

**Establishment Inspection Report**

Johnson County Egg Farm

Knob Noster, MO 65336

FEI:

**1930931**

EI Start:

05/02/2011

EI End:

05/04/2011

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**SUMMARY**

This comprehensive inspection of a Shell Egg Producer was conducted according to FACTS Assignment ID# 1271900, Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFPG Assignment #11-04, ORA Concurrence # 2011012601 (dated 02/08/2011), and the KAN-DO FY 11 work plan. Guidance was provided in the assignment, and requirements of 21 CFR 118; Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage and Transportation. This inspection included environmental sampling of five of the firms' laying hen barns. The inspection was pre-announced to the firms' Production Manager, Clyde Lynde on 4/27/2011.

This was the first inspection of Johnson County Egg Farms; there is no inspectional history for this firm. USDA is onsite in the processing facility daily to conduct egg grading only. The inspection was conducted to confirm compliance with FDA's "Egg Rule". The main objectives of the inspection were to assess compliance with 21 CFR 118 including evaluation of the firms' SE Plan and documentation related to the plan, also to determine if the firm is practicing adequate measures to prevent SE contamination of eggs and egg production areas.

The current inspection found the firm has a written Bio-Security plan which is incorporated within the firm's written SE Plan. Investigators Carmen Fisher, Cody Rickman, Adree Anderson, Bonnie Pierson, and I conducted environmental sampling and assessments of 5 laying barns; 3, 7, 9, 10, and 14.

At the conclusion of the inspection, the firm was issued a FDA 483, Inspectional Observations for the following: 1) Your written SE plan does not carry the signatures of the persons who administer the plan; 2) All required records do not include your name and the location of your farm. Verbal observations discussed with the firm at the close-out meeting include: 1) No hand sink in production area, 2) Reviewing and signing cooler logs in the middle of the month, 3) Small holes found at the roof peaks in laying hen houses 3, 7, 9, and 10.

No refusals were encountered during the inspection. Environmental samples were taken during the inspection; refer to the Samples Collected section of this report for more information. At the close of the inspection management was warned of their responsibilities to adhere and comply with the FD&C Act and consequences for failing to adhere were discussed. Management stated they would respond in writing to KAN-DO describing their corrective actions.

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**ADMINISTRATIVE DATA**

Inspected firm: Johnson County Egg Farm  
Location: 1275 S E Hwy Y  
Knob Noster, MO 65336  
Phone: 660-563-2775  
FAX:  
Mailing address: 1275 S E Hwy Y  
Knob Noster, MO 65336

Dates of inspection: 5/2/2011, 5/3/2011, 5/4/2011  
Days in the facility: 3  
Participants: Erin C. Dugan, Investigator  
Adree N. Anderson, Investigator  
Carmen Y. Fisher, Investigator  
Bonnie E. Pierson, Investigator  
Cody D. Rickman, Investigator

Administrative Data, Individual Responsibility, and Pest Control sections of this report are identified by initials ANA.

Upon arrival on 5/2/2011, credentials were displayed by all Investigators and a FDA 482, *Notice of Inspection*, was issued to Mr. David S. Hurd, Executive Vice President signed by Investigators Dugan, Fisher, Rickman, and Pierson. A second FDA 482, *Notice of Inspection*, dated 5/2/2011 was issued to Mr. Hurd and signed by me, Investigator Anderson.

On 5/4/11, FDA 484's, Receipt for Samples for INV 658155, INV 596869, INV 485550, INV 640638, and INV 572277, were issued to Mr. Clyde Lynde, Complex Manager of the firm.

On 5/4/11, the two item FDA-483, Inspectional Observations, was issued to Mr. Clyde Lynde.

Investigators Dugan, Fisher, Rickman, and I were present at the firm 5/2/11-5/4/11. Investigator Pierson was present at the firm 5/2/11-5/3/11.

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**HISTORY**

Johnson County Egg Farm LLC (JCEF) was incorporated in the state of Missouri in 1997; the firm operates as a shell table egg producer and is registered with the FDA as an egg laying operation. The firm is owned by Rose Acre Farms Inc; their corporate office is located in Seymour, Indiana. Rose Acre Farms Inc created Marshall Egg Products LLC in April 1994 to buy an egg breaking facility in Marshall, MO owned by KRAFT. Marshall Egg Products Inc the purchased Vauhn Brothers farm in June 1997 which is now Johnson County Egg Farm LLC.

Rose Acre Farms Inc. management stated that Marshall Egg Products Inc breaking facility is no longer used as a breaker; RAF uses it as a egg drying facility. Johnson County Egg Farm LLC sells all of their eggs as whole shell table eggs; only oversized and undersized eggs are sent to RAF breaking facilities. RAF breaking facilities include the following:

- 1) (b) (4)
- 2) (b) (4)
- 3) (b) (4)

These breakers use 5-Log reduction/pasteurization for all their egg products.

Johnson County Egg Farm LLC employs (b) (4) individuals both full and part time; the firm operates (b) (4) from (b) (4) Eggs are processed and shipped (b) (4).

**A copy of this report pursuant to Field Management Directive (FMD) 145 and all official correspondence should be sent to:**

**Clyde W. Lynde, Complex Manager**  
**Johnson County Egg Farm LLC**  
**1275 SE Hwy Y**  
**Knob Noster, MO 65336**

**INTERSTATE COMMERCE**

The firm ships approximately (b) (4)% of their shell eggs outside the state of Missouri. Management stated that (b) (4)% of their eggs are shipped to the table market. There is a processing facility onsite which packs the eggs in both wholesale and retail cartons. Third party carriers are used to transport the eggs across the country.

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**JURISDICTION**

The firm is a Shell Egg Producer with greater than (b) (4) laying hens producing shell eggs for the table market and is subjected to the requirements of 21 CFR 118. The firm packages their eggs with plant ID # P 1595 under several brand names including but not limited to: (b) (4)

(b) (4)

(b) (4)

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

**Clyde Lynde**, *Complex Manager*, is responsible for enforcing GMP's, biosecurity guidelines, and plant security policy. He is responsible for administration of programs and work instructions at plant/farm. He has been in his position with Johnson County Egg Farm LLC (JCEF) since 1999. He reports to Mr. Victor Riggerink, Vice President of Processing. Mr. Lynde was present for the majority of the inspection and provided relevant information. The FDA 483, *Inspectional Observations*, was issued to Mr. Lynde.

**David S. Hurd**, *Executive Vice President*, was the most responsible person on site and was issued the FDA 482's, *Notice of Inspection*. He provided relevant information during review of the firm's documents including but not limited to the firm's S.E. Plan, biosecurity measures, age and location of chicken populations, and facility layout.

**Edward R. Hopkins, Jr.**, *Safe Quality Foods (SQF) Practitioner Food Defense Coord/Assistant Grader Manager*, has been in his current position since 2009. Mr. Hopkins has been employed with JCEF since 1998 and started with the title of Assistant Manager. He assists with quality as needed. He stated he reports to Mr. Lynde.

**Abraham A. Ricardez**, *Production Manager*, has been employed with JCEF for 13 years. He has been employed with Rose Acres Farms for 15 years. He is responsible for daily operations of the chicken houses and has a team of managers reporting to him. He is responsible for environmental sample collection and administers work instructions in poultry houses. He reports to Mr. Lynde. He was present for the entire inspection and provided relevant information pertaining to the firm's integrated pest management program.

**Jason R. Chroeder**, *Marketing Director*, has been with JCEF for 13 years. He reports to Mr. Lynde. He was present for part of the inspection and close out.

**Daniel B. Long**, *General Manager of Rose Acres*, works with David S. Hurd on the JCEF layer facility. He is responsible for in house audits of JCEF. He has been employed by Rose Acres Farms for 17 years. He was present for the entire inspection and provided relevant information.

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A list of corporate officers was provided (See Exhibit 1). An organizational chart of Johnson County Egg Farm LLC was provided with names of employees, their titles, and their job responsibilities (See Exhibit 2).

### FIRM'S TRAINING PROGRAM

Johnson County Egg Farm employees are trained in several aspects of egg farm production including:

- 1) (b) (4)
- 2) (b) (4)
- 3) Bio-security
- 4) SE Prevention

### MANUFACTURING/DESIGN OPERATIONS

JCEF receives (b) (4)% of their pullets from Knobnoster Pullet Farm, owned by Rose Acre Farms, located across the street from the egg laying operation. The remainder of the pullets is purchased from (b) (4) out of (b) (4) and (b) (4). Rose Acre Farms Inc owns the laying hens, eggs, and farm including the processing facility.

JCEF produces approximately (b) (4) dozen shell eggs per (b) (4). There are 14 Layer houses, 12 (b) (4) houses and 2 (b) (4) houses (See Exhibit 3, JCEF Facility Map). Houses 1-12 are (b) (4) houses with (b) (4) rows and (b) (4) tiers, (b) (4) birds per cage; houses 13 and 14 are (b) (4) houses with (b) (4) rows, (b) (4) tiers, and (b) (4) birds per cage (See Exhibit 4, Flock Performance Comparison and Exhibit 5, Laying House Information).

The firms' operation is as follows:

- The caged hens on each tier lay eggs onto an egg belt
- The egg belt rolls to the corresponding de-escalator to the main egg belt
- The main egg belt continually moves throughout each house and transports the eggs into the farms packing area

### Farm Packing/Refrigeration/Shipping Operations

The eggs come into the packing facility on a common egg belt, all eggs are washed with warm water, sanitized with quaternary sanitizer and then rinsed again. The eggs are then hand packed into either one dozen size retail containers or 15 dozen wholesale boxes each container is printed with the plant number (P1595). The cartons are palletized and each pallet is plastic wrapped, weighed and

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identified. The palletized eggs are placed in a large walk-in cooler where the eggs are held below 45 degrees Fahrenheit.

The cooler temperature is monitored every (b) (4) and recorded on a Cooler Temperature Log (See **Exhibit 6, March-April Cooler Temp Log**). A review of these logs indicated the records are being reviewed prior to the (b) (4). This was discussed with management during the close-out of the inspection.

The packed shell eggs are shipped on refrigerated trucks by third party carriers throughout the United States.

**MANUFACTURING CODES**

Each carton and case of shell eggs is ink jetted with a date and plant number (P1595).

**SALMONELLA ENTERITIDIS PREVENTION PLAN**

Rose Acre Farms Inc. management provided a copy of the firms' SE Plan (See **Exhibit 7, JCEF Salmonella Enteritidis Plan**). Investigators Dugan, Anderson, Fisher, Rickman, and Pierson reviewed the plan and relating documents to assess compliance with the Final egg Rule; 21 CFR 118.

The plan covers the following items:

- Plan Administrators
- Definitions
- Pullet Procurement
- Poultry House Environmental Sampling Collection
- Bio-security Policy
- Bio-security Plan
- Cleaning and Disinfection Procedures
- Refrigeration Requirements for Shell Eggs
- Pest Management and Monitoring

Mr. Lynde stated the houses have never tested positive for SE. Rose Acre Farms and (b) (4) (b) (4) performs the SE lab testing for Johnson County Egg Farms; the swabbing of the barns is conducted by Clyde Lynde and Johnson County Egg Farm employees. According to management samples are tested in compliance with the FDA testing procedures for SE in egg laying operations. All test results for pullets and layers were reviewed, there were no positive results.

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Cleaning and Disinfecting

According to the firms' SE plan, hen houses are cleaned and disinfected only when the barn tests positive for SE. The firm does not maintain Cleaning and Disinfecting Logs at this time because there have been no SE positive houses.

Mr. Lynde stated houses 13 and 14 manure pits are cleaned out (b) (4). Currently houses are not being cleaned and disinfected between flocks.

Pest Control

(Written by ANA)

Johnson County Egg Farm LLC (JCEF) manages their pest control program internally. The firm's integrated pest control management system includes plans for rodent and fly monitoring, rodent indexing, and corrective actions.

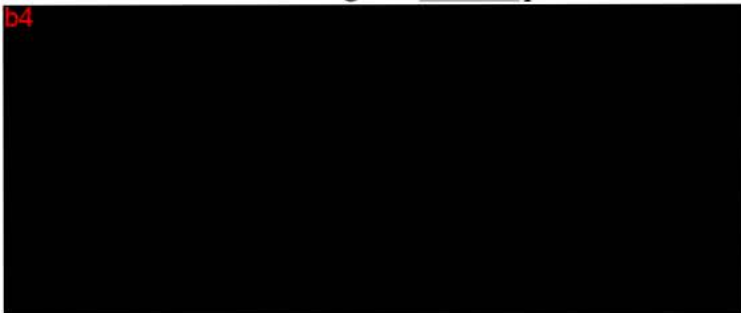
Houses 1-12 at JCEF use (b) (4) traps in lieu of (b) (4) (b4) due to the presence of roof rats. A minimum of (b) (4) traps are placed in Houses 1-12 and checked (b) (4) with activity documented on IPM 1.3.1F1. Once rat activity has been eliminated in houses 1-12, a transition to using (b4) is planned to be implemented per IPM 1.3.1 of the firm's plan.

Houses 13 and 14 have a minimum of (b) (4) (b4). Individual (b) (4) (b4) are checked (b) (4) and documented on the form, IPM 1.3.1F1. If a trap has not caught any mice for more than (b) (4), the (b4) is required to be moved to where rodent activity may be higher according to the firm's pest control program.

House counts of individual rodents are recorded under the 'HC' column on IPM Form A next to each house number and conducted on a (b) (4) basis. When over (b)(4) mice are counted, countermeasures are implemented such as (b) (4) of (b4) or administering (b4) (b4) rat is recorded as the equivalent of (b)(4) mice. I reviewed IPM Form A, (b) (4) from 9/7/10 – 4/28/11 and found no issues.

Number of Rodents Caught in (b) (4) per House

(b4)





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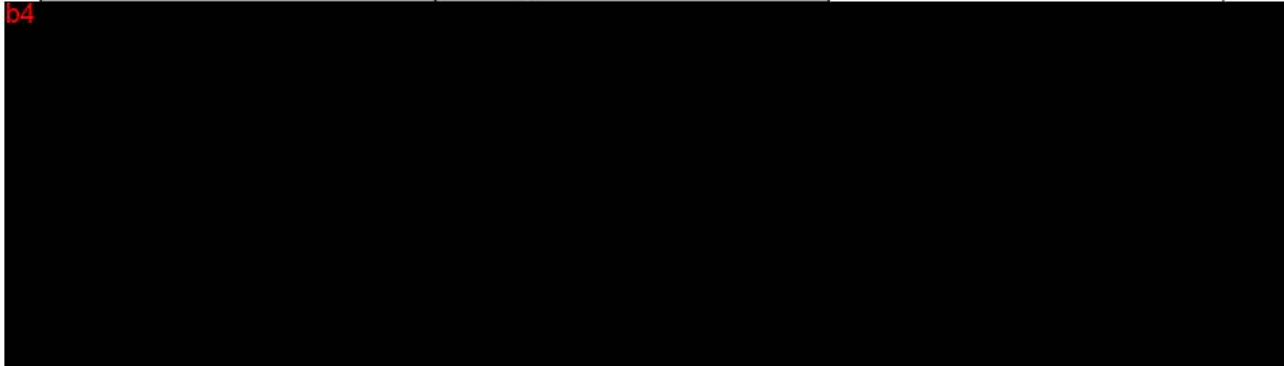
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House counts of individual flies are recorded under the 'FC' column on IPM Form A next to the house number and conducted on a (b) (4) basis. When fly rating is greater than (b) (4) countermeasures are implemented such as using (b) (4) in high population areas or (b) (4)

Number of Flies Caught in (b) (4) per House

Fly spots on card	Rating	Control
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(b) (4)



Form A and actual fly cards are both filed at the facility for (b) (4) years. Rodent and fly ratings are placed into the pest database (b) (4) according to Mr. Ricardez, Production Manager. I reviewed IPM Form A, (b) (4), from 9/7/10 – 4/28/11 and found no issues.

The firm maintains an inventory tracking sheet for purchasing pesticides and a pesticide sign out sheet for their administration. The firm uses pesticides such as (b) (4) for fly control, (b) (4) (b) (4) for rodent control, and (b) (4) for rodent control.

(b) (4) visual tests are performed (b) (4) during a perimeter walk. These (b) (4) visual tests are documented and maintained for (b) (4) years at the facility. I reviewed the firm's (b) (4) visual pest sighting log. A possum was observed on the (b) (4) of 1/13/11. The firm set a (b) (4) as a countermeasure. On 2/26/11, a cat was observed on the north side of House 14 outside by the fresh water lagoon. A live trap was set 2/26/11. No (b) (4) pest sightings were encountered in March or April of 2011.

Facility management for caged layer/pullet and breeder operations calls for clearing debris from and around chicken houses and maintaining an (b) (4) buffer zone along the exterior perimeter. Bait stations are monitored with maintenance activity and documented (b) (4) on IPM Form B. Water and feed delivery systems are to be checked (b) (4) for leaks and spills per the firm's pest control program.

I observed no live rodents during sampling. I observed no idle equipment or pest harborage areas in the yards around the chicken houses.

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**COMPLAINTS**

Mr. David Hurd, Executive Vice President RAF, stated there have been zero consumer complaints and illness concerning Johnson County Egg Farm LLC. Complaints go through Rose Acre Farms Inc. corporate office in Indiana and then are sent to the individual farms whose plant number is associated with that specific complaint.

**RECALL PROCEDURES**

No recalls have been associated with Johnson County Egg Farms LLC. The firm does have a written recall procedure in place (See Exhibit 8, Rose Acre Farms Recall Procedure).

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE****Observation 1**

1. Your written SE plan does not carry the signatures of the persons who administer the plan.

Specifically,

Your written SE Plan for Johnson County Egg Farm does not have individual names listed as administrators of the plan. Your plan only lists individual titles of persons who can administer the plan.

*Management Response: Management agreed with the observation and corrected the observation on 5/3/2011 by listing individual names in the SE Plan to reflect the administrators of the plan.*

**Observation 2**

2. All required records do not include your name and the location of your farm.

Specifically,

Your (b) (4) Environmental Submission Form does not list your farm name and location, and your Laboratory Results Forms do not list the farm location of which the samples were taken.

*Management Response: Management agreed with the observations and corrected the observation on 5/3/2011 by adding the farm name and location to the forms.*

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**GENERAL DISCUSSION WITH MANAGEMENT**

A close-out meeting was conducted on 5/3/2011 with all firm officials listed above in the Individual Responsibility section of this report along with Investigators Dugan, Rickman, Anderson, and Fisher. David S. Hurd, Executive Vice President for Rose Acre Farms was not present at the close-out meeting. A two item FDA 483, *Inspectional Observations* and was discussed and issued to Clyde W. Lynde, Complex Manager. Mr. Lynde signed and was issued all FDA 484's, *Receipt for Samples*.

At the conclusion of the inspection Mr. Lynde along with other firm officials were warned of their responsibility to comply with the FD&C Act and penalties were discussed.

**ADDITIONAL INFORMATION**

The following check list is inserted in this EIR as directed per assignment.

**Attachment B: Inspection/Data Collection Tool for *Comprehensive Inspections***

**B5 & B7e**

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**B5 & B7e**

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**B5 & B7e**

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**B5 & B7e**

**B5 & B7e**



**B5 & B7e**





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**B5 & B7e**

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**B5 & B7e****SAMPLES COLLECTED**

Environmental samples were collected using the following method:

**House 14 Drag Swabs** – Pre-made drag swabs, 2 per bag, were moistened with Nestle Carnation Evaporated Milk inside of the whirlpak bag. Using aseptic technique and sterile gloves, the pre-moistened swab was removed from the bag and used to drag along the right and left side of manure rows 1-10 in the manure pits. Each swab was immediately placed in an individual whirlpak bag, aseptically and strings were cut. Approximately 2-3 tablespoons of evaporated milk was poured into the whirlpak bags and the bags were closed.

**Houses 3,7,9,and 10 Hand Swabs** – Swabs were removed from sterile packages and moistened with Nestle Carnation Evaporated Milk inside of a whirlpak bag. Using aseptic technique and sterile gloves, the pre-moistened swab was removed from the bag grasped with a sterilized grabber and used to wipe across the manure belts on one side of each row. Each swab was immediately placed aseptically in an individual whirlpak bag. Approximately 2-3 tablespoons of evaporated milk was poured into the whirlpak bags and the bags were closed.

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**Environmental Samples**

- Sample #658155 consisting of 10 swabs was collected from House #10 on 5/3/2011
- Sample #572277 consisting of 10 swabs was collected from House #9 on 5/3/2011
- Sample #485550 consisting of 10 swabs was collected from House #7 on 5/3/2011
- Sample #640638 consisting of 10 swabs was collected from House #3 on 5/3/2011
- Sample #596869 consisting of 20 swabs was collected from House #14 on 5/3/2011

All environmental samples were sent to the Denver Laboratory and analyzed for SE. All samples were negative for SE.

**VOLUNTARY CORRECTIONS**

The firm voluntarily corrected both items listed on the FDA 483, Inspectional Observations; actual names of individuals were added as administrators of the SE Plan and the (b) (4) Form and Laboratory Results Forms were corrected by adding the name and location of the farm.

**EXHIBITS COLLECTED**

- 1- Corporate Officers List (1 page)
- 2- Organizational Chart (1 page)
- 3- Facility Map (1 page)
- 4- Flock Performance Comparison (1 page)
- 5- Laying House Information Sheet (1 page)
- 6- Cooler Temperature Logs (2 pages)
- 7- Johnson County Egg Farm LLC SE Plan (29 pages)
- 8- Rose Acre Farm Recall Procedure (3 pages)

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**ATTACHMENTS**

FDA 482, *Notice of Inspection*, issued to David S. Hurd, Executive VP on 5/2/2011

FDA 482, *Notice of Inspection*, issued to David S. Hurd, Executive VP on 5/2/2011

FDA 483, *Inspectional Observations*, issued to Clyde W. Lynde, Complex Manager on 5/4/2011

FDA 484, *Receipt for Samples*, signed by Clyde W. Lynde, Complex Manager dated 5/4/2011 for samples 658155 and 572277

FDA 484, *Receipt for Samples*, signed by Clyde W. Lynde, Complex Manager dated 5/4/2011 for sample 485550

FDA 484, *Receipt for Samples*, signed by Clyde W. Lynde, Complex Manager dated 5/4/2011 for sample 640638

FDA 484, *Receipt for Samples*, signed by Clyde W. Lynde, Complex Manager dated 5/4/2011 for sample 596869

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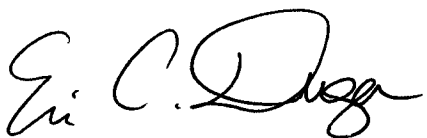
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Erin C. Dugan, Investigator



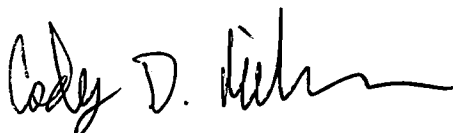
Adree N. Anderson, Investigator



Carmen Y. Fisher, Investigator



Bonnie E. Pierson, Investigator



Cody D. Rickman, Investigator