

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

6751 Steger Drive
Cincinnati, OH 45237
513 679 2700

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

05/21-23,26,29,30/2009 & 06/09/2009

FEI NUMBER

1021417

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Richard M. Barton, General Manager

FIRM NAME

Bi-County Farm Bureau Coop Association Inc

STREET ADDRESS

8300 Dixie Highway

CITY, STATE AND ZIP CODE

Florence, KY 41042

TYPE OF ESTABLISHMENT INSPECTED

Animal Feed Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

ADDENDUM to FDA 483

OBSERVATION 1

Effective measures are not being taken to exclude pests from the processing areas or to protect against the contamination of food on the premises by pests.

a. Specifically, on 05/21/2009:

1. Approximately twelve live rodents were observed in the feed mill. Approximately four rodents were observed traveling between a ceiling support rail and an opening in the ceiling caused from a sagging board approximately two feet from the south wall of the first floor. A live rodent was observed crawling under a pallet of feed oats approximately fifteen feet from the NW corner of the first floor. A live rodent was observed eating product spilled on the floor between pallets of alfalfa cubes and feed oats approximately fifteen feet from the NW corner of the first floor. Two live rodents were observed moving around near the bottom of the stairs in the basement of the mill. Approximately four live rodents were observed on the corn pile in the basement.
2. Approximately nine dead rodents were observed on the first floor of the feed mill in close proximity to various pallets of animal feeds. Two dead rodents were observed within a foot of a pallet of goat feed located approximately 10 feet from the SW corner. One dead rodent was within three inches of a pallet of trace mineral salt located along the west wall. Approximately seven dead rodents were observed on a shovel an employee was carrying after he swept them up from the floor; the three rodents described above were included in the count. Two dead rodents were observed on the floor, one within two inches and one within seven inches of a pallet of bagged Layena Sunfresh Recipe Pellet chicken feed located on the south wall.
3. Four live birds were observed flying inside the first floor of the feed mill and resting on a ceiling support brace near a bird's nest located approximately fifteen feet west of the loading dock.

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EMPLOYEE(S) SIGNATURE

Michael E. Campbell

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Michael E. Campbell, Investigator

DATE ISSUED

06/09/2009

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b. Specifically, on 05/22/2009:

1. Approximately 17 live rodents were observed in the feed mill. A live rodent was observed running along west wall into a bait box. Another live rodent was observed on north wall approximately five feet to the east of Legends Show & Pleasure Textured Horse Feed. A live rodent was observed in the northwest corner of the facility going under pallets and jumping on bags of product. Two live rodents were observed approximately 15 ft. from the northwest corner of the building behind and under product. A live rodent was observed running along the west wall. Approximately 11 live rodents were observed running in the basement.
2. Three dead rodents were observed in the feed mill. A dead rodent was observed in the crack between the floor and the west wall, approximately 15 ft from northwest corner and approximately six inches from a pallet of Agri-Flex Bentonite. Two dead rodents were observed on the basement floor.
3. Approximately three live birds were observed in the feed mill. The birds were flying above product all over the facility and sitting on the beams around a bird's nest that was in a wood crevice located approximately six beams from the east entrance along the south side of the building.
4. One lot containing 35/50 lb. paper bags of Legends Show & Pleasure Textured Horse Feed were found with evidence typical of rodent activity. The lot consisted of four pallets. The pallets were numbered and counted as followed: Pallet 4 had 10 bags; it was leaning against two overlapping pieces of cardboard which were leaning against the north wall. Pallet 3 had 10 bags; it was leaning against pallet 4. Pallet 2 had 8 bags; it was leaning against pallet 3. Pallet 1 had 7 bags; it was leaning against pallet 2. Eight of 35 of the bags in the lot were examined. These eight bags exhibited evidence of apparent rodent excreta pellets and/or fluorescing stains. This included five bags with one or more apparent rodent excreta pellets on the exterior of the bags, five bags with fluorescing stains varying from 1 1/2 to 5 inches in length on the exterior of the bags. There were a total of 44 apparent rodent excreta pellets and five fluorescing stains observed on the 8 bags examined of 35 bags in the lot. All 35 bags of Legends Show & Pleasure Textured Horse Feed were marked with lot # W9118. The bags were received on or about 04/30/2009 and had been in the feed mill for approximately 22 days. This product was stored approximately 25 feet from the northwest corner of the feed mill.

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5. Three pallets containing 28/50 lb. bags of Feed Grade Sodium Bicarbonate were found with evidence typical of rodent activity. The sodium bicarbonate consisted of 28 bags on three pallets. Pallet 3 contained 10 white bags; it was leaning against the west wall. Pallet 2 contained 9 white bags and one brown bag; it was leaning against pallet 3. Pallet 1 contained 8 brown bags; it was leaning against pallet 2. On 05/21/2009, three apparent rodent excreta pellets were observed touching product under a hole in the white paper bag on pallet 2. When investigators returned on 5/22/09, the hole on this bag had been taped over. The bags were counted; this bag is bag 10 on pallet 2. When the tape was peeled back, the same three apparent rodent excreta pellets were observed in the product. There were also several apparent rodent excreta pellets stuck to the tape. The white bags were not marked with a lot number. This product was stored approximately 25 feet from the southwest corner of the feed mill.

c. Specifically, on 05/23/2009:

1. Approximately 13 live rodents were observed in the feed mill. Three live rodents were observed on the north wall, approximately 10 feet from the northwest corner of the building. Three rodents were observed directly under and on products Reliance Horse Feed, Bio-Cube Alfalfa Cubes, and feed oats which are located on the north wall, approximately 10-15 feet from northwest corner of the facility. A live rodent was observed approximately 22 feet from the southwest corner of the facility and approximately three feet to the east of Home Grown Game Bird & Poultry product. Four live rodents were observed under Layena Sunfresh Recipe Pellet chicken feed along the south wall, approximately five feet to the east of Home Grown Game Bird & Poultry. Two live rodents were observed along the east wall of the second floor of the feed mill.
2. Three dead rodents were observed. A dead rodent was observed approximately one inch below a pallet of Home Grown Game Bird & Poultry product along the south wall, approximately 19 ft from southwest corner of the first floor of the feed mill. Two dead rodents were observed outside of the feed mill in an overflow of product near the northeast corner of the facility and underneath the auger, which has an approximately one foot square opening in the housing, which transports product from the outside dump pit to the hopper inside the building.
3. A dead bird was observed covered by dirt and dust on the second floor of the feed mill near the blender.

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d. Specifically, on 05/26/2009:

1. Approximately 10 live rodents were observed in the feed mill. Two live rodents were observed crawling in and out of the ingredient dump and then into the auger housing of the mixer, which contained ingredients used in mixing feed, located on the bottom of the mixer closest to the northeast corner of the feed mill. A live rodent and a live bird were observed in the scale buggy resting on top of product throughout the day; the scale buggy is used to weigh ingredients before dumping into the ingredient dump directly under the bottom of the mixers.
2. Spilled product on the manufacturing floor, near where apparent REP was sampled, was observed being swept into the bottom of the mixer by an employee using a broom. The spillage was caused by dumping ingredients into the bottom of the mixers from the scale buggy.
3. A lot containing 18 bags of Layena Sunfresh Recipe Pellet chicken feed was found with evidence typical of rodent activity. The lot consisted of 18 bags on two pallets. Pallet 2 contained 10 bags; it was leaning against two overlapping pieces of cardboard which were leaning against the south wall. Pallet 1 contained 8 bags; it was leaning against pallet 2. All bags in the lot were examined. 12 bags exhibited evidence of apparent rodent activity. This included eleven bags with one or more apparent rodent excreta pellets on the exterior of the bags and two bags which exhibited apparent rodent gnaw holes, one to the product. There were a total of 19 apparent rodent excreta pellets and three apparent gnaw holes on the bags. Apparent rodent excreta pellets too numerous to count were observed under and around each pallet. A dead rodent was observed approximately three feet northeast of the lot. All 18 bags of Layena Sunfresh Recipe Pellet chicken feed were marked with lot # 9APR28FRF. The bags were received on or about 05/12/2009 and had been in the feed mill for approximately 11 days. This product was stored approximately 20 feet from the southwest corner of the feed mill.

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4. A lot containing 10 bags of Bio-Cubes Alfalfa Cubes was found with evidence typical of rodent activity. The lot consisted of 10 bags on two pallets. Pallet 2 contained 7 bags; it was leaning against north wall. Pallet 1 contained 3 bags; it was leaning against pallet 2. All bags in the lot were examined. Nine bags exhibited evidence typical of rodent activity. This included eight bags with one or more apparent rodent excreta pellets on the exterior of the bags. Two bags exhibited apparent rodent gnaw holes which were observed open to product on 05/21/2009 and when Investigators returned on 05/22/2009 the two apparent gnaw holes were taped over. The lot was not sampled until 05/26/2009. There were a total of 184 apparent rodent excreta pellets and two apparent gnaw holes on the bags. Apparent rodent excreta pellets too numerous to count were observed under and around each pallet. All bags were marked lot 892. The bags were received on or about 02/16/2009 and had been in the feed mill for approximately three months. This product was stored approximately 15 feet east from the northwest corner of the feed mill. During the examination of this lot, two live rodents were running over, around and under the bags and the pallets, and running into and out of holes where the floor meets the north wall about three feet west of the lot and three feet east of the lot. Live rodents were also observed eating product spilled from an adjacent lot of oats around and under the lot of alfalfa.

5. During the examination of Layena Sunfresh Recipe Pellet chicken feed, at least eight birds were observed flying in and out of the west window about 25 feet away, eating spilled product from the floor about 15 feet east of the lot, and/or visiting an active nest.

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