

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

6th & Kipling St. (P.O. Box 25087)
Denver, CO 80225-0087
(303) 236-3000 Fax: (303) 236-3100
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

11/15/2010 - 11/22/2010

FEI NUMBER

1640846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Carl M. Duran, President/Owner

FIRM NAME

Duran and Sons, LLC

STREET ADDRESS

13 Mi N On Highway 187
Po Box 291

CITY, STATE, ZIP CODE, COUNTRY

Derry, NM 87933-0291

TYPE ESTABLISHMENT INSPECTED

Food Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Effective measures are not being taken to protect against the contamination of food on the premises by pests.

Specifically,

1. On 11/16-18/10 one live cat, one live bird, apparent bird-like nesting, bird-like droppings, rodent-like nesting material, rodent gnawings, rodent-like excreta pellets, apparent animal feces, apparent animal urine, cockroach-like insects, live and dead worm-like insects, worm-like insect larvae, moth-like insects were found throughout the entire finished product warehouse where finished dried whole chile pods, ground red pepper, and in-process whole chile pods are stored.

The following are specific locations of the observations listed above. (The listing of apparent rodent excreta pellets and apparent live and dead worm like insects is not an all inclusive listing of the rodent pellets and worm-like insects observed):

A. Live cat:

1. On 11/18/10, a cat was observed running along the exterior north wall of the warehouse and ran into a hole approximately 6" by 3" of the exterior north wall of the warehouse near the rain gutter.

B. Live bird observed:

1. On 11/18/10, one live bird was observed inside the finished product warehouse flying from structural I-beam to another I-beam and then exiting the warehouse.

C. Apparent bird's nesting:

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1. On 11/16/10, an apparent bird's nest was observed between the third center truss and a supporting pole from the east wall of the warehouse.
2. On 11/16/10, an apparent bird's nest was observed in the southwestern corner light fixture located approximately 12 ft. from the west wall.
3. On 11/16/10, an apparent bird's nest was observed on the west ceiling structural metal I-beam directly above pallets containing finished packaged whole chile pods.
4. On 11/17/10, an apparent bird's nest was observed on the west wall juncture approximately 2 ft. from the screen window of the west wall.
5. On 11/16-19/10, an apparent bird's nest was observed inside a damage ceiling insulation located on the northeast corner of the warehouse.

D. Apparent bird-like droppings:

On 11/16-18/10

1. Too numerous to count apparent bird droppings and rodent pellets were observed in the northwest area of the finished product warehouse, between 2 rows of palletized final product.
2. Apparent bird droppings on one used broken down corrugated box located on the cement floor approximately 8 ft. from the west wall of the warehouse.
3. Apparent bird droppings on approximately 5 used broken down corrugated boxes located on a pallet approximately 8 ft. from the middle of the west wall of the warehouse.
4. Approximately 35 bird droppings were observed on the cement floor next to packaged whole pods approximately 25 ft. from the middle of the west wall of warehouse.
5. Approximately 25 apparent bird droppings were observed on the top of two boxes of packaged whole pods of the first layer of pallet holding (b) (4) packages located approximately 15 ft. from the west wall of the warehouse.

On 11/16-17/10 FDA Consumer Safety Officers conducted a box by box break down of four pallets containing combined lots of (b) (4) (mild whole chile pods) which were staged perpendicular to the west wall of the warehouse. Apparent bird-droppings were observed in the following areas:

- An approximate 8 inch by 6 inch (near the packaging tape) area containing approximately 3 apparent bird dropping stains. Box was located on top layer #1 and was identified by FDA Consumer Safety Officers as layer #1, Box #1 of pallet #1, (b) (4) Top of boxes of layer #1 were exposed to the bird's nest located on structural I-beam near the west wall of the warehouse

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- One apparent bird dropping was observed on box#4, layer#1 of pallet #1 (near packaging tape).
- There were two apparent bird droppings observed on the top of box#5, layer#1 of pallet #1.
- There was an apparent bird dropping approximately 2" in length on the side of box #5, layer #3 of pallet #1.
- There was an apparent bird dropping directly on the packaging tape approximately 8" in length located on box #5, layer #5, of pallet #1.
- There was a small remnant of an apparent bird's nest located on box #1, layer#1, pallet #2.
- There were three apparent bird droppings on the top of the box# 3, layer#1 of Pallet #2.
- There were approximately 12 apparent bird droppings on the top of the box, (b) (4) box#6, layer#1 of pallet #2.
- There was one apparent bird dropping located on the side of the box located on box# 5, layer #2 of pallet #2.
- There was apparent bird droppings and remnants of apparent bird's nest that was located in structural beam above the pallets of product. On boxes # 4, 5, and 6, layer #1 of pallet #3 of lot# (b) (4)

E. Rodent-like nesting material:

1. On 11/16/10, apparent rodent nesting material was observed from box# 6, layer #1 of pallet #1. Apparent nest was found directly in mild chile pods approximately 2" by 6" deep into the boxed product. (b) (4)

F. Apparent rodent gnawings:

1. On 11/18/10, a gnawed hole approximately 4" by 3" in the side of a 25 lb. unlined cardboard box containing whole, dried chile pods. There was no label or identifying marks on this box located approximately at the midpoint of the south wall, 15 ft. north of the wall.
2. On 11/18/10, a gnawed hole approximately 3" wide on the side of a 25 lb. unlined cardboard box containing whole, dried chile pods. This box was located approximately at the midpoint of the south wall, 15 ft. north of the wall. There was no label or identifying marks on this box.
3. On 11/18/10, 6/8 ounce retail package bags of Duran's Chile whole dried mild pods contained apparent rodent gnaw marks. The bags were located in an open cardboard box, stacked on top of another box which was directly on the warehouse floor. This stack was located in the approximate middle of the warehouse. There was no lot number or code on the

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bags or the box they were held in.

4. On 11/17/10, a cardboard box with two apparent rodent gnaw holes located in the northeast corner of the warehouse was only labeled with the (b) (4) written in red marker.
5. On 11/17/10, a cardboard box with apparent rodent gnaws approximately 3" by 4" in diameter was located in the northeast corner of the warehouse. This box held 25 lb. of dried whole chile pods and there was no label or identifying marks on this box.

On 11/17/10, FDA Consumer Safety Officers conducted a box by box break down of four pallets containing combined lots of (b) (4) (mild whole chile pods) which were staged perpendicular to the west wall of the warehouse. Apparent gnawed holes were observed in the following areas:

- There was 1 apparent gnaw hole approximately 1 1/2" by 1/2" (near a corner edge), observed on box#5, layer# 4 of pallet#2, (b) (4)
- There was 1 apparent gnaw hole approximately 1 1/2" wide, observed on box#4, layer# 4 of pallet #4, (b) (4)

G. Rodent-like urine stains:

On 11/17/10, FDA Consumer Safety Officers conducted a box by box break down of four pallets containing combined lots of (b) (4) (mild whole chile pods) which were staged perpendicular to the west wall of the warehouse. Rodent-like urine stains were observed in the following area:

- 11/17/10, an approximate 4" by 2" rodent-like urine stain was observed on the corner of a label affixed to box# 4, layer#5 of pallet 1, (b) (4) On the opposite end of the box#4 contained rodent-like urine stain along the seam of the cardboard box approximately 10 inches long.

H. Rodent-like excreta pellets:

On 11/17/10:

1. Too numerous too count apparent rodent pellets were observed in the northwest area of the finished product warehouse, between 2 rows of palletized final product.

On 11/18/10:

2. Approximately 25 apparent rodent excreta pellets were observed on used broken down packaging located approximately 8 ft. from third structural beam on north wall of the warehouse.

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3. Approximately twelve apparent rodent excreta pellets were observed on the top of a box of packaged red chile powder. Box was contained on a pallet containing (b) (4) boxes, approximately 6 ft. from north wall. 4. Approximately 20 apparent rodent excreta pellets were observed on the cement floor in-between boxes of unlabeled package chile pods located approximately 15 ft. from the north wall and the 4th structural beam against north wall adjacent from the east wall. 5. Approximately 20 apparent rodent excreta pellets were observed on a pallet and on the floor beneath the pallet. The pallet was holding (b) (4) boxes of mild pods located approximately 5 pallets in length from the west wall of the warehouse. 6. Approximately 6 apparent rodent excreta pellets were observed on a pallet of used broken down packaging boxes on a pallet. This pallet of broken down packaging boxes was located approximately 10 ft. from west wall of the warehouse. 7. Approximately 10 apparent rodent excreta pellets were observed on a cardboard packaging material located on a pallet 2 ft. from the west wall of the warehouse. <u>I. Animal-like urine stains:</u> 1. Package containing whole (b) (4) contained apparent animal urine stains approximately 6"by 4", located between two small stacks of bulk totes, approximately 15 ft. from south wall of the warehouse <u>J. Animal-like feces:</u> On 11/16/10: 1. Four mounds, each approximately 4" in width, of apparent animal feces located on the floor in the southeastern corner of the warehouse, adjacent to unused equipment. On 11/17/10: 2. One mound of apparent animal feces located approximately 8 ft. from southeastern corner of the warehouse. 3. One mound of apparent animal feces located behind an approximate 4 ft. green turn top table approximately 2 ft. from the south wall. <u>K. Cockroach-like insects:</u> On 11/17/10: 1. Approximately six live cockroach-like insects were observed coming out of and from underneath the bottom box of a stack of boxes located near the north wall in the northwest portion of the		
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warehouse. The box was directly on the ground and had apparent rodent gnaw marks in two different locations.

On 11/18/10:

2. One dead cockroach-like insect was observed approximately 10 ft. from southeastern corner of the warehouse.

L. Live and dead worm-like insects, worm-like insect larvae, and moth-like insects:

On 11/16-17/10, FDA Consumer Safety Officers conducted a box by box break down of four pallets containing combined lots of (b)(4) (mild whole chile pods) which were staged perpendicular to the west wall of the warehouse. Live and dead worm-like insects, worm-like insect larvae, and moth-like insects were observed in the following areas:

1. There were five live worm-like insects observed inside product of the top portion of the box #6, layer #1 of pallet #1, (b)(4). Insect-like webbing was observed in-between a chile pod and it's broken off stem on the opposite end of box #6.

The following were observed on the outside of the boxes of each pallet:

Pallet #1: Contained (b)(4) /25lb boxes of (b)(4) (mild whole chile pods): Approximately 12 apparent moth-like insects.

- Approximately 71 apparent live and dead worm-like insects.
- Approximately 21 apparent spider-like insects.
- There was one apparent cocoon-like object.

Pallet #2: Contained (b)(4) /25 lb boxes of (b)(4) (mild whole chile pods):

- Approximately 17 apparent moth-like insects.
- Approximately 34 apparent live and dead worm-like insects.
- Approximately 8 apparent spider-like insects.

Pallet #3: Contained (b)(4) /25 lb boxes of (b)(4) (mild whole chile pods):

- Approximately 2 apparent moth-like insects.
- Approximately 6 apparent live and dead worm-like insects.
- Approximately 2 apparent spider-like insects.
- Approximately 13 apparent worm-like insect larvae.

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- Approximately 2 apparent insect castings.

Pallet #4: Contained (b) (4) /25 lb boxes of (b) (4) (mild whole chile pods):

- Approximately 3 apparent moth-like insects.
- Approximately 7 apparent live and dead worm-like insects.
- Approximately 4 apparent spider-like insects.
- One apparent worm-like insect larvae.

2. On 11/15-18/10, the following was observed in the processing warehouse which is part of the manufacturing building and across the street from the finished product warehouse.

A. On 11/18/10, a field exam was conducted on approximately (b) (4) cardboard containers containing various products including: ground red pepper, crushed red pepper, and chile seed. The (b) (4) cardboard containers were located in the northeastern corner of the whole chile pod cooling area.

1. Too numerous to count insect castings was found inside three cardboard containers containing chile seed.
2. Cob-webbing and spider-like insects were observed on approximately (b) (4) cardboard containers.
3. The interior of a cardboard container holding red chile powder contained seven apparent live worms and three apparent live moths. The container holding red chile was located west of a container containing chile seed. The cardboard container was covered with a lid, but the lid was not securely closed.

B. An unlabeled cardboard box from (b) (4) whole, dried, hot chile pods, was observed stored directly on the floor, the bottom right corner of the box had apparent rodent gnawings. Furthermore, too numerous to count apparent rodent pellets and a live cockroach were observed around the box.

OBSERVATION 2

Failure to maintain buildings in repair sufficient to prevent food from becoming adulterated.

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Specifically, the following gaps leading directly to the outside were observed in the finished product warehouse on 11/16-19/10:

1. Along the west wall there is an approximately 18 ft. long by 4 ft. high metal screen in the facility wall. This gap is covered with a metal screen, but is not fully closed to the outside
2. Inside the restroom that is located in the southwest corner of the warehouse there is an approximately 5 ft. long by 8" wide gap between the bottom of the wall and the floor.
3. In the southeast corner of the warehouse a pedestrian door was left open. When the door is closed, there is an approximately 1.5" tall by 36" wide gap between both the bottom of the door and the floor and the top of the door and the wall.
4. Adjacent to the pedestrian door is a hole that is approximately 2 ft. by 1 ft. that was cut out of the wall for a conveyor belt.
5. On the north wall there is an approximately 6" by 3" hole near a rain gutter.
6. Along the south wall there is an approximately 68" by 4" gap between the wall and the floor.

OBSERVATION 3

Failure to properly store equipment, remove litter and waste, and cut weeds or grass that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures.

Specifically,

On 11/16/10, around the perimeter of the processing building the following were observed:

1. Vegetation that could serve as pest harborage was observed along the full length of east exterior side of the processing building.
2. A torn trash bag containing various trash debris was observed approximately 2 ft. north of a detach building and approximately 20 ft. from the main dock door of the processing building.

On 11/15-18/10, the following were noted within the processing building:

3. All along the northeastern wall of the processing building there is an accumulation of packaging material, cardboard containers, unused equipment, large (b) (4) chile pods, and too numerous to count 25 lb. packages of whole dried chile pods. The items listed above were stored in a manner that may allow pest harborage.

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On 11/16/10, around the perimeter of the finished product storage warehouse the following were observed:

1. Vegetation that could serve as pest harborage was observed along the full length of both the north and west sides of the warehouse.
2. On the exterior of the south wall of the warehouse is an accumulation of unused equipment and debris that includes but is not limited to old machinery, hoses, boxes for packaging, litter, and storage equipment.
3. Unorganized equipment and debris stored along the exterior east wall in a manner that may allow pest harborage.

On 11/17/10, the following were noted within the finished product warehouse. The following list is not all inclusive because instances of places which may constitute an attractant, breeding place, or harborage area for pests were too common to note all of them:

4. In the northeastern corner of the warehouse there is an accumulation of boxes, pallets, old furniture, paper reels, and general debris. There are more than (b) (4) boxes with unidentified content spread throughout this corner of the warehouse.
5. Along the north wall there are old storage sacks, barrels, boxes, wood and old labels which are stored in a manner that may allow pest harborage. The materials were stored directly against the warehouse's exterior wall and there were rodent-like pellets observed on some of the boxes.
6. Along the west wall, underneath the 18 ft. screen, there is an accumulation of old equipment, boxes, barrels, burlap sacks and other materials. There is also a wooden crate approximately 3 ft. wide by 4 ft. long and 4 ft high that is filled with cardboard and other debris. Furthermore, there is a shredded tarp draping from the large screen. Rodent-like pellets were observed in the area.
7. On the floor of the ladies restroom on the southwest corner of the warehouse there was a pile of paper towels with apparent fecal material on them.
8. Just south of the center support I-beam, near the middle of the warehouse, there were (b) (4) organized in (b) (4) directly on the floor. The top two boxes were open and inside were retail package plastic bags of whole chile pods with apparent rodent gnaw marks on them.
9. On 11/16/10, in the south central portion of the warehouse there were boxes with rodent-like pellets, a pile of crushed up product and apparent feline feces found in the vicinity.

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OBSERVATION 4

The plant is not constructed in such a manner as to prevent drip and condensate from contaminating food, food-contact surfaces, and food-packaging materials.

Specifically, on 11/16-17/10, the following was observed in the processing building:

1. Water droplets were observed condensing on the ceiling directly above the grading conveyor which contained exposed whole chile pods. The dried chiles traveled on an uncovered conveyor to an employee grading area, through an enclosed steamer, before being packaged for distributions.
2. The condensed steam on the ceiling was observed to drip on to approximately 115 empty corrugated cardboard boxes used to hold the finished bulk chiles.
3. The condensed steam on the ceiling was observed to drip on the de-stemming table holding exposed dried whole chile pods.

OBSERVATION 5

Failure to maintain equipment, containers and utensils used to hold and store food in a manner that protects against contamination.

Specifically,

1. Approximately 115 empty corrugated cardboard boxes used to hold the finished bulk chiles were observed staged directly on the concrete floor of the processing building.
2. Finished bulk packages of dried chili pods were stored directly on the floor and against the wall of the processing building and the finished product warehouse. Additionally, damaged packages of bulk dried chili pods were observed throughout the warehouse.

OBSERVATION 6

The construction of equipment and utensils fails to preclude the adulteration of food with metal fragments.

Specifically, on 11/16/10, the end of the metal blade inside of the John Deere grinder, located south of the packaging tables in the processing building, was damaged with an approximate 1" chip. This grinder is used to make ground chile pepper.

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Elisa J. Beard, Investigator *EJB*
Jennifer R. Mather, Investigator
Zachary L. Stamm, Investigator
Tamara L. Setzer, Investigator
Matthew A. Linton, Investigator *MAL*

PURGED

DATE ISSUED

11/22/2010

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

6th & Kipling St. (P.O. Box 25087)
Denver, CO 80225-0087
(303) 236-3000 Fax: (303) 236-3100
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

11/15/2010 - 11/22/2010

FEI NUMBER

1640846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Carl M. Duran, President/Owner

FIRM NAME

Duran and Sons, LLC

STREET ADDRESS

13 Mi N On Highway 187
Po Box 291

CITY, STATE, ZIP CODE, COUNTRY

Derry, NM 87933-0291

TYPE ESTABLISHMENT INSPECTED

Food Manufacturer

OBSERVATION 7

The materials of equipment does not allow proper cleaning and maintenance.

Specifically, on 11/15-18/10,

1. A damaged piece of cardboard is duct taped to top portion of the fixed metal spreader leading the chiles to the first employee grading lines.
2. A piece of cardboard is duct taped to the receiving end of the conveyer which conveys the chiles to the two employee grading lines.

OBSERVATION 8

Failure to maintain toilet facilities in a sanitary condition.

Specifically, the west restroom of the finished product warehouse contained an open cardboard box full of soiled paper towels and soiled paper towels were surrounding the open cardboard. Furthermore the toilet bowl was observed to be unsanitary.

OBSERVATION 9

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility after each absence from the work station.

Specifically, on 11/16/10, three employees were observed washing their hands outside of the processing building using the water faucet adjacent to the north dock door. The water faucet was position approximately 1 ft. from the ground. Furthermore, the employees did not use hand washing soap.

OBSERVATION 10

Failure to provide safety-type lighting fixtures suspended over exposed food.

Specially, on 11/16/10 the following was observed in the processing building:

1. The light fixture above retail packaging sorting tables did not contain a protective covering. The retail sorting tables hold uncovered dried and steamed whole chile pods.
2. Two light fixtures which are directly above the two whole chile grading lines did not contain a protective covering.

SEE REVERSE
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- Each grading conveyor is used to convey in-process washed whole chile pods to the steamer.
- A light bulb directly above the conveyor which takes washed whole chile pods on wooden trays to the wooden tray stacker did not contain a protective covering.

OBSERVATION 11

Hand-washing facilities lack running water of a suitable temperature.

Specifically, on 11/15-18/10, the running water of the hand washing sinks in each of the employees restrooms located in the processing building did not achieve an appropriate temperature.

OBSERVATION 12

Employees were observed to be eating food in areas where food is exposed.

Specifically, on 11/16/10, an employee was observed eating candy while de-stemming dried whole chile pods. De-stemmed chiles are used for the grinding process.

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Tamara L. Setzer, Investigator
Matthew A. Johnson, Investigator

Elisa J. Beard

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