

Establishment Inspection Report

Lake Wohlford Ranch
Valley Center, CA 92082

FEI: **3008895967**
EI Start: 05/31/2011
EI End: 06/02/2011

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SUMMARY (AP)

This comprehensive pre-announced team inspection of a Shell Egg Producer was conducted for the LOS-DO FY'11 work plan. This high priority inspection was conducted in accordance with PAC 03F836 for the amended assignment – FY 11 Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFIG Assignment # 11-04, ORA Concurrence # 2011012601, FACTS no. 1258067.

This was the first FDA inspection of the egg farm, Lake Wohlford Ranch. The corporate firm, Armstrong Farms Inc. (FEI: 3005332266), and the related egg farm, Mac Tan Ranch, at 28442 Mac Tan Rd., Valley Center, CA 92082, were previously inspected by the FDA on 3/8-9/11 and 3/11/11. The related egg farm, Woods Valley Ranch (FEI: 3008895900) located at 26959 N. Lake Wohlford Rd., Valley Center, CA 92082, was also previously inspected by the FDA on 5/9-11/11.

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The inspection followed the guidance given in the assignment and requirements of 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation. During the inspection we assessed the firm's compliance with 21 CFR 118 including evaluation of the firm's SE prevention plan and records pertaining to its implementation, egg laying operation, and environmental testing and documentation. Additionally, the inspection was to determine individual responsibility for the firm's SE prevention plan, who owns the layer hens, and who packages the eggs, as well as perform a walk-through of 3 of the firm's 6 poultry houses. Documents reviewed during the inspection include the firm's written SE Prevention and Monitoring Plan, pullet receiving records, environmental testing records, biosecurity records, rodent and pest control records, and refrigeration records.

This inspection of the farm revealed deficiencies and an FDA-483, Inspectional Observations, was issued to Mr. Alan W. Armstrong, General Manager, at the close-out of the inspection for the following: 1) On 5/31/11 three small wild birds were observed inside poultry house 3 and 2) the firm is not maintaining refrigeration records showing that the eggs processed after time of lay from house 5 were held under refrigeration at 45°F or below.

Items that were not included on the FDA-483, Inspectional Observations, were discussed during the close-out of the inspection regarding the following: 1) records including the Armstrong Nest Run Processing Plant logs, Armstrong Nest Run Cooler logs, and finished product Cooler Temperature logs do not include the facility name and address, and the Armstrong Nest Run Processing Plant logs and the Armstrong Nest Run Cooler logs did not include the English translation; 2) approximately nine hen body remnants were observed outside between House 2 and 3 that could become an attractant for pests, rodents and stray animals and; 3) pooling water was observed between House 3 and the Processing Plant from a broken roof sprinkler system and pooling water was observed in House 5 from two leaking water dispenser cup systems that could potentially become an attractant for pests and rodents. The firm promised to make corrections.

The firm made the following voluntary corrections during the inspection: 1) the firm modified the rodent control section of the plan to include that their Pest Control Associate will also be responsible for ensuring that all debris, animal carcass, and any other potential harborage areas are removed and that they will additionally be responsible for accessing and performing weed abatement at the ranch and 2) the rodent control section of the SE plan was changed to include that all lay houses will be monitored for any access from wild birds, and if there is a problem action must be taken. These corrections were entered into CARS. All other corrections were promised by management.

No refusals were encountered and no samples were collected.

ADMINISTRATIVE DATA (AP)

Inspected firm: Lake Wohlford Ranch

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Location: 27023 N. Lake Wohlford Rd.
Valley Center, CA 92082
Phone: 760-749-1058
FAX: 760-749-6539
Mailing address: 27023 N LAKE WOHLFORD RD
Valley Center, CA 92082
Dates of inspection: 5/31/2011, 6/1/2011, 6/2/2011
Days in the facility: 3
Participants: Alexandra B. Pitkin, Lead Investigator
Ana Djurdjevic, Investigator
Rochelle A. Rolnik, Investigator

Credentials were presented by Investigators Alexandra Pitkin, Ana Djurdjevic, and Rochelle Rolnik and two FDA-482's, Notice of Inspection, were issued on 5/31/11 to Mr. Alan W. Armstrong, General Manager, who introduced himself as the most responsible person available at the firm during the issuance of the FDA-482 for the corporate office (Armstrong Egg Farms, Inc.) and the inspected farm, Lake Wohlford Ranch. Credentials were also presented and an FDA-482, Notice of Inspection, was also issued on 5/31/11 to Ms. (b) (4) who introduced herself as the Compliance Manager of (b) (4) located in (b) (4) and the most responsible person during the issuance of the FDA-482. A second FDA-482, Notice of Inspection, was issued on 6/1/11 to (b) (4) Compliance Manager of (b) (4) of (b) (4) (b) (4) stated that she provided the incorrect legal name of the firm that owns the chickens and the eggs at Lake Wohlford Ranch (b) (4) on 5/31/11, and stated that the correct name should be (b) (4). The FDA-482 issued on 6/1/11 reflects the correct firm name.

During the close-out of the inspection held at the corporate office, an FDA-483, Inspectional Observations, was issued to Mr. Alan W. Armstrong, General Manager and the most responsible individual available at the firm during the issuance of the FDA-483.

This team inspection was conducted by Investigators Alexandra Pitkin, Ana Djurdjevic and Rochelle Rolnik. All investigators were present during the entire inspection. Sections of the report have been written by the team members identified below and the initials of the investigator that wrote each section of the report are included next to each heading.

Alexandra Pitkin – **AP**Ana Djurdjevic – **AD**Rochelle A. Rolnik - **RAR**

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HISTORY (AD)

Lake Wohlford Ranch is one of the four ranches operated by a family owned corporation, Armstrong Farms, Inc. (FEI# 3005332266) which has been in operation since the 1940's when it was owned by the grandfather of the current owners. It was incorporated as Armstrong Farms, Inc. in California in 2006. Armstrong Farms, Inc. has four locations: one ranch for brooding and three laying ranches, named after the road on which they are located: Woods Valley (b4 [redacted]), Cole Grade and Lake Wohlford (used to be called b4 [redacted] b4 [redacted]). Lake Wohlford Ranch came into production in 1986, with the b4 [redacted] being built in 2002. The corporation also has a shell egg processing, and packaging facility (Plant Number 7549) that is USDA inspected, located at Lake Wohlford Ranch. The corporate office is located at 27431 North Lake Wohlford Road, Valley Center, CA 92082. This is the only office location, and is where all records are kept for each of the firm's four ranch locations. The firm has a retail store, Armstrong Feed & Supply, located at 28520 Cole Grade Rd., Valley Center 92082. The firm requires all visitors to first visit the corporate office before proceeding to any of the ranches. There are no other locations or affiliated firms.

Armstrong Farms Inc. Facilities

| Name and Address of Ranch | Registration Number | Number of Houses | Total Number of Layers | Flock Strain |
|--|---------------------|------------------|------------------------|--------------|
| Lake Wohlford Ranch/Processing Facility 27023 North Lake Wohlford Rd. Valley Center, CA 92082 | 20725625962 | 6 | (b) (4) | (b) (4) |
| Cole Grade Ranch 29550 Cole Grade Rd. Valley Center, CA 92082 | 22754812240 | 11 | (b) (4) | (b) (4) |
| Woods Valley Ranch 27025 Woods Valley Rd. Valley Center, CA 92082 | 28765811312 | 12 | (b) (4) | (b) (4) |
| Brooder Ranch/Corporate Office 24731 North Lake Wohlford Rd. Valley Center, CA 92082 | 28105894976 | 21 | (b) (4) | (b) (4) |

The farm is co-owned by brothers Ryan R. Armstrong, President and Alan W. Armstrong, General Manager, who purchased the farm from their mother in 2009. In February 2011 they began a joint venture with (b) (4) located at (b) (4)

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(b) (4) exists as two corporations, (b) (4) and (b) (4), both having the (b) (4) address. It is (b) (4) (b) (4) that owns the chickens and the eggs. Armstrong Farms, Inc. is responsible for management of the facilities and management of the birds. Gross annual sales are between (b) (4) U.S. dollars. There are approximately (b) (4) employees among all the ranches, with (b) (4) employees being employed at Lake Wohlford Ranch, which includes processing facility employees. The vast majority of the firm's employees live on the farm they work on.

Office Hours are 7:00 AM to 5:00 PM Monday through Friday.

Ranch operating hours are (b) (4). The eggs at Lake Wohlford Ranch are collected (b) (4). Most of the eggs which are collected from the (b) (4) are moved the day they are collected into the firm's nest egg cooler. The eggs collected from the (b) (4) are sent on the same day to the processing facility, on the days when the processing facility is working. On the days when the processing facility is not operating, those eggs are also placed into the firm's nest egg cooler. Eggs are processed on (b) (4) (b) (4) in the firm's processing facility.

There is no previous inspectional history for this ranch. According to Mr. Alan Armstrong the firm has not conducted any recalls. On 03/08-11/2011 FDA conducted an initial inspection of this corporation at another of the Armstrong Farms, Inc. ranches, known as Mac Tan Ranch, located at 28442 Mac Tan Rd., Valley Center, CA 92082. The inspection was classified as VAI. Mac Tan property was leased by Armstrong Farms from a local farmer, and since the FDA concluded its inspection, Armstrong Farms, Inc. has decided not to renew the lease for that property, and they no longer operate from that location. On 05/09-11/11 FDA conducted an initial inspection at the corporation's Woods Valley Ranch. The inspection was classified as VAI.

Registration status: The firm is registered per the egg registration requirements.

FDA correspondence should be addressed to:

Mr. Ryan R. Armstrong, President
Armstrong Farms, Inc.
P.O. Box 2299
Valley Center, CA 92802

INTERSTATE COMMERCE (AD)

Armstrong Farms, Inc. manages birds owned by (b) (4) located at (b) (4). The birds are received from various hatcheries located nationwide. Chicks are received at one day old and are either grown at the firm's Brooder

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Ranch, or are received as 17-18 week old pullets. The firm's egg production is primarily distributed wholesale to (b) (4) (b) (4) % with a (b) (4) portion (b) (4) % sold under the Armstrong Egg Farms brand name at Armstrong Feed and Supply retail location in Valley Center, CA.

According to Mr. Alan Armstrong, the percentage of eggs distributed in interstate commerce varies from week to week depending on the location of (b) (4) customers. He approximated that (b) (4) % of the eggs stay in California. (b) (4) customers include: (b) (4), and (b) (4), located mostly in states throughout western United States, like (b) (4), (b) (4), (b) (4). Some of the customers like (b) (4) arranges for direct pick-up of eggs from Armstrong Farms, Inc. The rest of the eggs owned by (b) (4) are transported by (b) (4) via common carrier or firm-owned (b) (4) trucks from Armstrong Egg Farms in Valley Center, CA to (b) (4) distribution center in (b) (4) where they are further packaged and distributed to (b) (4) customers nationwide according to demand.

The firm maintains a website, <http://www.armstrongeggfarms.com/justhatched.htm>, which contains information on the egg farm and products (eggs, compost) as well as contact information for firm management. The firm does not do any advertising according to Mr. A. Armstrong.

For a copy of (b) (4) Chick Delivery Report No. (b) (4), dated July 29, 2010, and July 30, 2010 showing that Armstrong Egg Farm, P.O. Box 2299, Valley Center, CA 92082 received (b) (4) chicks on July 29th, and (b) (4) chick on July 30th from hatchery, (b) (4) (b) (4), please see Exhibit 1.

JURISDICTION (AD)

Products produced by the firm are subject to the FD&C Act. The firm is a shell egg producer with greater than 3,000 laying hens. The firm packages and distributes white and brown shell eggs for the table egg market which is subject to the requirements in 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation. Armstrong Egg Farms produces and packs chicken shell eggs primarily for (b) (4) located (b) (4). Shell eggs are packed for table use in retail cartons or packed in bulk flat packages which may be used as table eggs or for boilers (hard boiled eggs), scrambled eggs and/or liquid egg products.

Eggs are packed in bulk flat cartons at Armstrong Egg Farms' processing plant. Bulk flat packaged shell eggs are shipped to (b) (4) where they are packaged under (b) (4) brand name or under (b) (4) customer's brands including: (b) (4), (b) (4), (b) (4), (b) (4), etc., or processed for boiled eggs, scrambled eggs, and liquid egg products. Mr. A. Armstrong estimated that (b) (4) % of their shell eggs are sold at their retail feed store located in Valley Center, CA under the firm's brand, Armstrong Egg Farms.

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INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (AD)

Ryan R. Armstrong, President/Co-Owner: Mr. R. Armstrong was intermittently present during this inspection. However, Mr. Alan Armstrong stated that his brother, Mr. Ryan Armstrong is the President/Co-Owner ((b)(4)%) of the company. According to Mr. A. Armstrong, his brother controls financial aspect and all aspects of the business related to processing/packaging and maintenance. Mr. R. Armstrong has held this position since February of 2011. As president, he has ultimate responsibility for the firm; he has the power, duty, and responsibility to detect, prevent, and correct violations. Mr. Ryan Armstrong has the authority to hire and fire employees and can make unlimited capital expenditures.

Alan W. Armstrong, Vice President/General Manager/Co-Owner ((b)(4)%): Mr. Alan Armstrong stated that he has held the current position since 2000. He is responsible for overseeing all production, managing all birds, purchasing, and is very involved in all aspects of the business. He has the power, duty, and responsibility to detect, prevent, and correct any problem at the firm. Mr. A. Armstrong has the authority to hire and fire personnel and can make unlimited capital expenditures. He was present for most of the inspection, and provided information to each investigator about the firm's operations. Mr. A. Armstrong has attended an FDA provided seminar on 21 CFR 118 regulations, and has a lifetime of experience in food safety. All major decisions for the company are made by these two brothers.

John E. Dodrill, Production Manager: Mr. Dodrill has been employed with the firm for 15 years. He has held the current position since 2001. Mr. Dodrill has the responsibility of day to day bird management operations. He accompanied us throughout the inspection and provided the majority of information contained in this report. He has the authority to hire and fire employees although he usually confers with Mr. Alan Armstrong and Mr. Ryan Armstrong prior to making any hire/fire decisions. He has purchasing authority, but for any high expenditures he needs upper management approval. Mr. Dodrill has attended an FDA provided seminar on 21 CFR 118 regulations. Mr. Dodrill reports to both Mr. Ryan and Alan Armstrong.

(b)(4) Compliance Manager: (b)(4) is an employee of (b)(4), but has been advising Armstrong Farms, Inc. on compliance issues since January 2011. She is responsible for the development of SE prevention plan and aids in its implementation, and she is responsible for quality assurance issues at Armstrong Farms. (b)(4) does not have any hire/fire or monetary expenditure authority. She provided information regarding SE prevention plans and sampling program. (b)(4) maintains her office in (b)(4) and visits Armstrong Farms, Inc. on an as needed basis. She has a degree in Business Management, is HACCP certified, has attended an FDA provided seminar on 21 CFR 118 regulations, has had training at the National Egg Quality School on SE Prevention, and has numerous other laboratory certifications. (b)(4) participated in the entire inspection and was present for the close-out meeting.

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b6 & b7e Ranch Manager: Mr. **b6 & b7** is the Ranch manager at Lake Wohlford Ranch. He has been employed with the company since **b7** 1985. He is responsible for lights, feed, water and egg gathering. He does not have hire and fire authority and his expenditures authority is capped at \$(**b**) (**4**). Mr. **b6 & b7** reports to Mr. Dodrill. We did not interview or obtain any information from Mr. **b6 & b7**.

FIRM'S TRAINING PROGRAM (AD)

Mr. John Dodrill is the Production Manager. He has attended training from the California Egg Quality assurance Program on the following subjects:

- Biosecurity, cleaning and disinfection
- Egg Processing
- Preparing a Quality Assurance Plan
- Insect Vector Control
- Rodent Control
- Flock Health Management

Most of the firm's employees are Spanish speaking, and upper management is able to communicate in Spanish with them. Employees are trained by having someone read the procedures to them in Spanish. The employees then sign a log for the class they attended. According to Mr. A. Armstrong, all employees are trained on the specifics of their duties. He is in charge of training the vaccinating crew and de-population crew.

Biosecurity training is given by the farm, and is provided to all new hires, whereby they watch a video and discuss policies, such as "no pet birds" or not visiting places with pet birds. Biosecurity training also includes a discussion of visitor and sanitation policies. Employees also have to sign a sheet for a "Code of Conduct" for treating birds humanely.

According to Mr. A. Armstrong the firm has not hired any new employees recently, and most of the firm's employees live on the ranch they work on.

MANUFACTURING/DESIGN OPERATIONS (RAR)

Armstrong Farms, Inc.'s Lake Wohlford Ranch consists of six houses with a total of (**b**) (**4**) hens. In addition, the firm has their Processing Plant and Nest Run Cooler on the ranch. The firm has the following two different styles of lay houses on the ranch; **b4** style and **b4** house. According to the firm all pullets start off as being **b4** (**b**) (**4**) (**b**) (**4**). All pullets receive (**b**) (**4**). House 1, 2, 3, 6, and 7 range from (**b**) (**4**) to (**b**) (**4**) feet, and are the **b4** level style houses containing (**b**) (**4**) rows. The firm

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stated that House 1, 2, 3, 6, and 7 are considered to be one unit due to the openness of the houses. House 5 is (b) (4) feet long, and is the firm's only (b) (4) containing (b) (4) rows that are (b) (4) high. The firm's House 4 is now their new processing plant that contains a (b) (4) sq. ft. finished product cooler.

According to the firm (b) (4) pullets are moved a (b) (4). The firm stated that they generally raise the pullets at their Brooder Ranch, and then move them over once they have reached an egg production age. During this inspection the ages of the flocks within each different style of lay houses were as follows:

| Flock Number | Hen House Style | Flock Age | Number of Hens | Flock Strain |
|--------------|-----------------|-----------|----------------|--------------|
| LWA103 | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| LWA103 | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| LWA103 | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| H53698 | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| LWA103 | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| LWA103 | (b) (4) | (b) (4) | (b) (4) | (b) (4) |

On 05/31/2011 an interior and surrounding exterior walk-through was conducted of House 1 and 3 (both (b) (4)). On 06/01/2011 a complete interior and surrounding exterior walk-through was conducted of House 5 (b) (4). In addition, on 06/01/2011 a complete interior walk-through was

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conducted of the firm's Nest Run Cooler, Processing Plant and the finished product cooler within it. Each house was found to contain the following set-up:

b4
The firm has a total of five b4 cage style hen houses that contain (b) (4) rows. The firm stated that there are approximately (b) (4) hens per cage. The b4 cage style houses contain b4. According to the firm well water is used in the b4 in which the b4. The firm stated that the well water is tested (b) (4) for b4. The hen houses then have b4. Laid eggs are b4 picked up from these styles of houses. According to the firm these houses have only approximately (b) (4) eggs per day that are being laid because the hens are just barely coming into egg production. As the weeks pass the hens will begin to lay more and more eggs. On 5/31/11 we observed three small wild birds inside House 3, and were entering the poultry house through an approximate gap of four inches between the roof and the South wall (FDA-483 Observation 1)(Exhibit 2).

b4
The firm has only one b4 house that contains (b) (4) rows that are (b) (4). The firm stated that there are approximately (b) (4) birds per cage. The b4 contains an b4 called the (b) (4). The house contains feed troughs where b4. The house also contains b4 that dispense well water b4. The b4 house contains (b) (4) manure belts with scrapers that scrape the belts, and transport it up to a chute that then drops it into the back of a truck that is located outside of the house. The firm stated that the manure belts in the house are scraped (b) (4). According to the firm this house lays approximately (b) (4) eggs per day. Laid eggs are transported by way of an automated conveyor belt that leads directly into the firm's Processing Plant.

Lay House Collection and Distribution

Eggs are generally gathered (b) (4) throughout the day from the firm's b4 style houses. Eggs from the firm's b4 house are gathered by way of automated belts that transport the laid eggs into the firm's processing plant. The firm's processing facility then operates (b) (4). Most of the eggs from the b4 house (House 5) are washed, packaged, and shipped out immediately except when the processing plant is not operating in which the eggs are then moved into the Nest Run Cooler. Eggs that are gathered manually are generally placed in the Nest Run Cooler to await washing and packaging. Once the eggs have been washed and packaged they are then placed in the firm's finished product cooler within the Processing Plant. The firm stated that generally the cooler is cleaned out of all eggs at the end of the production day.

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According to the firm their manufacturing codes have not changed since the inspection that was conducted at their Woods Valley Ranch on 05/09-11/2011. During this inspection we confirmed that the firm's manufacturing codes are the same as what was previously stated for the Woods Valley Ranch inspection. The firm does print manufacturing codes on all of the eggs, and that it is this manufacturing code that allows them traceability of the product. The firm stated that their manufacturing codes consists of the following information; Julian date, a sell by date (b) (4) (b) (4), and their plant number (P1158). The firm stated that they recently changed their plant number after becoming a USDA plant on 04/08/2011. The firm's previous plant number was CA-7549.

COMPLAINTS (RAR)

According to the firm their complaint handling procedures have not changed since the inspection that was conducted at their Woods Valley Ranch on 05/09-11/2011. During this inspection we confirmed that the firm's complaint procedures are the same as what was previously stated for the Woods Valley Ranch inspection. The firm does have a consumer complaint file; however complaints are generally received and are handled by (b) (4) since they own, sell, and distribute the eggs to their various customers. (b) (4) Compliance Manager for (b) (4), maintains spreadsheets of received complaints and identifies those that have come from eggs received from Armstrong Farms, Inc. The firm stated that they have never received any reports of illness or injury. (b) (4) monitors customer complaints and has the ability to generate "Customer Service Reports." According the (b) (4) the firm has not received any new complaints since their inspection at the Woods Valley Ranch that related to complaints of customers receiving the incorrect size eggs. A search in FACTS revealed that the firm does not have any FDA sourced complaints. Mr. Ryan R. Armstrong, President, is responsible for handling any of the firm's future complaints that are received to them by (b) (4)

RECALL PROCEDURES (RAR)

According to the firm their recall procedures have not changed since the inspection that was conducted at their Woods Valley Ranch on 05/09-11/2011. During this inspection we confirmed that the firm's recall procedures are the same as what was previously stated for the Woods Valley Ranch inspection. The firm stated that they do have written recall procedures in place. According to the firm they conduct mock recalls (b) (4) and they have never been involved in a recall. The firm stated that they have traceability of their product based upon their manufacture code containing a Julian date that allows them to know the exact house the eggs came from. Mr. Ryan R. Armstrong, President, is responsible for any of the firm's future recalls which would involve notifying (b) (4) (b) (4) would then be responsible for carrying out the firm's details of the recall since all eggs are owned and distributed by them.

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OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (RAR)

Mr. Alan W. Armstrong, General Manager, Mr. John E. Dodrill, Production Manager, and Ms (b) (4) (b) (4), Compliance Manager for (b) (4), were present during the close-out of the inspection and issuance of the FDA-483, Inspectional Observations. I, Alexandra Pitkin, provided the firm with a warning and explained that the observations listed on the FDA-483 were our observations during the current inspection and after further review by the agency, the observations may be considered to be violations of the Food, Drug & Cosmetic Act. Legal sanctions including a warning letter, seizure, injunction, civil money penalties and prosecution are available to the FDA.

Observations listed on form FDA 483

OBSERVATION 1 (RAR)

Stray animals are not prevented from entering poultry houses.

Specifically, on 5/31/11 we observed three small wild birds inside poultry house 3. These birds were observed entering the poultry house through an approximate gap of four inches between the roof and the South wall of the house.

Reference: 21 CFR 118.4(b)(4)

Supporting Evidence and Relevance: Refer to **Exhibit 2** for digital photos of small wild birds that were observed inside poultry house 3. The wild birds were able to gain entry to the hen house because of a gap between the roof and the walls of the house. These small wild birds can become a source of contamination to the hens in the hen house.

Discussion with Management: Mr. Armstrong stated that the firm is going to place (b) (4) around the houses to close the gap between the walls and the roof. He stated that the (b) (4) has already been ordered. Mr. Armstrong stated that we will be responsible for implementing this corrective action plan, and should have it complete within (b) (4).

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OBSERVATION 2

You do not maintain records documenting compliance with refrigeration requirements.

Specifically, you do not maintain records showing that the eggs processed after time of lay from house # 5 were held under refrigeration at 45°F or below.

Reference: 21 CFR 118.10(a)(3)(iv)

Supporting Evidence and Relevance: The firm sometimes packages and ships out the eggs from House 5 on the same day that they are laid; however, records are not maintained that provide evidence of this practice. We therefore could not confirm that refrigeration controls were in place or that the eggs were immediately being packaged and shipped before 36 hours after lay.

Discussion with Management: Mr. Alan Armstrong stated that they were already aware of this refrigeration observation. He stated that on 6/1/11 he spoke with the employees regarding placing all the eggs from all houses into the Nest Run Cooler after collection. The firm will then document the date and time that the eggs were laid (collected) and the date and time that they are placed into the Nest Run Cooler to show evidence of refrigeration even though some eggs are immediately packaged and shipped out the same day of lay.

REFUSALS

There were no refusals encountered during the inspection.

GENERAL DISCUSSION WITH MANAGEMENT (RAR)

Mr. Alan W. Armstrong, Vice President/General Manager/Co-Owner, Mr. John E. Dodrill, Production Manager, and (b) (4) Compliance Manager for (b) (4) were present during the close-out of the inspection, held on 06/02/2011, and issuance of FDA-483, Inspectional Observations. Four items, not included on the FDA-483, that were discussed included the following:

1. The firm did not have their facility name and address on the following records; Armstrong Nest Run Processing Plant logs, Armstrong Nest Run Cooler logs, and finished product Cooler Temperature logs (**Exhibits 3-5**). In addition, the Armstrong Nest Run Processing Plant and Armstrong Nest Run Cooler logs did not include the English translation (**Exhibits 3 and 4**). (b) (4) stated that she will modify all records to include the name and address of the firm and the English translation.

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2. On 05/31/2011 approximately nine hen body remnants were observed outside between House 2 and 3 (**Exhibit 6**). The firm stated that the hen remnants could have potentially come from some of their compost piles in which stray animals could have dug them out, or come from the depopulation that they conducted a few weeks prior. It was discussed with the firm that they should be cleaned up because it could become an attractant for pests, rodents and stray animals.
3. On 05/31/2011 pooling water was observed between House 3 and the Processing Plant from a broken roof sprinkler system (**Exhibit 7**). The firm stated that the roof sprinkler systems are used to help keep the houses cooler during the warm seasons, and that generally when they are running it causes pooling water. We informed the firm that pooling water near and/or outside the houses could potentially become an attractant for pests, rodents and stray animals.
4. On 06/01/2011 pooling water was observed in House 5 from two leaking (b) (4) systems (**Exhibit 8**). The firm stated that sometimes the (b) (4) systems malfunction and begin to leak. The firm said that when this happens it is generally fixed within the same day. We informed the firm that pooling water in the houses could potentially become an attractant for pests, rodents and stray animals.

ADDITIONAL INFORMATION

Salmonella Enteritidis (SE) Prevention Plan (AP)-

At the start of our inspection, Mr. Alan W. Armstrong reported that the firm had no SE positive houses and that there were no ill birds. The firm provided a copy of their current Armstrong Egg Farms Salmonella Enteritidis Prevention and Monitoring Program Plan for Lake Wohlford Ranch, updated on May 2011-version 3, which included signatures on the Management Review signature page on 5/2/11 and 5/4/11 (**Exhibit 9**). Mr. Armstrong (b) (4) and Mr. John Dodrill are responsible for administering the SE prevention plan. The firm's current SE Prevention Plan was modified by (b) (4) in consultation with Mr. Alan Armstrong.

The firm's written SE plan includes the following:

a) Pullets (AP)

The firm's SE plan dated 5/4/11 states that pullets are raised under SE-monitored conditions. In addition, the plan states that the "chicks shall be purchased from "SE monitored" breeding flocks meeting the National Layer Improvement Plan's (NPIP) standards for "U.S. Salmonella Enteritidis Clean" status or equivalent, and that "all purchased chicks shall be accompanied by an NPIP VS Form 9-3, or equivalent, which certifies that the breeder flock is participating in the NPIP U.S. Salmonella Enteritidis Clean" program or equivalent.

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The firm receives pullets either from the Brooder Ranch located at the corporate office at about 14-16 weeks of age or from pullet suppliers such as (b) (4), when they are 17-18 weeks of age.

The farm currently has birds from two different flocks. Flock H53698 are (b) (4) weeks of age and flock LWA103 are (b) (4) weeks of age. Birds from both flocks were received by the firm as day old chicks and were raised and grown by the Brooder Ranch. We reviewed records for these flocks and determined that the chicks were procured from SE-monitored breeder flocks. I collected a copy of the NPIP VS Form 9-3 dated 7/29/10 for flock H53698 consisting of (b) (4) and NPIP VS Form 9-3 dated 1/7/11 for flock LWA103 consisting of (b) (4) which were "S. Enteritidis Clean" (**Exhibit 10**). In addition, the pullet environment for these two flocks was tested for SE when the pullets were 14 to 16 weeks of age by the firm. The analytical results from the (b) (4) located in (b) (4) revealed negative test results for both flocks. **Exhibit 11** includes the analytical results for flock H53698, dated 11/23/10, when the birds were 16 weeks of age.

b) Biosecurity (AD)

According to Mr. A. Armstrong, the firm views Lake Wohlford Ranch as a Bio-Security area divided between 5 (b) (4) houses and the (b) (4) house present on the ranch. Components of the Bio-Security requirements are addressed in the firm's SE plan as follows:

Limiting of visitors on farm and poultry houses:

The firm has locked gate policy where all gates must be closed and secure (locked) at all times, with keys and entrance codes being assigned only on an approval basis. We observed the front gate and back gate, to the Lake Wohlford Ranch to have a large lock in place. The firm's visitor policy is by appointment only and no unescorted visitors are allowed on premises. Employees are told to ask unannounced visitors to go to main office and ask for Mr. A. Armstrong or R. Armstrong. They are also required to report unannounced visitors to management. Since all visitors are required to first visit the main office, there is one Visitor's Log at that location. A Visitor's Log is also kept at the Lake Wohlford Ranch location. Please see **Exhibit 12** for an example of the Visitor's Log kept at Lake Wohlford Ranch. There is a (b) (4) restriction for visitors who have been at a poultry farm not owned by the Armstrong Farms Inc. Once the visit is approved, the management will determine the sequence of the visit depending on age of the chicks and their disease status. We were questioned by the management when the last time was that we had come in contact with any birds or have been on a farm.

The firm's Bio-Security Protocol states that the front entrances of all facilities have a tire wash station, and any vehicles traveling onto the premises will have the tires washed. The tire wash station has (b) (4) sanitizer. Movement between locations will be limited and monitored. Mr. A. Armstrong added that visits to ranches are kept to only absolutely necessary vehicles like feed trucks, egg trucks, and company vehicles. Since we did not enter the ranch with our vehicle and

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were allowed to park outside on the side of the road, we were not required to sanitize the tires of our vehicle.

Personnel and equipment practices preventing cross-contamination between houses

The firm divides the Bio-Security area on the farm between the 5 **b4** houses, which are treated as one area, and the **b4** style house, which is treated as the second area. According to Mr. Dodrill, the **b4** style house uses dedicated equipment and has one dedicated employee who only works in that house. The rest of the farm's personnel do not wear any special clothing when moving between other 5 **b4** houses, and the equipment between those ranch houses is shared, although sharing is limited. However Mr. A. Armstrong stated that the employees that work on a particular ranch also usually live on that ranch. He also added that equipment is rarely shared between ranches and when it is, it is first disinfected using the disinfecting stations used to sanitize vehicle tires, placed at the front entrance to the ranch. For the firm's "Equipment Disinfecting Log" please refer to **Exhibit 13**. We observed Lake Wohlford Ranch employees to be moving freely between houses, and not to be changing clothing, or wearing protective suits between **b4** houses, which were populated by the same flock. According to Mr. Dodrill, the practices of upper management who need to move between ranches in the same day are to shower and change clothes between ranches. Once on the ranch they try to visit younger chickens first, before visiting houses that house older chickens.

According to the firm's SE Plan for Bio-Security Protocols all ranches and pullet ranches have foot baths located at the main entrance, and employees have been trained to use the footbaths. Foot baths are cleaned and maintained regularly, which is documented in the "Foot Bath Log" (**Exhibit 14**) and under the Bio-Security Protocols it is stated exactly how this maintenance is to be accomplished, and how the foot baths are to be prepared. We observed a foot bath at the inside of the walk-through gate, next to the second drive-in gate to Lake Wohlford Ranch, and were asked to walk through the foot bath and to roll our coolers through it. Visitors are required to wear tyvek suits and shoe covers, and are required to change them between visiting different flocks. If the same flock of birds is housed in two houses, visitors are not required to change in between the two houses.

Prevention of stray animals entering houses

The firm's SE plan addresses the monitoring of stray animals in the Pest Control section, where a pest control associate will monitor the perimeter **(b) (4)** to ensure that there is no area through which larger wild animals or vermin would be able to enter the property. We observed perimeter fencing around the ranch, which limits access from stray animals and cattle on the ranch from entering the poultry houses and a locked gate is in place. Lake Wohlford Ranch has 5 newer style, (not open sided), **b4** style houses, and one completely enclosed **b4** style house. All of the **b4** style houses have a gap between the walls of the buildings and the roofs, which allow for entrance of small animals and birds. This was addressed with management during the close-out of the inspection. During this inspection on 5/31/11 we observed three small wild birds inside **b4** poultry house # 3 (**Exhibit 2**) (**FDA-483 Observation 1**). We did not observe any stray live animals in the **b4** house.

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Employees are forbidden from owning "birds of any kind" as written under the Bio-Security Protocols "Visitors and Employees" heading. According to Mr. A. Armstrong all potential employees are asked if they own pet birds at the initial interview, and are asked to sign a statement on firm's pet bird and bird contact policy. See **Exhibit 15**.

c) Rodents, flies, and Other Pest Control (RAR)

The firm's SE plan includes procedures for rodents which were reviewed during the inspection (**Exhibit 9, p.10-11**). The firm's plan states that their in-house Pest Control Associate will be responsible for monitoring activity and documenting it on a (b) (4) basis to ensure the maintenance of the program. The plan then outlines the following procedures/responsibilities of their Pest Control Associate to maintain rodent control; rodent (b) (4) must be placed strategically throughout the facility and/or laying houses then checked and documented (b) (4), rodent (b) (4) must be distributed, no more than (b) (4) feet apart, throughout the exterior of the facility, effectiveness of pest control followed up by a compliance associate during internal inspections, and then throughout the plant pest control devices must be placed around the walls, no more than (b) (4) feet apart, and must be monitored and documented (b) (4). The firm's plan states that if there is a rodent problem then immediate action must be taken in order to eliminate the problem. The plan also addresses the training of the Pest Control Associate in which a (b) (4) representative is responsible for training the employee in all of their pest control duties. The plan states that the (b) (4) representative has been trained by the supplier to administer, dispose of, and monitor all pesticides and rodenticides. The firm's plan did not address the need to remove vegetation surrounding the lay houses that could potentially create harborage areas, and did not address the issue of preventing wild birds and/or strays animals from entering the poultry houses. Both of these observations were immediately discussed with the firm, and were added to their SE plan before the close-out of this inspection on 06/02/2011.

According to the firm, they have (b) (4) located along the perimeter of the lay houses, and traps located within. The firm then stated that their in-house Pest Control Associate monitors the bait stations and traps (b) (4). Rodent activity inside and outside the lay houses is monitored and documented on the firm's "Lake Wohlford" pest control documents (**Exhibit 16**). The firm documents the pest activity per house, and therefore the documents for each house contains a layout of the house with numbered bait stations and tin cats in their specific location. The firm then documents the activities seen in each (b) (4). The firm categorizes rodent activity as the following (b) (4). The firm's SE plan does establish a rodent index in which (b) (4) rodents caught in (b) (4) days with (b) (4) traps is considered to be "low." A rodent index of "moderate" is then (b) (4) rodents caught in (b) (4) days with (b) (4) traps. Then finally a rodent index of "high" is then (b) (4) or more rodents caught in (b) (4) days with (b) (4) traps. The firm additionally documents the number of DOA's (dead rodents) found outside of their lay houses in order to evaluate the effectiveness of their pest control program. The firm documents any necessary corrective actions on their "Rodent Action Log." The firm stated that they had a rodent control problem in 2003 due a fire that occurred in the Valley

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Center, CA area. The firm stated that in the event of a rodent problem they contact their (b) (4) supplier who then suggests the following solutions; repositioning of the (b) (4) s, and/or switching to a different type of (b) (4). Mr. Alan W. Armstrong, General Manager, stated that he is responsible for the firm's rodent control program. A record review of the firm's "Lake Wohlford" pest control documents were reviewed for the following lay houses 1, 3, and 5 from 04/06/2011-05/25/2011. During this time period the firm did not have any unacceptable rodent activity in which activity never reached a "high" status as set in their rodent index.

The firm's SE plan includes procedures for fly control which were reviewed during the inspection (Exhibit 9, p.11). The firm's plan states that their fly monitoring will be done by using a (b) (4). It continues to state that the Pest Control Associate will use (b) (4) that is (b) (4).

(b) (4)
(b) (4). Once complete the employee then (b) (4). The firm's SE plan identifies a fly index of less than (b) (4) being satisfactory with no corrective action necessary. The firm documents any necessary corrective action on the "Fly Action Log."

According to the firm fly monitoring is also done (b) (4), and then documented on the same record that they document their rodent control on (Exhibit 16). A record review was done of the firm's "Lake Wohlford" pest control documents for the following lay houses 1, 3, and 5 from 04/06/2011-05/25/2011. During this time period the firm did not have any unacceptable fly activity in which fly activity was never above the firm's set fly index of unsatisfactory.

d) Cleaning and Disinfection (RAR)

The firm's SE plan includes procedures for cleaning and disinfection of SE positive houses (Exhibit 9, pg. 7). The firm stated that the plan also outlines their general "dry" cleaning procedure that is conducted on every house after depopulation of each flock. The firm's "dry" cleaning procedure involves (b) (4) on various areas of the house starting with the inside and working their way outside. Then the (b) (4)

(b) (4)
(b) (4)

The firm's SE plan for cleaning and disinfection of SE positive houses follows the same "dry" cleaning procedures; however also has the additional procedure of (b) (4). The firm's plan then also stated that if a house tests positive for SE for two successive flocks then senior management will review the cleaning and disinfection procedures before placing another flock in that same house. The firm is currently using (b) (4) to sanitize the houses; however are currently researching a different (b) (4)

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sanitizer that is less abrasive. The firm stated that they are now implementing this stated cleaning and disinfection procedure after depopulation of the hen houses whether the house was SE positive or not. Cleaning and disinfection between flocks is documented on the firm's "House Preparation Log" (Exhibit 17).

e) Refrigeration (AP)

The firm's SE prevention plan includes refrigeration under the "Refrigeration of Eggs" heading which states that "all eggs coming from the farm will be documented with the date collected to ensure that the eggs are processed and refrigerated before 36 hours" and "Refrigerate eggs at 45 F (9.44 C) within 36 hours after lay, during storage and transportation" (Exhibit 9, pg. 13).

According to Mr. Armstrong and Mr. Dodrill, eggs are collected by hand throughout the day (b) (4) (b) (4). The eggs are placed directly into the Nest Run Cooler on non processing days which are (b) (4). The firm documents the ranch that the eggs are collected from (b) (4) is Lake Wohlford Ranch), the day of lay, and the date and time that the eggs are placed into the cooler on the "Armstrong Nest Run Cooler" log under the "Huevo Entrante" heading (Exhibit 4). The time the eggs are collected is not documented on this record and the English translation is also not included. This was discussed with management and (b) (4) stated that she would modify the record to include the time and the English translation. A review of these records revealed that the eggs were collected and placed into the nest run cooler on the same day which is well under 36 hours after the eggs are layed and collected.

On processing days (b) (4), the eggs from Houses 1, 2, 3, 6 and 7 are placed into the finished product cooler in the processing plant after they are collected the same day. The ranch name, the date and time of egg collection, and the date and time that the eggs are placed into the finished product cooler is documented on the "Armstrong Nest Run Processing Plant" record (Exhibit 3). A review of these records revealed that all eggs were placed into the cooler on the same day of collection. The temperature of the finished product cooler is documented (b) (4) during processing on the "Cooler Temperature Log" record (Exhibit 5). In addition, the firm's finished product cooler has a continuous recording data logger that measures the temperature of the cooler (b) (4) (Exhibit 19). We did not observe any temperatures exceeding 45°F.

The eggs collected from House 5 ^{b4} (house) on processing days are taken to the processing plant after they are collected, are washed, processed, and packaged, and then are distributed the same day. Mr. Armstrong stated that these eggs are distributed less than 36 hours after time of lay. The firm documents when the eggs are collected and are taken to the Processing Plant; however, the date and time that the eggs are shipped/distributed is not documented to provide evidence that the farm does not need to refrigerate these eggs prior to shipment (FDA-483 **Observation 2**). Since the eggs are transported within 36 hours after time of lay, the farm does not need to comply with the refrigeration requirements specified in the regulations stating that the eggs

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must be held and transported at or below 45°F ambient temperature beginning 36 hours after time of lay for these eggs.

Environmental Testing for SE (AP)

The firm's SE prevention plan dated 5/4/11 outlines when environmental testing for SE will occur including when pullets are between 14-16 weeks of age, at 40-45 weeks, 4-6 weeks after molt, and two weeks prior to the depopulation of a house.

The farm's SE plan also includes environmental swabbing procedures for each type of house. In the

b4
houses that have b4
b4

Mr. John Dodrill, Production Manager, is responsible for conducting environmental sampling of the firm's poultry houses. Environmental samples are collected and sent to the (b) (4)

(b) (4) for analysis of SE.

The environment for all pullets was tested for SE 14-16 weeks of age. This is included in the Pullets section of the report. Environmental testing has not yet been performed for the two flocks. According to Mr. Dodrill, flock H53698 which is currently b4 weeks of age will have their environment tested for SE b4 when the birds are 45 weeks of age.

In the event of a positive result for SE the firm will immediately shut down the egg belt in the SE positive house and the SE team will be notified. The house will be quarantined and all traffic into the lay house will be restricted to a minimum of works that are assigned only to that house. The USDA grader assigned to the packing plant will then be notified. The plant management will then determine whether the company plans to test the eggs from the identified layer flock or will divert the eggs to treatment for the remainder of the life of the flock. The SE team will review rodent control logs to decide if the pest control associate should b4 stations on interior and exterior to infected barn, or if other corrective measures will take place regarding rodent control. All eggs from the infected lay house will be processed at the end of the day after all other houses are clear. Once eggs are ran the egg belt will be disinfected until egg testing proves house to be negative for SE or the flock is destroyed. All eggs from the positive house will be tagged, segregated and diverted to the Breaker Plant for 5 log reduction in accordance with the 21 CFR 118 rule.

Environmental Testing for an Induced Molting (AP)

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According to Mr. Dodrill, the farm has not induced molting for the group of laying hens within the firm's 6 poultry houses since the required regulations became effective on 7/9/10. Mr. Dodrill stated that the birds are typically molted between ^{b4} weeks of age. Since the farm's birds have not molted during the time period starting 7/9/10, the farm is not required to perform environmental testing for SE 4-6 weeks after the end of any molting process. The firm's SE prevention plan states that environmental testing for SE will be performed 4-6 weeks after molting which is required per the regulations (Exhibit 9, pg. 4).

Egg testing for SE (AP)

The firm has not had any of their eggs tested for SE since the regulations became effective on 7/9/10 due to the firm not having any confirmed positive results for environmental testing for SE.

The firm's SE prevention plan dated 5/4/11 states that senior management will decide whether to test eggs or destroy the flock upon receiving a positive result for SE in environmental swabbing. The plan states that if the firm decides to perform egg testing, then (b) (4) (b) (4) 4 consecutive tests. If any of these four tests is positive then the flock is considered positive and the eggs must be diverted from being packed as shell eggs. If all four pooled sample tests are negative then the flock would be considered clean until the next scheduled test.

Attachment A: Inspection/Data Collection Tool for Targeted Inspections



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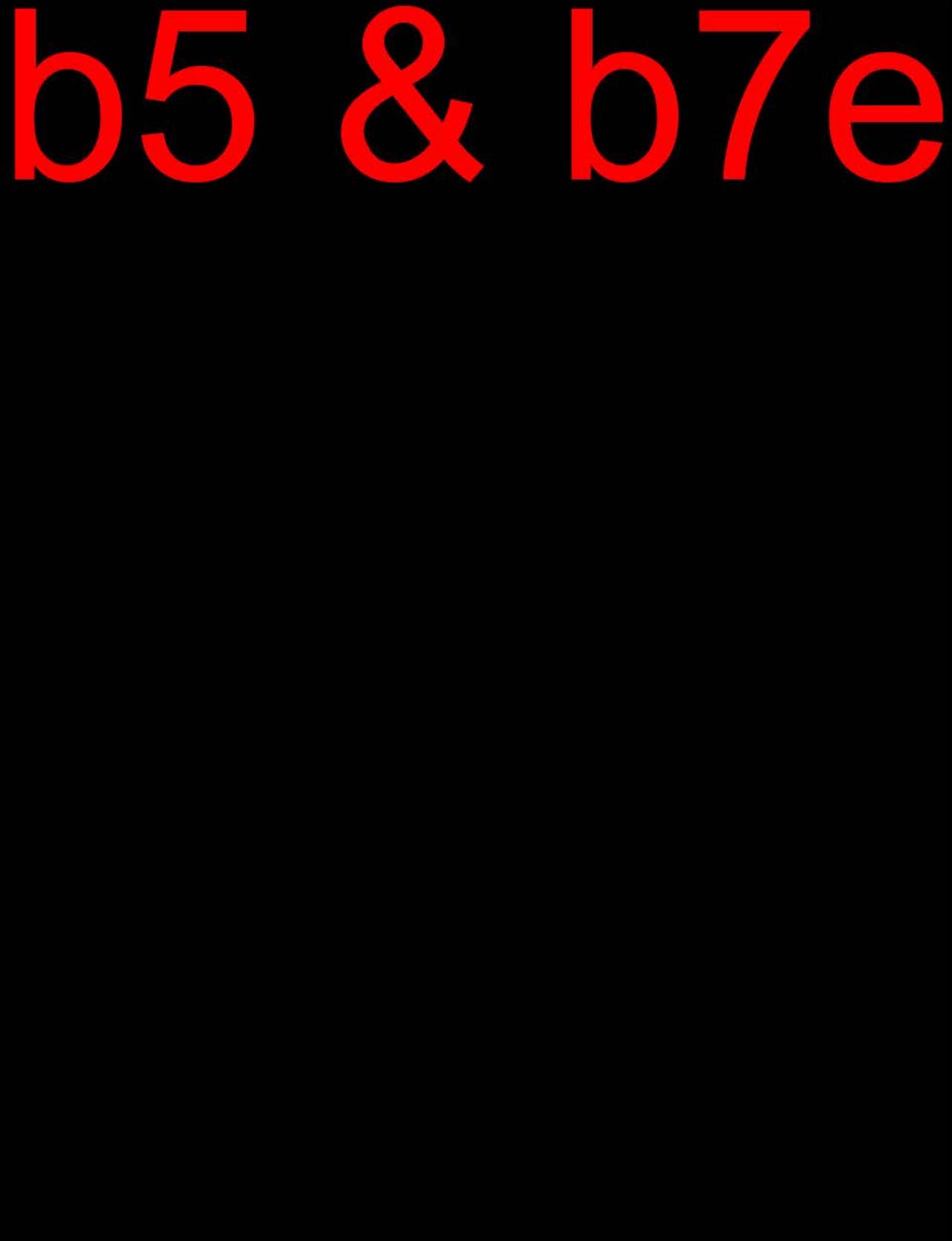
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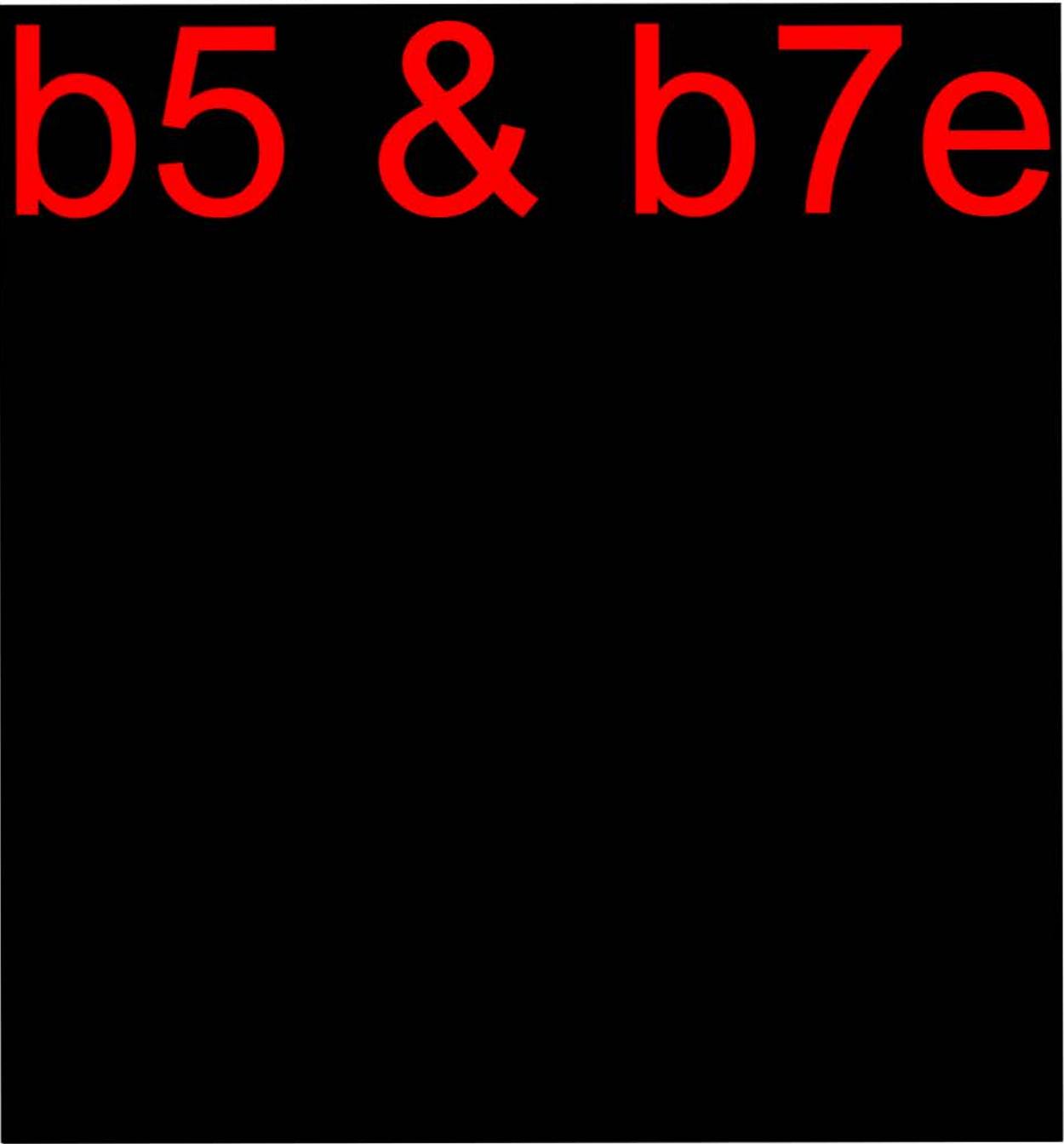
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SAMPLES COLLECTED

No samples were collected during the inspection.

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VOLUNTARY CORRECTIONS (RAR)

During this inspection the firm voluntarily corrected the following items pertaining to their SE plan:

1. The firm modified the rodent control section of the plan to include that their Pest Control Associate will also be responsible for ensuring that all debris, animal carcass, and any other potential harborage areas are removed (**Exhibit 18**).
2. The firm modified the rodent control section to include that their Pest Control Associate will additionally be responsible for accessing and performing weed abatement at the ranch (**Exhibit 18**).
3. The firm changed the rodent control section by including that all lay houses will be monitored for any access from wild birds, and if there is a problem action must be taken (**Exhibit 18**).

These corrections were entered into CARS.

EXHIBITS COLLECTED

1. **(b) (4)** Chick Delivery Report No. **(b) (4)**, dated July 29, 2010, and July 30, 2010 showing that Armstrong Egg Farm, P.O. Box 2299, Valley Center, CA 92082 received **(b) (4)** chicks on July 29th, and **(b) (4)** chick on July 30th from hatchery, **(b) (4)** **(b) (4)**
2. Digital photos of a small wild bird that we observed inside House 3 on 5/31/11 which entered the poultry house through an approximate gap of four inches between the roof and the South wall, 2 pages.
3. Armstrong Nest Run Processing Plant logs dated 5/19/11, 5/17/11, 4/22/11, 4/8/11 and 4/7/11, 5 pages.
4. Armstrong Nest Run Cooler logs dated 5/31/11, 5/24/11, 5/23/11, and 5/20/11, 4 pages.
5. Armstrong Egg Farms Cooler Temperature Log for May 2011.
6. Digital photos of hen body parts that we observed outside House 2 and 3 on 05/31/2011 which could become an attractant to pests, rodents and stray animals.
7. Digital photo of pooling water that was observed between House 3 and the Processing Plant from a broken roof sprinkler system on 5/31/11 which could become an attractant to pests, rodents and stray animals, 2 pages.
8. Digital photos of pooling water that was observed in House 5 from two leaking **(b) (4)** **(b) (4)** systems on 6/1/11 which could become an attractant to pests and rodents, 2 pages.
9. Armstrong Egg Farms SE plan dated 5/4/11 for Lake Wohlford Ranch, 16 pages.
10. NPIP VS Form 9-3 dated 7/29/10 for flock H53698 consisting of **(b) (4)** **(b) (4)** birds and NPIP VS Form 9-3 dated 1/7/11 for flock LWA103 consisting of **(b) (4)** **(b) (4)** **(b) (4)** birds which were "S. Enteritidis Clean", 2 pages.

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11. (b) (4) analytical results for flock H53698, dated 11/23/10, 3 pages.
12. Visitors and Vendors sign-in sheet dated 5/18/11 to 6/1/11, 2 pages.
13. Equipment Disinfecting Log dated 5/2-6/11.
14. Armstrong Egg Farms Foot Bath Log dated 5/31/11.
15. Armstrong Egg Farms statement on firm's pet bird and bird contact policy which is signed by the firm's employees.
16. Pest and Fly monitoring records for poultry houses 1, 3 and 5 dated 5/25/11, 3 pages.
17. House Preparation Log record dated 5/10/11.
18. Modified Rodent Control section of the SE plan dated 5/4/11.
19. Data logging data for the Processed Egg Cooler from 5/2-10/11.
20. CD-R containing digital photos taken during the inspection.

ATTACHMENTS

1. FDA-482, Notice of Inspection, issued to Allen W. Armstrong, General Manager of Armstrong Egg Farms, Inc. (corporate office), on 5/31/11.
2. FDA-482, Notice of Inspection, issued to (b) (4) Compliance Manager of (b) (4) LLC, on 5/31/11.
3. FDA-482, Notice of Inspection, issued to Alan W. Armstrong, General of Lake Wohlford Ranch, on 5/31/11.
4. FDA-482, Notice of Inspection, issued to (b) (4) Compliance Manager of (b) (4) on 6/1/11.
5. FDA-483, Inspectional Observations, issued to Alan W. Armstrong, General Manager of Lake Wohlford Ranch, on 6/2/11.

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Alexandra B. Pitkin, Investigator



Ana Djurdjevic, Investigator



Rochelle A. Rolnik, Investigator