eat (12oz.) product label states "0%" in the Percent Daily Value (DV) column. This column should be left blank because FDA has not established a DV for trans fat.

Finally, your labeling contains misspelled words, missing spaces and missing punctuation that may affect consumers' ability to read and understand required information on the label (see section 403(f) of the Act [21 U.S.C. 343(f)]). For example, in the ingredient statement on your Filete de Bacalao Desalado Ready to Eat (12oz.) product, potassium, vitamin B12, and selenium are all spelled incorrectly.

In addition to the aforesaid labeling violations and comments, during the inspection the FDA investigator observed that your seafood import establishment did not have and implement written verification procedures that complied with the seafood Hazard Analysis Critical Control Point (HACCP) regulation [21 CFR 123.12(a)]. Specifically, the investigator brought to your attention that your firm's verification procedures did not have and implement written product specifications for all of the fish and fishery products that you import from China [21 CFR 123.12(a)(2)(i)]. As an importer, you must have evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with the seafood HACCP regulation, to comply with 21 CFR 123.12(d). We acknowledge the receipt of your letter response dated September 15, 2006. We find that your commitments to implement corrective actions as discussed in your response letter will address the concerns regarding the HACCP requirements brought to your attention by the investigator during the inspection. These corrective actions will be verified during our next scheduled establishment inspection.

We may take further action if you do not correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations. You should include in your response documentation for our evaluation of your corrective actions. If you cannot complete all corrections within 15 working days, we expect you to explain the reasons for your delay and state when you will correct any remaining deviations.

This letter is not intended to be an all inclusive review of your products and their labeling. You are responsible for ensuring that your business operates in compliance with the Act, and applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, San Juan District Office, 466 Fernández Juncos Ave., San Juan, P.R. 00901-3223, Attention: Carlos A. Medina, Compliance Officer. If you have questions regarding any issue in this letter, please contact Mr. Medina at 787-474-9538 or at carlosa.medina@fda.hhs.gov.

Sincerely,

Jorge L. González
Acting District Director
San Juan District