



March 25, 2003

**WARNING LETTER NO. 2003-NOL-13**

**FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Mr. Thomas C. Riggs, President  
Southern Seasonings, Inc.  
206 Burgess Drive  
Broussard, Louisiana 70518

Dear Mr. Riggs:

On December 4 - 6 and 9, 2002, we inspected your acidified canned food manufacturing facility, located at 206 Burgess Drive, Broussard, Louisiana. During the inspection, our investigator collected a sample of Bootsie's South Louisiana Cooking Etouffée Sauce (etouffée sauce) manufactured by your firm (FDA sample #184748, collected on December 6, 2002). As a result of our investigation and sample analysis, we have determined this acidified food product fails to comply with the Acidified Food regulations, located in Title 21 of the *Code of Federal Regulations*, Parts 108 and 114 (21 CFR 108 and 114). In addition, we note that this etouffée sauce is formulated exactly the same as Southern Seasonings Gourmet Etouffée Sauce. Failure to comply with all of the requirements of 21 CFR 108.25 and certain requirements in 21 CFR 114 constitutes a basis for the immediate application of the emergency permit control provisions of Section 404 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 344) [*See* 21 CFR 108.25(a)]. In addition, such failure renders your acidified food adulterated within the meaning of Section 402(a)(4) of the Act [21 U.S.C. 342(a)(4)], in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You can find the Act and the Acidified Food regulations through links in FDA's Center for Food Safety and Applied Nutrition's website, located at <http://www.cfsan.fda.gov/list.html>.

During the inspection, our investigator discussed with you his evaluation of your firm's compliance with applicable aspects of the Current Good Manufacturing Practices (CGMPs) requirements and Acidified Foods provisions. The investigator explained that your etouffée sauce deviates from these requirements and regulations as follows:

- Your firm failed to manufacture, process, and package your etouffée sauce so that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in a scheduled process and maintained in the finished foods [21 CFR 114.80(a)(1)]. During

the inspection, our investigator collected samples of your etouffée sauce for analysis. The pH results of original analysis ranged from 4.59 to 4.69 and the check analysis ranged from 4.60 to 4.71.

- At the time of the inspection, your firm had failed to register with FDA as a commercial processor of acidified foods. A commercial processor of acidified foods is required, not later than 10 days after first engaging in the manufacture, processing, or packing of acidified foods, to register and file a Form FDA 2541 with FDA [21 CFR 108.25(c)(1)].
- Your firm did not manufacture its etouffée sauce in accordance with a scheduled process [21 CFR 114.80(a)(1)]. A “scheduled process” is the process selected by the processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance [21 CFR 114.3(e)]. The scheduled process includes control of pH and other critical factors equivalent to the process established by a competent processing authority [21 CFR 114.3(e)].
- Your firm’s process for its etouffée sauce has not been established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods [21 CFR 114.83].
- Your firm failed to have all plant personnel involved in acidification, pH control, heat treatment, or other critical factors of the operation, under the operating supervision of a person who has attended a school approved by the Commissioner of the U.S. Food and Drug Administration for giving instruction in food-handling techniques, food protection principles, personal hygiene, plant sanitation practices, pH controls, and critical factors in acidification, and who has satisfactorily completed the prescribed course of instruction [21 CFR 108.25(f) and 21 CFR 114.10)].
- Your firm did not mark each etouffée sauce product with an identifying code [21 CFR 114.80(b)].
- Your firm failed to comply with the requirements in 21 CFR 114.89, which provides that whenever any process operation deviates from the scheduled process for any acidified food and/or the equilibrium pH of the finished product is higher than 4.6, the commercial processor of the acidified food shall either: (1) fully reprocess that portion of the food by a process established by a competent processing authority as adequate to ensure a safe product; (2) thermally process it as a low-acid food under 21 CFR 113; or, (3) set aside that portion of the food involved for further evaluation as to any potential public health significance. Unless this evaluation demonstrates that the food has undergone a process that has rendered it safe, the food set aside shall either be fully reprocessed to render it safe or be destroyed. A record shall be made of the procedures used in the evaluation and the results (21 CFR 114.890).

Our investigator reviewed your firm’s records of pH testing and noted five tests of etouffée sauce indicated a pH of 4.7. Specifically, the records show that etouffée sauce

analyzed on the following dates had pH values of 4.7: 1 batch tested on November 16, 2001; two batches tested on December 13, 2001; one batch tested on January 4, 2002; and, one batch tested on February 21, 2002. Any product that has a pH above 4.6 may not be adequately acidified to control *Clostridium botulinum* growth and toxin formation. There was no record documenting the final disposition of these lots as required by 21 CFR 114.89.

We are in receipt of your letter, dated January 10, 2003, addressing the observations discussed with you during our inspection. According to your letter, you have committed to a number of corrective actions to address the observations, including registering your establishment, filing your scheduled process, attending an acidified food processing course, coding your etouffée sauce products, and establishing and maintaining cleaning/sanitizing procedures and CGMPs, among others.

In addition, we have the following specific comments on your response:

1. You state your firm submitted a scheduled process filing form (Form FDA 2541a) on January 9, 2002. We suspect you intended to state January 9, 2003. Review of FDA files reveals on January 13, 2003, FDA received a Form FDA 2541a for etouffée sauce with Submission Identifier (SID) 2002-01-08/001 from your firm. It appears the SID reflected on this form is incorrect. To avoid confusion, your firm may want to consider replacing Form FDA 2541a identified by SID No. 2002-01-08/001 with a new form correctly identified with SID No. 2003-01-08/001. We suggest you carefully read and follow the instructions for replacing scheduled process forms.
2. You require only one entry of the temperature during filling and capping on your form entitled Etouffée Sauce, Cooking Instructions/Production Sheet. According to your scheduled process, you committed to filling the product at . You must monitor the temperature of the product periodically throughout the filling and capping operation to assure it is maintained at .

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. It is your responsibility to ensure that all of your food products comply with applicable laws enforced by the FDA. We advise you to take prompt action to correct any violations, including those identified in this letter. Failure to promptly correct violations may result in regulatory action without further notice, such as seizure, injunction and/or issuance of an Order of Need to Obtain and Hold a Temporary Emergency Permit.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. Please include documentation demonstrating that the corrective actions identified in your letter of January 10, 2003, have been properly implemented. You also may wish to include in your response documentation that would be useful in assisting us in evaluating your corrections. If you cannot complete all corrective actions before you respond, we expect that you will explain the reason for your delay and state when you will correct remaining deficiencies. In addition, in your response, please explain the final disposition of the etouffée sauce products which were discovered to have a pH above 4.6, as discussed above.

Your reply, relating to these concerns, should be directed to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions concerning the contents of this letter, you may contact Mr. Rivero at (504) 253-4519.

Sincerely,

A handwritten signature in cursive script that reads "F. Dwight Herd".

F. Dwight Herd  
Acting District Director  
New Orleans District