



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Baltimore District Office  
Central Region  
6000 Metro Drive, Suite 101  
Baltimore, MD 21215  
Telephone: (410) 779-5454  
FAX: (410) 779-5707

04-BLT-17

April 5, 2004

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Tok S. Na, Owner  
Dong Hae Mul San Inc.  
407 Morse Street, N.E.  
Washington, D.C. 20002-7009

Dear Mr. Na,

This letter is in reference to your firm's product repackaging operation, documented during our inspection at your facility located at the above address, on November 13-17, 2003. The inspection revealed that your firm repacks food products, from bulk containers, into small, unlabeled containers for sale to restaurants and at retail (i.e. directly to the consumer). The repackaged products offered for retail sale are misbranded under Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Part 101 – Food Labeling.

The following six repackaged products are unlabeled:

- Salted shrimp repacked into unlabeled [redacted] oz glass jars for sale to restaurants and retail.
- Southern Fish Fry Meal repacked into unlabeled [redacted] lb plastic bags for primarily retail sale.
- Sesame seeds repacked into unlabeled [redacted] lb plastic bags for primarily retail sale.
- Cinnamon sticks repacked into unlabeled [redacted] lb plastic bags for sale to restaurants and retail.
- Dried Fernbrakes repacked into unlabeled [redacted] lb plastic bags for sale to restaurants and retail.
- Dried anchovy repacked into unlabeled [redacted] lb plastic bags for primarily retail sale.

The repackaged products above that are offered for retail sale are misbranded as follows:

1. Your repackaged products that are offered for retail sale are misbranded under Section 403(e)(1) of the Act, in that the product label fails to bear the name and place of business of the manufacturer, packer, or distributor as required by **21 CFR 101.5**.

2. Your repackaged products that are offered for retail sale are misbranded under Section 403(e)(2) of the Act, in that the product label fails to declare an accurate statement of quantity of contents in terms of weight, measure, or numerical count as required by **21 CFR 101.105**.
3. Your repackaged products that are offered for retail sale are misbranded under Section 403(i)(1) of the Act, in that the food is not identified on the retail container (i.e., the glass jar or plastic bag) by its common or usual name as required by **21 CFR 101.3**.
4. Your packaged products that are offered for retail sale are misbranded under Section 403(q)(1) of the Act, in that the products do not bear a "Nutrition Facts" statement as required by **21 CFR 101.9**. If you employed fewer than an average of 100 full-time equivalent employees and sold fewer than 100,000 units of one or more of these products in the United States within the past 12 months, you may be eligible to claim an exemption from nutrition labeling for these products under **21 CFR 101.9(j)(18)**. To claim this exemption, follow the procedure outlined in **21 CFR 101.9(j)(18)(iv)**, located on page 45 at <http://www.cfsan.fda.gov/~lrd/CFR101.9.HTML>.
5. Your unlabeled jars of Salted Shrimp/Krill that are offered for retail sale are misbranded under Section 403(i)(2) of the Act, in that they fail to declare the ingredients in the food by their common or usual names as required by **21 CFR 101.4**. The inspection documented that the product consists of shrimp and krill. Therefore, both ingredients (i.e. shrimp and krill) must be listed separately in the ingredient statement in descending order of predominance by weight.
6. Your retail packages of Southern Fish Fry Meal are misbranded under Section 403(i)(2) of the Act, in that the packages fail to declare the ingredients in the food by their common or usual names as required by **21 CFR 101.4**. The declaration of wheat is of particular concern because wheat is an allergenic substance. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergen in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergenic responses are milk, eggs, fish, crustaceans, tree nuts (including cashews), wheat, peanuts, soybeans, and derivatives of these products.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are manufactured and labeled in accordance with all applicable laws and regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action by FDA without further notice. Such action includes seizure of your products and/or injunction.

We request that you notify this office in writing, within thirty (30) working days of receipt of this letter. Your response should include the specific steps you have taken to correct the deviations. If you can not complete all of the corrections within 30 working days, state the reason for the delay and the time within which corrections will be completed.

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Your response should be directed to: Ms. Vinetta Howard-King, Compliance Officer, U.S. Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. If you have any questions, please do not hesitate to contact Ms. Howard-King at (410) 779-5454, extension 413.

Sincerely,

A handwritten signature in black ink, appearing to read 'LB', with a large loop on the left side and a flourish on the right.

Lee Bowers  
Director, Baltimore District