



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Southwest Region

Food and Drug Administration  
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Denver, Colorado 80225-0087  
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April 30, 2004

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ms. Susan K. Smith  
President  
Food Concepts, Inc.  
2545 Kipling St.  
Lakewood, CO 80215

Dear Ms. Smith:

On November 19 through 26, 2003, an investigator from the Denver District office of the Food and Drug Administration conducted an inspection of your seafood processing facility located at 2545 Kipling St., Lakewood, Colorado. This inspection was conducted to determine your firm's compliance with FDA's seafood Hazard Analysis Critical Control Point (HACCP) regulation, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," and the Current Good Manufacturing Practice (CGMP) requirements for foods, 21 CFR 110. The seafood HACCP regulation was issued pursuant to Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood that is processed in violation of the HACCP regulation is adulterated, according to the Act, because it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find the Act, the seafood HACCP regulation, as well as FDA's Fish and Fisheries Products Hazards and Controls Guidance: *Third Edition* published to assist seafood processors in developing their HACCP systems through links in FDA's home page at <http://www.fda.gov>.

The seafood processing regulation, which became effective on December 18, 1997, requires that you implement a preventive system of food safety controls known as HACCP. HACCP involves identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. Prudent processors already take these kinds of measures. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During our inspection, the investigator provided you with the form FDA-483, which presents her evaluation of your firm's performance regarding various aspects of the HACCP requirements. As you indicated to the investigator during the inspection and in your response letter, you do not have a seafood HACCP plan. According to your letter, you plan to arrange for an employee to attend a seafood HACCP training course and you will develop a seafood HACCP plan thereafter.

We understand that, prior to the inspection, you were unaware of the FDA seafood HACCP requirements. It appears that you were processing your fishery products under a plan you developed for meat and poultry products. When developing your seafood HACCP plan, you should bear in mind that different hazards may be posed by fishery products. For your information, we have provided the following examples regarding how your current plan for meat and poultry products fails to meet the requirements for seafood HACCP plans:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur in the fish and fishery products you process and have a HACCP plan that, at a minimum, lists those food safety hazards to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR Part 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." The plan you use for soups and chowders, however, fails to list controls for the hazard of *Clostridium botulinum* associated with your refrigerated soup packed in reduced or modified oxygen packages (closed plastic bags).
2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur in the fish and fishery products you process 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, the plan you use for soups and chowders fails to list critical control points for:
  - Cooling the soups and chowders to control pathogen growth. Cooling should occur with sufficient speed to assure that pathogen growth is prevented.
  - Post Pasteurization/Hot Filling to control pathogen survival. Your firm should assure that the temperature of the soups and chowders at the fill step is sufficient and that the pouch integrity is adequate to prevent post pasteurization contamination.
3. 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, the plan you use for soups and chowders fails to list critical limits at the following critical control points:

- "Cook/Pasteurization" critical control point (9-B) fails to list a critical limit for time to indicate how long your cook/pasteurization process must last.
  - "Holding of Cooked Product Prior to Packaging" critical control point (10-B) fails to list critical limits to assure that cooling from 140 degrees to 70 degrees F and 70 degrees to below 40 degrees F occurs rapidly enough to ensure that pathogen growth is controlled.
  - "Storage" critical control point(s) (10-B and 13-B) provides for the use of internal temperatures which are not considered adequate critical limits due to the variation in temperatures that can occur at various locations within a cooler.
4. You must have a HACCP plan that, at a minimum, lists monitoring procedures and frequencies for each critical control point, to comply with 21 CFR 123.6(c)(4). However, the plan you use for soups and chowders does not list a monitoring frequency for temperature at the Cook/Pasteurization critical control point (9-B) and Storage critical control points (10-B and 13-B).

We acknowledge your letter dated November 29, 2003, in which you state that you will arrange for an employee to attend a seafood HACCP training course and you will develop a seafood HACCP plan by June 30, 2004. That is not an adequate timeframe for developing a seafood HACCP plan. Your fishery products continue to be adulterated every day that you produce them without a seafood HACCP plan. Please respond within 30 calendar days from your receipt of this letter. After we receive your response, we will work with you to resolve any outstanding issues associated with your seafood HACCP system.

If we do not hear from you we will schedule a follow-up inspection for the immediate future.

Please send your reply to the Food and Drug Administration, Attention: William H. Sherer, Compliance Officer, P.O. Box 25087, Denver, CO 80225. If you have any questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Mr. Sherer at (303) 236-3051. We look forward to working with you to achieve a successful HACCP program in your plant.

Sincerely,



B. Belinda Collins  
Director, Denver District