



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Kansas City District  
Southwest Region  
11630 W 80<sup>th</sup> Street  
Lenexa, KS 66214

Telephone: (913) 752-2100

October 15, 2010

Gary Bartness  
Hillandale Farms  
Box 106  
Hampton, Iowa 50659

Dear Mr. Bartness:

This is in regard to your request, dated October 1, 2010, to resume the distribution of shell eggs to the table market from the Hillandale facility located at 13706 230<sup>th</sup> Street, West Union, Iowa.

In August 2010, FDA performed an inspection at your West Union and Alden, Iowa facilities. This inspection was initiated in follow-up to a large multi-state outbreak of *Salmonella* Enteritidis (SE). During this inspection, our investigators noted several deviations from the Egg Safety Rule, 21 CFR Part 118, that were cited on an FDA-483, and also collected environmental samples that were found to be positive for SE. We note that you no longer are producing eggs at the Alden, Iowa facility.

In your September 7, 2010 letter, you agreed to discontinue shipping shell eggs intended for the table market until FDA agreed to your resumption. You submitted a response to the FDA-483, dated September 20, 2010, in which you described the actions you took to remedy the objectionable conditions noted during the August inspection. On October 1, 2010, you submitted further information regarding your actions, including results from egg testing.

FDA has reviewed the information you submitted in response to the FDA-483, your SE prevention plan, biosecurity plan, and information provided in your October 1 letter. In addition, FDA performed an inspection of your facility from October 13 to 15, 2010.

FDA finds your corrective actions to be adequate. We note your agreement to clean and disinfect houses 1 and 2 prior to repopulation, and commitment to comply with the requirements of the Egg Safety Rule, including with regard to egg testing from houses with environmental positives. Based on your representations, FDA's confirmation of your corrections as noted during our October inspection, and the consistent SE negative test results for both the environment and eggs at houses 3, 5, and 7, FDA does not object to your resumption of shell egg production for the table market at these West Union houses at this time.

You have committed to not shipping eggs to the table market from houses 4, 6, 8 and 9 until they go through the 4 rounds of egg testing which we believe is prudent. We believe it is acceptable to hold and ship these eggs pending the results of all 4 rounds of egg testing.

During our inspection in August, FDA noted that you had a number of positive environmental samples. Your response has been a commitment to perform monthly environmental testing of houses 4, 6, 8 and 9 for the life of the current flock, as one step to ensure that your environment will not lead to SE contaminated eggs. This is a prudent step given that your West Union facility had an epidemiological association to an SE outbreak.

Sincerely,

*for*/John W. Thorsky  
District Director  
Kansas City District