



March 12, 2018

Mr. Travis Cundiff, COO  
Pony Express Foods, LLC  
P.O. Box 189  
Blue Ball, PA 17506-0189

Dear Mr. Cundiff,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at 1016 E. Main Street, New Holland, PA 17557-9623 on January 18, 2018 through January 19, 2018 by the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 C.F.R. 20.64 (d) (3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of that effort. The copy being provided to you contains the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the FOIA and 21 C.F.R. Part 20. This, however, does not preclude you from requesting additional information available under FOIA.

If there is any question about the released information, feel free to contact:

Randy F. Pack  
U.S. Food and Drug Administration  
6000 Metro Drive, Suite 101  
Baltimore, Maryland 21215  
Telephone: (410) 779-5417

Sincerely,

Anthony M. Criscuolo Jr.  
Supervisory Consumer Safety Officer

CST: PDL

**Establishment Inspection Report**

Pony Express Foods LLC  
New Holland, PA 17557-9623

FEI: **3011223579**  
EI Start: 1/18/2018  
EI End: 1/19/2018

Location: 1016 E Main St  
New Holland, PA 17557-9623  
Phone: 717-354-4593  
FAX: 717-355-0131  
Mailing address: PO Box 189  
Blue Ball, PA 17506-0189  
Dates of inspection: 1/18/2018-1/19/2018  
Days in the facility: 2  
Participants: **Sean D Duke, Investigator**

**Non-FDA Participants:**

On 01/18/2018, I arrived at Pony Express Enterprises, LLC, located at 121 Jaylyn Dr., New Holland, PA 17557, presented my credentials and issued an FDA-482, Notice of Inspection, Pony Express Enterprises, LLC, (**Attachment 1**) to Ted D. Cundiff, Part Owner and President. It was at this point Mr. Cundiff explained, although Pony Express Foods, LLC and Pony Express Enterprises, LLC are owned by the same people and have the same corporate officers, it was Pony Express Foods, LLC that produced all animal feed and treats in which they deal.

I was able to collect History, Interstate and Jurisdiction information on their pet production from Ted D. Cundiff prior to relocating to his business, Pony Express Foods, LLC, located just a few miles away.

On 01/18/2018, I arrived at Pony Express Foods, LLC, located at 1016 E Main St, New Holland, PA 17557, presented my credentials and issued an FDA-482, Notice of Inspection, Pony Express Foods, LLC, (**Attachment 2**) to Ted D. Cundiff, Part Owner and President. Also present at this meeting was Travis Cundiff, COO, and Dwight Casey Martin, Plant manager at Pony Express Foods, LLC. Mr. Martin was most knowledgeable about the actual production of the pet treats the firm makes, while Travis Cundiff demonstrated to me to be the most responsible for the operations at the facility.

On 01/19/2018, a close-out discussion was conducted, at which Travis Cundiff and I were the only attendees. No FDA-483, Inspectional Observations, was issued, nor were any items related to pet food manufacturing safety deficiencies discussed. Items discussed, specific to FDA Consumer Complaint 150449 (**Attachment 3**), are addressed in the Complaints and Voluntary Corrections Section of this EIR.

**HISTORY**

(Ted Cundiff provided the information reflected in this portion of this EIR, unless otherwise noted.)

Pony Express Foods, LLC registered as a Limited Liability Corporation in PA in 2008. [REDACTED] annual sales in both human and animal food combined and has about 92 employees. Hours of operation are 6:00 am to 11:00 pm, Monday through Friday. The firm's FDA FFR registration was current at the time of the current inspection.

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**SUMMARY**

This directed inspection of a pet food/treat manufacturer was conducted in response to FACTS Consumer Complaint # 150449, in which a pet-owner alleges the death of her dog was directly caused by Earth Animal Ventures No-Hide Chicken Chews. Previous investigations related to this complaint revealed this product was contract manufactured by Pony Express Foods, LLC in New Holland, PA. Additionally, an FDA-3719, Report of Inspection for Compliance with 21 CFR 589.2000 & 589.2001 was completed. This EI was reported under MARCS OP ID 89219.

This facility is also a USDA regulated plant that produces human food in the form of beef and chicken jerky products.

The scope of this inspection focused on the production of Earth Animal Ventures No-Hide Chicken Chews, Pork Chews, Beef Chews, and Salmon Chews offered in four, seven and eleven inch varieties. I reviewed and/or collected invoices, letters of guarantee/warranty, production records, and labeling of both finished products and raw ingredients. No FDA-483, Inspectional Observations, was issued, nor was any item related to pet food manufacturing safety deficiencies discussed. Items discussed related to FACTS Consumer Complaint # 150449 are addressed in the Complaints and Voluntary Corrections section of this EIR.

I directed the firm to [www.FDA.gov](http://www.FDA.gov) regarding regulatory/compliance information with respect to their industry.

No Samples were collected, no refusals were encountered and no evidence of pest activity was observed.

**ADMINISTRATIVE DATA**

Inspected firm: Pony Express Foods LLC

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According to those interviewed, the firm has had no other complaints and no recalls, but do have procedures for both.

Travis Cundiff stated Pony Express Foods, LLC has an on-sight USDA/FSIS inspector that oversees the production of the human food meat products the firm produces. She was not available for interview during the current inspection.

Post inspectional correspondence should be directed to:

Travis Cundiff, COO  
Pony Express Foods, LLC  
PO Box 189  
Blue Ball, PA 17506-0189

**INTERSTATE (I.S.) COMMERCE**

(Ted Cundiff provided the information and documents reflected in this portion of this EIR, unless otherwise noted.)

Pony Express Foods, LLC gets about 50% of their human and animal food ingredients from sources outside the state of PA and introduces about 90% of their products into interstate commerce. Ted Cundiff stated the company's distribution area is nationwide and includes international distribution to Canada.

Commercial Invoice International Air Waybill [REDACTED] with Accompanying Labeling (**Exhibit 3**) shows shipment of Chicken Gelatin, which is used in the production of Earth Animal Ventures No-Hide Chicken Chews by Pony Express, from [REDACTED] to Pony Express Foods, LLC.

**JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)**

(Ted Cundiff provided the information reflected in this portion of this EIR, unless otherwise noted.)

Pony Express contract manufactures pet treats for Earth Animal Ventures located in Southport, CT.

I was provided me with a copy of Pony Express Foods LLC Item Listing List (**Exhibit 1**) and Earth Animal No-Hide Chicken Chews Label (**Exhibit 2**).

**MANUFACTURING/DESIGN OPERATIONS**

The following description of Earth Animal Ventures No-Hide Chicken Chews was described to me by Pony Express Foods, LLC Plant Manager, Dwight Martin.

**Step 1: Mixing of No-Hide Ingredients**

1. Brown Rice Flour
2. Chicken Gelatin
3. Egg Whites

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4. Olive Oil
5. [REDACTED] Enzyme Blend [REDACTED]
6. Water (Municipal)

The above listed ingredients are mixed in an industrial size bakery-style mixer until desired batter consistency and uniformity is reached. [REDACTED] of the actual production date. All ingredients are listed on Pony Express Ingredient Traceability (Chicken No-Hide) (Exhibit 7). This document lists all ingredients used in the process and identifying information for traceability.

I observed the Chicken Gelatin referenced above stored [REDACTED]

I observed the [REDACTED] referenced above in a paper/poly bulk bag with the following labeling: "Enzyme Blend 35# 17201211". Travis Cundiff provided me with [REDACTED] Purchase Order # 1129 (Exhibit 4), which documents purchase [REDACTED] Enzyme Blend [REDACTED] lot 17201211 [REDACTED]

**Step 2: Extrusion**

Batter is placed in a [REDACTED] extruder and extruded [REDACTED] into a continuous 11 inch wide sheet. The dye used to form the sheet was one-of-a-kind piece created by a third party metal fabricator. The continuous sheet is cut into five inch sections as it leaves the dye.

**Step 3: Sheeting**

The [REDACTED] sheets of batter are put through a sheeter that presses them into [REDACTED] pieces.

**Hand-Rolling**

Each of the sheets then is rolled into [REDACTED] cylinders and placed on cooking racks prior to entering the ovens.

**Initial Heat Treatment**

Racks of the raw treats are placed into ovens and cooked [REDACTED] for about [REDACTED]

**Cutting**

Each of the treats is removed from the ovens and the racks to be cut to desired length: 4", 7", or 11" varieties.

**Protein Application**

Previously thawed boneless and skinless raw Chicken is ground to desired granulation and applied to the exterior and exposed interior spaces of the treats.

Dwight Martin provided me a copy of [REDACTED] Chicken Tender Pieces Label (Exhibit 6), lot 5703, which he states was used in the production of Earth Animal Ventures No-Hide Chicken Chews. He also provided me with [REDACTED] Invoice 3216542 (Exhibit 5), which Mr. Martin stated reflects the chicken listed above listed under Item No.: 1205703, and Description: White Label Chicken Tender Trim 5703 FZN.



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Chews are in fact a rawhide substitute, rather than actual rawhide, as stated by the complainant in the above referenced FDA Consumer Complaint.

**VOLUNTARY CORRECTIONS**

In an effort to improve future labeling on the Earth Animal Ventures No-Hide pet treats the plant produces, Ted Cundiff explained to me Pony Express Foods, LLC plans to:

1. Remove the statement "Manufactured in our USDA Inspected Human Food Facility" from future labeling.
2. Include statements on future packaging to reflect the size of dog that each size of Earth Animal Ventures No-Hide pet treats is intended. Examples, as explained by management, are listed below:
  - Four inch variety for small dogs
  - Seven inch variety for medium size dogs
  - Eleven inch variety for large dogs

**EXHIBITS COLLECTED**

- 1 Pony Express Foods LLC Item Listing, 1 page
- 2 Earth Animal No-Hide Chicken Chews Label, 2 pages
- 3 Commercial Invoice International [REDACTED] with Accompanying Labeling, 3 pages
- 4 [REDACTED] s Purchase Order # 1129, 1 page
- 5 [REDACTED] Invoice 3216542, 1 page
- 6 [REDACTED] Farms Chicken Tender Pieces Label, 1 page
- 7 Pony Express Ingredient Traceability (Chicken No-Hide), 2 pages
- 8 Pony Express Foods LLC Production Record for Earth Animal Ventures No-Hide Chicken Chews, 1 page
- 9 Luna Science and Nutrition Examination of Rawhide vs. No-Hide Chews, 2 pages
- 10 Earth Animal No-Hide Pork Chews Label, 2 pages
- 11 Earth Animal No-Hide Beef Chews Label, 2 pages
- 12 Earth Animal No-Hide Salmon Chews Label, 2 pages

**ATTACHMENTS**

- FDA-482, Notice of Inspection, Pony Express Enterprises, LLC, 1 page
- FDA-482, Notice of Inspection, Pony Express Foods, LLC, 1 page
- 3 FDA Consumer Complaint 150449, 4 pages
- 4 BSE Checklist, 8 pages

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X Sean D Duke  
Investigator  
Signed By: 2001264221  
Date Signed: 01-29-2018 10:34:27

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