



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. The firm does approximately \$5 million in gross 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.

**Establishment Inspection Report**  
Pony Express Foods LLC  
New Holland, PA 17557-9623

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

---

TABLE OF CONTENTS

Summary .....	1
Administrative Data .....	1
History .....	2
Interstate (I.S.) Commerce .....	3
Jurisdiction (Products Manufactured and/or Distributed).....	3
Manufacturing/Design Operations.....	3
Manufacturing Codes.....	5
Complaints .....	5
Voluntary Corrections.....	6
Exhibits Collected.....	6
Attachments .....	6

**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

**Establishment Inspection Report**

Pony Express Foods LLC  
New Holland, PA 17557-9623

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

---

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 Number 412970595915 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 Shanghai China 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**



**Establishment Inspection Report**  
Pony Express Foods LLC  
New Holland, PA 17557-9623

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

[REDACTED]

[REDACTED]

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 in a paper/poly bulk bag with no apparent labeling on it, other than "32638 55853", which was hand written in black marker.

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

**Step 2:**

[REDACTED]

**Step 3: Sheeting**

[REDACTED]

**Initial Heat Treatment**

[REDACTED]

**Cutting**

[REDACTED]

[REDACTED]

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

**Establishment Inspection Report**  
Pony Express Foods LLC  
New Holland, PA 17557-9623

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

Travis Cundiff provided me with a copy of Pony Express Foods LLC Production Record for Earth Animal Ventures No-Hide Chicken Chews (**Exhibit 8**), which Dwight Martin stated shows the production of Earth Animal Ventures No-Hide Chicken Chews, 7", in row number 4 of the record. This record documents the time and temperature of the cook step and shows the firm reached the desired a<sub>w</sub>

#### **Packaging and Distribution**

Finished No-Hide Chews are place into packaging by and readied for wholesale distribution. Ted Cundiff stated customers typically set up their own contract shipping of the pet treats.

Mr. Martin and Travis Cundiff stated the process is identical for each of the other varieties of Earth Animal Ventures No-Hide Chews, such as Pork, Beef, Salmon. The only difference would be the gelatin and the proteins used would be specific to the labels, which were provided by management.

- No-Hide Pork Chews use [REDACTED] Earth Animal No-Hide Pork Chews Label (**Exhibit 10**)
- No-Hide Beef Chews use [REDACTED] Earth Animal No-Hide Beef Chews Label (**Exhibit 11**).
- No-Hide Salmon Chews use [REDACTED] Earth Animal No-Hide Salmon Chews Label (**Exhibit 12**).

#### **MANUFACTURING CODES**

Travis Cundiff stated the codes Pony Express, LCC applied to all the Earth Animal Ventures No-Hide Chew packages was a MM/DD/YYYY date code and reflects a two year shelf-life from the production date.

#### **COMPLAINTS**

FDA Consumer Complaint 150449 (**Attachment 3**), in which a consumer makes a complaint regarding the death of her dog, which she believes is directly caused by Earth Animal Ventures No-Hide Chicken Chew she had purchased and provided to her large dog.

The defense provided by Travis Cundiff and Dwight Martin was that the pet owner lodging the complaint referenced above, apparently, provided her dog the four inch variety of the No-Hide Chews, which the company insists are intended for small dogs, although not explicitly stated on packaging.

Commercial Invoice International Air Waybill Number 412970595915 with Accompanying Labeling (**Exhibit 3**) reads in part: "Gelatin is extracted from chicken skin". I brought this to the attention of owner Ted D. Cundiff. He then stated, although this gelatin is derived from chicken skin and contains collagen, it was his understanding that this does not constitute hide, in the technical sense. Therefore, the chews his company produces are free of animal hide.

Furthermore, Travis Cundiff provided me a copy of Luna Science and Nutrition Examination of Rawhide vs. No-Hide Chews, 12-13-2018 (**Exhibit 9**), which he stated shows that the Earth Animal Ventures No-Hide

**Establishment Inspection Report**  
Pony Express Foods LLC  
New Holland, PA 17557-9623

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

---

#### **Second Heat Treatment**

Treats are placed back on racks and back into the ovens at >165° F until .78 a<sub>w</sub> of the treats is met.

Travis Cundiff provided me with a copy of Pony Express Foods LLC Production Record for Earth Animal Ventures No-Hide Chicken Chews (**Exhibit 8**), which Dwight Martin stated shows the production of Earth Animal Ventures No-Hide Chicken Chews, 7", in row number 4 of the record. This record documents the time and temperature of the cook step and shows the firm reached the desired a<sub>w</sub>.

#### **Packaging and Distribution**

Finished No-Hide Chews are placed into packaging by and readied for wholesale distribution. Ted Cundiff stated customers typically set up their own contract shipping of the pet treats.

Mr. Martin and Travis Cundiff stated the process is identical for each of the other varieties of Earth Animal Ventures No-Hide Chews, such as Pork, Beef, Salmon. The only difference would be the gelatin and the proteins used would be specific to the labels, which were provided by management.

- No-Hide Pork Chews use [REDACTED] Earth Animal No-Hide Pork Chews Label (**Exhibit 10**)
- No-Hide Beef Chews use [REDACTED] Earth Animal No-Hide Beef Chews Label (**Exhibit 11**).
- No-Hide Salmon Chews use [REDACTED] Earth Animal No-Hide Salmon Chews Label (**Exhibit 12**).

#### **MANUFACTURING CODES**

Travis Cundiff stated the codes Pony Express, LLC applied to all the Earth Animal Ventures No-Hide Chew packages was a MM/DD/YYYY date code and reflects a two year shelf-life from the production date.

#### **COMPLAINTS**

FDA Consumer Complaint 150449 (**Attachment 3**), in which a consumer makes a complaint regarding the death of her dog, which she believes is directly caused by Earth Animal Ventures No-Hide Chicken Chew she had purchased and provided to her large dog.

The defense provided by Travis Cundiff and Dwight Martin was that the pet owner lodging the complaint referenced above, apparently, provided her dog the four inch variety of the No-Hide Chews, which the company insists are intended for small dogs, although not explicitly stated on packaging.

Commercial Invoice International Air Waybill Number 412970595915 with Accompanying Labeling (**Exhibit 3**) reads in part: "Gelatin is extracted from chicken skin". I brought this to the attention of owner Ted D. Cundiff. He then stated, although this gelatin is derived from chicken skin and contains collagen, it was his understanding that this does not constitute hide, in the technical sense. Therefore, the chews his company produces are free of animal hide.

Furthermore, Travis Cundiff provided me a copy of Luna Science and Nutrition Examination of Rawhide vs. No-Hide Chews, 12-13-2018 (**Exhibit 9**), which he stated shows that the Earth Animal Ventures No-Hide

**Establishment Inspection Report**

Pony Express Foods LLC  
New Holland, PA 17557-9623

FBI: 3011223579  
EI Start: 1/18/2018  
EI End: 1/19/2018

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 Air Waybill Number 412970595915 with Accompanying Labeling, 3 pages
- 4 [REDACTED] Purchase Order # 1129, 1 page
- 5 [REDACTED] Inc Invoice 3216542, 1 page
- 6 [REDACTED] 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

**Establishment Inspection Report**  
Pony Express Foods LLC  
New Holland, PA 17557-9623

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

---

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

---