



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFF-35

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Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-30977  
Telephone: (513) 679-2700  
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May 11, 1999

**WARNING LETTER**  
**CIN-WL-1999-162**

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

Mr. Lewis Shuckman, President  
Shuckman's Food Company & Smokery  
3001 West Main Street  
Louisville, KY 40212

Dear Mr. Shuckman:

An inspection of your fish processing and smoking plant was conducted by an Investigator of the U.S. Food and Drug Administration on January 26 and 27 and February 2, 3 and 4 of 1999. At the conclusion of the inspection you were presented with a Form FDA-483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123. This section of the regulation covers the requirements specific to the processing of fish and fishery products. Further, 21CFR 123.16 Subpart B for Smoked and Smoke-Flavored Fishery Products Process Controls requires processors of smoked and smoke flavored fishery products to include as part of their HACCP plans how they control the food safety hazard associated with the formation of toxin by Clostridium botulinum. In addition, 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food generally applies to your firm's operation.

Your firm's HACCP plan as implemented does not control the factors necessary to assure Clostridium botulinum will not form toxins. Smoked fish products produced under the conditions found during the inspection are adulterated under the Federal Food, Drug and Cosmetic Act, 21USC 342(a)(4). Some of the objectionable conditions and practices are as follows:

1. Failure to properly establish the critical limits required by 21CFR 123.16 for the control of the food safety hazard associated with the formation of toxin by Clostridium botulinum for at least as long as the shelflife of the product under normal and moderate abuse conditions.

(Please note that documentation must be provided which demonstrates that the critical limits set at the critical control points of brining, smoking, and/or drying steps consistently result in a critical limit of 3.5% (or more) water phase salt in the finished product in vacuum packages. Water phase salt measurements should be taken until it is documented that the critical limit is consistently achieved over the entire range of processing conditions, e.g., temperature of brine, brining time, thickness of fish and brine to fish ratio.

2. Failure to identify finished product storage as a critical control point [21 CFR 123 (c)(2)].
3. Failure to establish critical limits for brining, e.g., brine temperature, brine to fish ratio, brining time and thickness of fish [21 CFR 123(c)(3)].

(Your firm cites a study that shows that thickness of fish affects % water phase salt, but it has set no critical limit and does not monitor thickness. In addition, the study concludes that 20mm is appropriate as long as the product is brined for at least 75 minutes. However, results of product brined beyond 75 minutes are below 3.5% water phase salt. Brining time and brine to fish ratio should be stated as critical limits.)

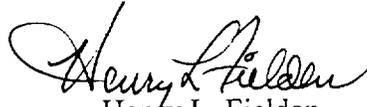
4. Failure to provide an adequate recordkeeping system as required under 123.6(c)(7), e.g., processing records are discarded and processing charts do not document the date, time or lot number. These problems result in an inability to assess the safety of a given lot of product.
5. Failure to implement appropriate monitoring procedures as required under 123.6(c)(4), e.g., more than one probe should be used to determine product temperature during the cook.
6. Failure to take corrective action when a critical limit was not achieved as required under 123.7(b) and (c), e.g., cook charts indicated that 30 minutes at 145 F was not achieved for any of the cooks for which there are records. No corrective action was recorded as having been taken. This violation is also based on the record provided for lot 1231 (trout). Your firm did not take corrective action when the brine time fell below the minimum 45 minute brine time provided in the study.

This letter does not list all of the deviations observed and discussed with you by the Investigator. You should include corrective actions you have taken to address all the issues raised by the FDA Investigator and this letter. Please respond in writing within 15 days detailing how you will correct these issues. You are encouraged to reply in person at the Cincinnati District Office. Failure to promptly correct these deviations may result in regulatory action without further notice. The actions may include injunction and/or seizure.

Please be advised that the regulations promulgated under the Nutrition Labeling and Education Act may require changes in your labeling. It is your responsibility to become familiar with these regulations and to make the appropriate changes to bring your labeling into compliance.

Your reply should be directed to the Food and Drug Administration. Attention: Leonard J. Farr, Compliance Officer, or you may call (513) 679-2700, x-164.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Henry L. Fielden".

Henry L. Fielden  
District Director

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