



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

g3486d

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WARNING LETTER
NWE-29-02W

VIA FEDERAL EXPRESS

August 26, 2002

Steven Zenlea
President
Hans Kissle Co., Inc.
330 Ballardvale Street
Wilmington, MA 01887

Dear Mr. Zenlea:

We inspected your firm located at 330 Ballardvale Street, Wilmington, MA on May 22 and 23, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention cause your seafood salads to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 on-line through links in FDA's home page at www.fda.gov.

The serious seafood HACCP deviations were as follows:

1. 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 that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 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 for seafood salad does not list the critical control point of Thawing for controlling the food safety hazard of pathogens and toxin formation. FDA recommends that Thawing be a critical control point in all HACCP plans for Ready-to-Eat products; refer to Chapter 12 of the Fish and Fisheries Products Hazards and Controls Guidance).

2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the required eight elements of sanitation with sufficient frequency to ensure control as evidenced by the numerous deficiencies that were noted on the FDA 483 at the close of the inspection. For example, monitoring frequency at the storage critical control point should be continuous.

We may take further action if you do not promptly correct these above 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 fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations, including a copy of your revised HACCP plans. You may also wish to include documentation such current monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110).

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gail T. Costello
District Director
New England District Office