



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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Food and Drug Administration  
Atlanta District Office  
HFI-35

60 8th Street, N.E.  
Atlanta, Georgia 30309

December 29, 1998

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

Susan B. Yandle, Owner/President  
Harold Food Company  
P.O. Box 410487  
Charlotte, NC 28241

**WARNING LETTER**

Dear Ms. Yandle:

The Food and Drug Administration (FDA) conducted an inspection of your sandwich and salad manufacturing plant located at 11949 Steele Creek Rd., Charlotte, NC, on December 1 & 2, 1998. At the conclusion of the inspection a FORM FDA 483 (copy enclosed) was issued to, and discussed with, P. Edward Cox, Production Manager. This form lists a number of insanitary conditions and/or practices which were present in your facility at the time of the inspection. These conditions cause the salad products processed at your firm's "Cabbage Room" (a.k.a. Non-Meat Production Room) to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Some of the noted insanitary conditions are as follows:

- ▶ A cleaning rag was observed in direct contact with blocks of cheddar cheese.
- ▶ A cleaning hose was observed in direct contact with diced pimentos.
- ▶ During production, a high pressure hose was used to clean the floor and equipment, which resulted in a "cloud" of water spray/vapor that reached other areas where food (e.g. shredded cheese) was exposed. This is very significant in light of our positive findings for Listeria monocytogenes from a swab collected by our investigators off the floor drain located between the cheese shredder and the egg mixer.
- ▶ Employees entering the production room were observed to routinely skip the hand sanitizing station after washing their hands. This also represents a deviation from your firm's *Sanitation SOP*.
- ▶ On 12/2/98, our investigators observed two instances in which the employee's forearm came in direct contact with the food while performing a manual mixing operation.

During the inspection, our investigators also collected several in-line and finished-product samples of *Egg Salad* and/or *Pimento Cheese Spread*. The two subs of the *Pimento Cheese Spread* (FDA sample #34930) tested positive for L. monocytogenes upon analysis by FDA's Southeast Regional Laboratory (SRL). The egg salad samples (in-line and finished product) tested negative for L. monocytogenes. In addition, on November 30, 1998, another FDA investigator collected samples from five unopened containers of *Deviled Egg Salad* manufactured by your firm and coded "USE BY DEC. 18 1998," which were in possession of a sandwich manufacturer located in Longs, SC. Again, that sample (FDA sample #36948) tested positive for L. monocytogenes. These results appear to indicate that there is a very serious problem of cross contamination with L. monocytogenes at your facility. Please be advised that FDA has a zero tolerance policy with regards to product contaminated with L. monocytogenes.

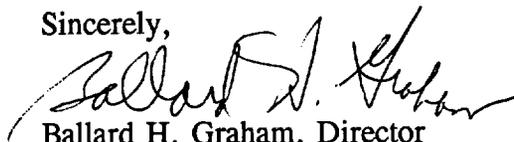
This letter as well as the List of Inspectional Observations (FDA Form 483) is not meant to be all-inclusive of the deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and all applicable regulations.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the Food and Drug Administration without further notice. These include seizure and/or injunction.

Please notify this office in writing within fifteen (15) days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state your reason for the delay and the time within which the corrections will be completed. Your response should be addressed to Carlos A. Bonnin, Compliance Officer, at the above address.

We acknowledge receipt of a letter (copy enclosed) dated December 21, 1998, from Ed Cox, Production Manager, and addressed to Eileen Bannerman, containing your firm's response to the FDA 483 issued on 12/2/98. You may refer to that letter in your response to this one.

Sincerely,



Ballard H. Graham, Director  
Atlanta District

Enclosures

cc: P Edward Cox, Production Manager  
Harold Food Company  
P.O. Box 410487  
Charlotte, NC 28241