

TABLE OF CONTENTS

SUMMARY.....	1
ADMINISTRATIVE DATA.....	2
HISTORY.....	4
INTERSTATE COMMERCE.....	5
JURISDICTION.....	5
INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED.....	8
FIRM'S TRAINING PROGRAM.....	9
MANUFACTURING/DESIGN OPERATIONS.....	9
MANUFACTURING CODES.....	30
COMPLAINTS.....	31
RECALL PROCEDURES.....	31
OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE.....	31
REFUSALS.....	32
GENERAL DISCUSSION WITH MANAGEMENT.....	32
ADDITIONAL INFORMATION.....	33
SAMPLES COLLECTED.....	33
VOLUNTARY CORRECTIONS.....	33
EXHIBITS COLLECTED.....	33
ATTACHMENTS.....	34

**SUMMARY**

The inspection of this pet treat manufacturer was conducted in accordance with DFFI FACTS assignment #1395243, OP ID #6054300 as follow-up to complaints received by FDA's Center for Veterinary Medicine (CVM) relating to sick and dying dogs following the consumption of imported chicken jerky treats (CJT). The issue of illness in dogs following the consumption of jerky treats first came to the attention of CVM in 2007. Illnesses in dogs continued being reported to CVM in the following years. A variety of tests were performed on the jerky treats without a determination made of the causative agent. Following a notice which was put out by the Canadian Veterinary Medical Association relating to jerky treats imported from China, CVM issued a CVM Update in November 2011 which led to the receipt of a significant number of consumer complaints reporting severe GI signs, hepatic disease, renal disease and Fanconi like syndrome in dogs associated with the consumption of CJT. As of March 1, 2012, CVM had received over 1,000 complaints relating to the consumption of imported chicken, duck or sweet potato jerky treats. FDA determined that inspections were warranted for Chinese firms that manufactured jerky treat products and which were identified as having received the bulk of these complaints.

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

FDA identified five firms for inspection in a letter dated 3-13-12 to the Department of Supervision on Animal and Plant Quarantine, General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ). Shandong Honva Food Co., Ltd was one of the five firms recommended for inspection. FDA also questioned whether AQSIQ would be interested in observing these inspections. Representatives of AQSIQ and the Chinese Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China (CIQ) observed these inspections. This inspection was pre-announced.

This inspection found the firm is a manufacturer of plain chicken jerky as well as other meat jerky pet treats. The firm also manufactures a variety of chicken wrapped products, formulated-shaped jerky treats and meat-free seasoned chip pet treats. Firm management estimated that over (b) (4) of their products are exported to the United States for customers such as (b) (4) (4) (b) (4). The firm also sells a small amount of jerky treats domestically.

An evaluation was made of the firm's manufacturing operations including ingredients and raw materials (meats) used, equipment used, the heat treating of products, packaging, quality control, sanitation and product testing. Photographs were taken to document the various steps which are used to manufacture the jerky products. Records were also reviewed relating to manufacturing, quality control, shipping and ingredient and product testing among others.

No FDA-483 was issued although one GMP deficiency was discussed with the firm management. A torn door gasket was observed on mixer #1. This gasket was replaced by the conclusion of the inspection.

It was AQSIQ's position during the previous CJT inspections that FDA would not be allowed to collect samples unless certain sampling conditions were agreed to by FDA. These conditions included having the samples analyzed in a Chinese laboratory although FDA representatives could observe the analysis. A Shandong CIQ representative who observed this inspection and was representing AQSIQ when the AQSIQ representative was absent on one day of the inspection also confirmed that samples could not be collected during the inspection unless certain sampling conditions were agreed to by FDA. Meetings between FDA and AQSIQ were held with additional meetings scheduled to be held in an attempt to resolve this issue. No samples were collected during the inspection.

The firm was manufacturing plain chicken jerky during the inspection.

#### ADMINISTRATIVE DATA

Inspected firm: Shandong Honva Food Co. Ltd.

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

Location: No.2 North Yanshan Rd.  
Liaocheng Economic Development Zone  
Liaocheng,  
China

Phone: 086-6358513326  
FAX: 086-6358516186

Mailing address: No.2 North Yanshan Rd.  
Liaocheng Economic Development Zone  
Liaocheng,  
China

Dates of inspection: 4/16/2012, 4/17/2012, 4/18/2012  
Days in the facility: 3  
Participants: Dennis L. Douppnik, Investigator  
Clotia Abbey-Mensah, Investigator  
Evid Liu, Medical Research Scientist

In a letter to AQSIQ dated 3-13-12, FDA's Beijing office identified five firms including Shandong Honva Food Co, Ltd (Shandong Honva) which were to be inspected as follow-up to the CJT issue. A copy of this letter is identified as Attachment #1.

AQSIQ was requested to inform FDA whether they wished to observe these inspections. Meetings between FDA and AQSIQ were subsequently held to determine the order for the inspections of these firms and when they would begin. FDA agreed that representatives from AQSIQ and CIQ would observe these inspections. This inspection was pre-announced. This was the initial FDA inspection of this firm.

On arrival at the firm on 4-16-12, my credentials were shown to Mr. Mingcun Bai, general manager. Mr. Bai stated that he is the most responsible individual at the firm on a daily basis. FDA investigator, Clotia Abbey-Mensah, joined the inspection team on 4-17-12. Investigator Abbey-Mensah presented her credentials to Mr. Bai on 4-17-12.

On hand as the AQSIQ representative was Dr. Shulong Dou, Deputy Director Biospecies Supervision Division for AQSIQ. Also on hand were representatives from the Shandong CIQ and the local Liaocheng CIQ.

No FDA-483 was issued at the conclusion of the inspection.

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

This EIR was written by me, Dennis L. Douppnik.

## HISTORY

Shandong Honva Food Co., Ltd was established as a new firm in October 2008. The owners of Shandong Honva are:

Mr. Jinqun Liu – (62.5% ownership)  
Shandong Ruifulong (Shandong Evergreen) Industrial & Trading Co., Ltd, Jinan, Shandong Province (Ms. Yalin Zhang – Primary Owner) (37.5% ownership)

According to Mr. Bai, (b) (4) Shandong Honva only and do not take an active role in the firm's day to day operations. Mr. Bai stated that Mr. Jinqun Liu resides and has his office in Liaocheng, Shandong Province, PRC. Mr. Bai stated that Mr. Liu visits the firm once or twice each year during the annual board meeting.

Mr. Bai stated that (b) (4) (b) (4) that receives product from Shandong Honva. A check of FDA's FACTS MARCS Firm found (b) (4) is registered with FDA under the Bioterrorism Act of 2002,

Mr. Bai stated that (b) (4) do not have ownership in any other firms which export products to the U.S. Mr. Bai stated that he has no ownership in Shandong Honva.

Mr. Bai is the most responsible individual at the firm on a daily basis. All correspondence should be addressed to Mr. Bai at the firm's physical address. Any correspondence with the firm's owners, Mr. Liu and Ms. Zhang should also be addressed to them at the physical address of Shandong Honva.

According to Mr. Bai, Shandong Honva manufactures jerky pet treat products on the receipt of customer order so processing during some months may be busier than others. However, the firm generally manufactures year around, seven days per week using three shifts. The firm's three production shifts are:

- 8:00AM to 4:00PM (break at 11:00AM – 12:00PM)
- 4:00PM to 12:00AM (winter break at 5:00PM – 6:00PM, summer break at 6:00PM – 7:00PM)
- 12:00AM to 8:00AM (no specified breaks)

The firm employs (b) (4) persons. Some employees live in off-campus dormitories.

The firm's gross dollar volume of business to the U.S. was approximately (b) (4) during 2011.

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

The firm is registered with FDA in accordance with the Bioterrorism Act of 2002.

The firm holds a business license to operate from the Liaocheng Municipality Industry and Commerce Administration. A copy of the firm's business license with translation is identified as Exhibit #1/1a.

The firm has been issued an export registration certificate from the Shandong CIQ. A copy of this registration with translation is identified as Exhibit #2/2a.

Identified as Exhibit #3/3a is a copy of a presentation with translation which was made by the firm at the start of the inspection. This presentation provides an overview of the firm's operations.

### INTERSTATE COMMERCE

According to Mr. Bai, the firm exported more than (b) of the firm's products to the U.S. with the remaining product sold domestically in 2012. Mr. Bai stated that approximately (b) of the firm's products were exported to South Korea until these sales were discontinued at the end of 2011.

Mr. Bai stated the firm exported (b) (4) of jerky products to the U.S. during 2011. Mr. Bai estimated that the firm has increased exports to the U.S. by each year.

The firm exports their products to the U.S. through several shippers/brokers. Identified as Exhibit #4/4a is a list of the shippers/brokers used by the firm to export products to U.S. customers.

According to this record, (b) (4)  
(b) (4)

### JURISDICTION

According to Mr. Bai, Shandong Honva manufactures the following types of jerky treat products:

- Plain jerky meat treats
  1. Chicken (b) (4)
  2. Pork
  3. Duck
  4. Lamb
  5. Beef liver
  6. Fish (only in production approximately 3 months)
    - Salmon pieces
    - Minced tilapia
- Wrapped products (chicken wrapped products only)

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

1. Sweet potato
  2. Apple
  3. Banana
- Formulated shaped jerky treats
  - Seasoned chips (meat free)

Mr. Bai stated the firm manufactures no rawhide chew products.

Mr. Bai stated the firm manufactures jerky treat products for the following customers by volume of business, brand and type of jerky treat products:

(b) (4)



According to Mr. Bai, the firm began manufacturing jerky treat products to the following U.S. customers as follows:

(b) (4)



**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

(b) (4)

A large black rectangular redaction box covers the majority of the page content below the header.

The firm does not export any jerky treat products to the U.S. under their own brands. Mr. Bai stated that the U.S. customers are responsible for all information on product labels.

Identified as Exhibit #5/5a is a listing of all jerky treat products manufactured by the firm for U.S. customers by brand package size and ingredients used with translation. Product labels collected during the inspection are as follows:

(b) (4)

A very large black rectangular redaction box covers the entire lower half of the page, obscuring all text and graphics that would follow the 'as follows:' statement.

(b) (4)



#### **INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

According to Mr. Mingcun Bai, general manager, the owners of Shandong Honva are:

Mr. Jinqun Liu – (62.5% ownership)

Shandong Ruifulong (Shandong Evergreen) Industrial & Trading Co, Ltd, Jinan,  
Shandong Province (Ms. Yalin Zhang – Primary Owner) (37.5% ownership)

According to Mr. Bai, (b) (4) only and do not take an active role in the firm's day to day operations. Mr. Bai stated that Mr. Jinqun Liu resides and has his office in Liaocheng, Shandong Province, PRC. Mr. Bai stated that Mr. Liu visits the firm once or twice each year during the annual board meeting. Mr. Bai stated that (b) (4) acts as a shipper/broker for several customers who receive product from Shandong Honva. Any correspondence with Mr. Jinqun Liu or Shandong Evergreen (Ms. Yalin Zhang – primary owner) should be addressed to the physical address of Shandong Honva.

Mr. Mingcun Bai stated that he is the most responsible individual at Shandong Honva on a daily basis. Mr. Bai stated that all department managers at the firm report directly to him. A copy of an organizational chart for the firm with translation is identified as Exhibit #39/39a. This organizational



**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

chart identifies Mr. Bai as the most responsible individual at the firm. Identified as Exhibit #40/40a is a document prepared by the firm which provides information on the responsibilities and duties of the various department managers for the firm with translation.

An opening meeting was held with Mr. Mingcun Bai, his staff and representatives from AQSIQ and CIQ. A sign-in sheet identifying the persons who were present at the start of this meeting with translation is identified as Exhibit #41/41a. Identified as Exhibit #42 is a business card which was received from Mr. Bai. Also included with Exhibit #42 are copies of business cards which were received during previous inspections from the AQSIQ and CIQ officials who were present.

A closing meeting was held with Mr. Bai, his staff and representatives from AQSIQ and CIQ at the conclusion of the inspection. A sign-in sheet identifying the persons who were present at the closing meeting with translation is identified as Exhibit #43/43a.

Information for this report was provided by Mr. Bai; Mr. Fadian Xu, QC manager, and other managers and staff for the firm. We were accompanied during the inspection by Mr. Bai; Mr. Fadian Xu, QC manager; other members of the firm's staff; Dr. Dou, AQSIQ representative; Dr. Congping Huang, Shandong CIQ; Dr. Ting Yu, Shandong CIQ; and other representatives from the Liaocheng CIQ.

#### **FIRM'S TRAINING PROGRAM**

While the firm provided some information on GMP and HACCP training for managers and employees during a presentation at the start of the inspection, the firm's training program was not evaluated or further discussed during the inspection.

#### **MANUFACTURING/DESIGN OPERATIONS**

**(NOTE TO FOI OFFICER: FIRM CONSIDERS ALL MANUFACTURING OPERATIONS TO BE CONFIDENTIAL AND A TRADE SECRET AND NOT TO BE RELEASED.)**

The Shandong Honva facility is located on a campus which is (b) (4) in size. All jerky is processed in one workshop which is located on this campus. The size of the workshop is approximately (b) (4). The firm has an on-site freezer for the storage of meat. Identified as Exhibit #44 are photos which were taken to document manufacturing operations at the firm.

According to Mr. Xu, QC manager, the (b) (4) has a representative on site to oversee production operations whenever the firm is manufacturing jerky which is intended to be exported to the U.S. This individual is also responsible for collecting samples which are then submitted to a third party laboratory for testing.

We requested to meet with this individual during the inspection. According to Mr. Xu, this individual was asked to not come to the firm during the inspection. We questioned whether the firm or AQSIQ requested that this individual not be at the firm. Mr. Xu stated that the firm had requested that he not be present. It should be noted that the AQSIQ and CIQ representatives were present when this question was asked.

The firm was manufacturing plain chicken jerky under the (b) (4) brand during the inspection.

HACCP Program:

The firm has a written HACCP program for the production and packaging of jerky treat products. According to Mr. Bai, the firm developed their own HACCP plan.

The firm has identified three critical control points (CCPs) in their HACCP plan. These are:

CCP 1: The inspection of incoming raw materials (meat products) received from suppliers. Each shipment of raw materials is checked for temperature to ensure the product is received frozen. The firm verifies that each shipment includes the supplier's animal health certificate.

CCP 2: Drying of the jerky.

CCP 3: Metal detection for the jerky prior to packaging

Ingredient Suppliers:

Meat Suppliers:

According to Mr. Bai, the firm purchases raw meat from a large number of suppliers. These suppliers are primarily located in Shandong Province and neighboring provinces. Identified as Exhibit #45/45a is a list of the firm's suppliers of meat from 2009 to date with translation.

Mr. Bai estimated that the closest suppliers are located approximately one hour from the firm. The farthest suppliers are located approximately (b) (4) from the firm. Mr. Bai stated that all meat is delivered frozen using the supplier's trucks or third party logistics trucks. Mr. Bai stated that only refrigerated trucks deliver frozen meat to the firm although he did not know if the refrigeration was on at the time the meat was delivered.

Auxiliary Ingredients:

The firm uses a large quantity of auxiliary ingredients in the manufacture of the jerky treat products. The firm purchases the base material for chicken wraps (i.e. biscuits, sweet potato, etc) from outside suppliers. Identified as Exhibit #46/46a is a list of the firm's auxiliary ingredient suppliers which have been used since April 2010 with translation.

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

Mr. Bai stated that the firm is responsible for selecting the auxiliary ingredient suppliers. Mr. Bai also stated that some customers audit some of the selected suppliers.

Mr. Bai stated that the firm adds glycerin as a softening agent to a number of products although a number of the firm's jerky products contain no glycerin. The firm uses (b) (4) in the manufacture of the jerky treats. According to Mr. Bai, the firm has only used (b) (4) in the manufacture of jerky treats since the firm began exporting products to the U.S. in 2009.

The firm had an uncounted number of (b) (4) in the ingredient warehouse during this inspection. Identified as Exhibit #44, Photo #1 is a picture of the drums of glycerin which were observed in the firm's ingredient warehouse during the inspection.

The firm documents the testing of glycerin shipments received on an Auxiliary Material Inspection Record. Identified as Exhibit #47 is an example of this record along with the glycerin certificate of analysis (COA) for the shipment of (b) (4) which was on hand during our inspection. According to this record, the firm received a total of (b) (4) of this lot of glycerin on 3-20-12.

A review was made of the firm's Auxiliary Material Inspection Records for glycerin from 2010 to date. It was observed that the firm had only received (b) (4) during this time period although the corresponding glycerin Certificate of Analysis (COA) for these shipments identified the glycerin as (b) (4). Each COA identified the glycerin was USP and FCC grade. A comparison of the COA's for (b) (4) (Exhibit #47) and (b) (4) (Exhibit #48) found the specifications were the same and all tests performed were essentially the same.

The firm documents the receipt and usage of glycerin using a Material Warehouse Tracking Card. A review was made of the firm's glycerin receiving and usage records from 2010 to date. These records were compared against Chinese customs taxation forms (fapiao) for 2010, 2011 and 2012. The firm's glycerin receiving and usage records were also compared against random production records for selected weeks in 2010 through 2012.

A review of the firm's glycerin receiving records noted shipments of glycerin were generally received every month or several times per month; however, several large time gaps were found for the purchase of glycerin. For example, the firm's receiving records showed no glycerin receipts between 7-6-10 and 1-2-11 (5 months), between 2-23-11 and 5-11-11 (3 months) and 6-28-11 and 10-24-11 (4 months). The concern was whether we were being shown all of the receiving records for glycerin purchases and whether other brands of glycerin may have been purchased during these time periods. We asked Mr. Bai to explain the time gaps when glycerin was not purchased for extended period of time.

Mr. Bai gave two explanations. These were:

- The firm was aware that glycerin prices would go up and the firm purchased additional drums of glycerin to have on hand when prices went up or were expected to go up.
- (b) (4) informed the firm that a new jerky treat product was planned for production which used significantly more glycerin in the formula than the plain jerky product. Mr. Bai stated that the firm anticipated the manufacture of this product by stockpiling glycerin in advance.

(Note: a telephone conversation was held with Mr. John Chapple, manager Asia QA/technical support China chief representative for the (b) (4) after the inspection. Mr. Chapple confirmed that (b) (4) had initially planned that Shandong Honva would manufacture a new product called (b) (4) during the summer of 2011 which called for a significant amount of glycerin in the formula. Due to delays, this product was not produced by Shandong Honva until December 2011. Mr. Chapple acknowledged that the firm may have stockpiled glycerin in anticipation of this product rollout.)

As best determined, the firm has only used (b) (4) during at least the past several years as Mr. Bai stated. Glycerin usage also appeared to approximate the quantities observed during this inspection.

The firm uses city of Liaocheng water in the manufacture of jerky products. Water is added to the glycerin with the meat during the mixing/tumbling operation.

An examination of the firm's auxiliary ingredient warehouse found the following ingredients on hand:

(b) (4)




**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

(b) (4)



(b) (4)

A large black rectangular redaction box covers the majority of the page content below the header.

Product Formulation:

The inspection found Shandong Honva manufactures a large number of jerky treat products using a number of different ingredients. Depending on the customer, some of the jerky treat products are formulated with the addition of glycerin and other products contain no glycerin. A summary of the different jerky products manufactured and glycerin usage in these products is as follows:

(b) (4)

A large black rectangular redaction box covers the entire lower half of the page, obscuring all text and graphics that would follow the 'Product Formulation' section.

(b) (4)



Mr. Bai stated that in some cases, the jerky formulations have been developed by the firm and in some cases by the customer. Mr. Bai stated that in either case both parties must review the formulas before the firm manufactures the products.

**Processing of Chicken Jerky:**

The firm was processing (b) (4) brand chicken jerky during the inspection. Photographs were taken to document the firm's chicken jerky manufacturing operations. These photographs are identified as Exhibit #44.

**Raw Material (Meat) Receiving:**

Ingredient receiving is CCP1 of the firm's HACCP program. Mr. Xu stated that when an order to manufacture jerky is received from a customer, the firm places an order for the meat with a supplier. Mr. Xu stated that meat shipments are generally received at the firm between 8:00AM and 6:00PM.

According to Mr. Xu, all meat is received frozen. Chicken is generally received in 10 kg bags, 12 kg cartons and 20 kg bags. Lamb is generally received in 20 kg bags. Salmon and tilapia are generally

---

received in 20 kg cartons. The firm identifies pallets of products using a Material Warehouse Tracking Card which contains the following information:

- Date received
- Name of supplier
- Name of material
- Amount received
- Supplier's lot #
- Firm's lot #
- Amount used
- Amount remaining

The firm verifies the supplier's certificates and the temperature of the meat at the time of receipt. Mr. Xu stated that the internal temperature of the meat is checked by randomly sampling three to five cases from each lot received. The temperature of the meat is required to be below -12°C (10.4°F) at the time of receipt. Mr. Xu stated that the firm has never had to reject a shipment of meat due to meat temperatures above -12°C.

The firm uses two on-site freezers for the storage of meat. The firm's freezers are maintained at a minimum temperature of (b) (4). Temperatures in the freezers are documented every four hours.

The freezer designated as the "North Warehouse" was stated to have a capacity of (b) (4). The temperature in this freezer at the time of our visit on 4-16-12 was observed to be (b) (4). Seven lots of chicken, lamb, and salmon were stored in this freezer during our visit. Identified as Exhibit #44 Photo #2 is a picture of pallets of frozen meat being stored in the North Warehouse during our visit on 4-16-12.

The freezer designated as the "South Warehouse" was stated to have a capacity of (b) (4). The temperature in this freezer at the time of our visit on 4-16-12 was observed to be (b) (4). Two lots of chicken were stored in this warehouse during our visit.

According to Mr. Xu, shipments of meat generally remain in the freezer no more than one month before being processed. However, shipments can be used within one or two days of receipt or the meat can remain in the freezers for several months or longer.

Thawing:

The meat is removed from the freezers and is immediately de-cased (inner product bags of meat removed from outer containers) in a hallway between the freezers and thawing rooms. The bags of meat are placed on metal racks and the racks are moved to either of two thawing rooms. Mr. Xu



stated the temperature in the thawing rooms is maintained at (b) (4). The firm was only using thawing room #2 during our visit on 4-16-12. The temperature in thawing room #2 was found to be (b) (4) during our visit.

The meat is allowed to thaw for 10 – 20 hours depending on the size of the product bags. For product bags which are 2 kg (4.4 lbs) in size, the thawing time is 4 – 6 hours.

Each thawing rack is identified with a Thawing Process Tracking Record Card. Information on this card is as follows:

- Production date
- Order #
- Product name
- Product lot #
- Raw material/size (i.e. small chicken breast)
- Raw material lot #
- Count (i.e. quantity of lot thawing)
- Thawing time
- Name of person completing record

(b) (4)

(b) (4)

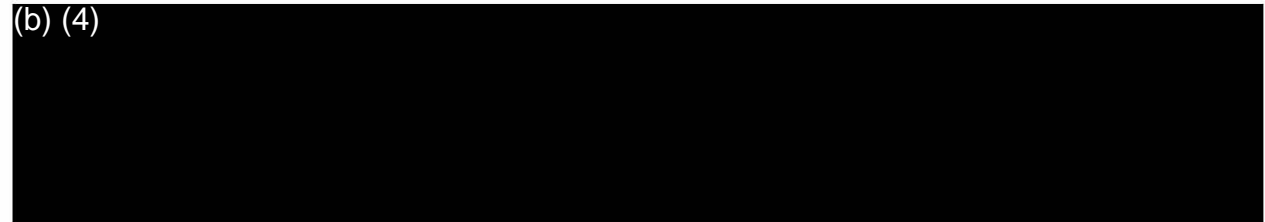
(b) (4)

Identified as Exhibit #44, Photo #4 is a picture of the firm's bulk glycerin tank (left in picture) and the chicken fat tank (right in picture). These tanks are filled by pumping glycerin/chicken fat from drums in the ingredient storage room which is located adjacent to the ingredient weighing room.

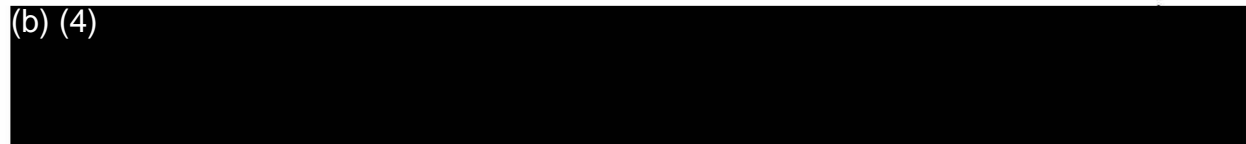
(b) (4)




(b) (4)



(b) (4)



(b) (4)



Each container of glycerin, water, or ingredients is identified with a tag containing the following information before it is taken to the processing workshop:

- Name of ingredient
- Quantity
- Supplier
- Date of manufacture
- Best by date
- Manufacturing lot #

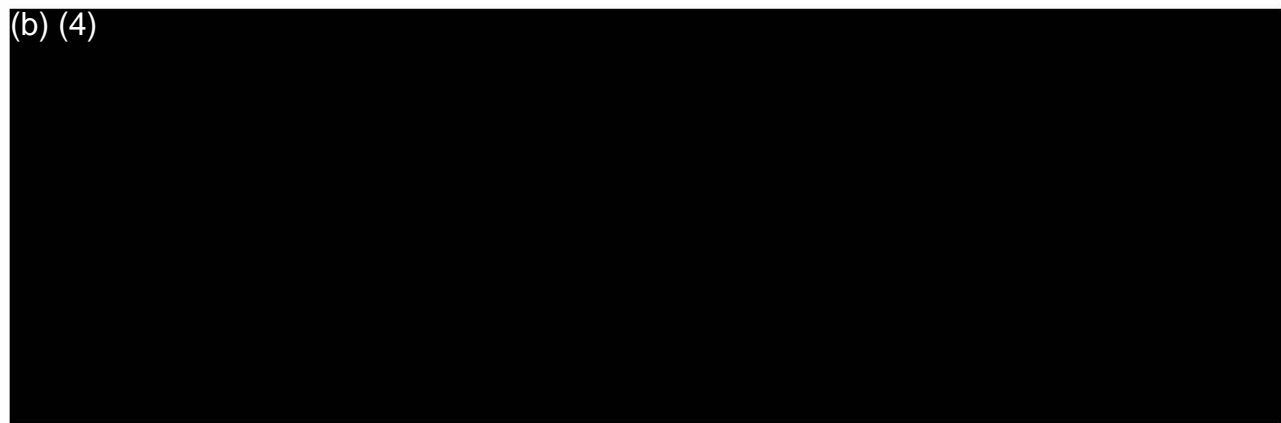
(b) (4)

A large black rectangular redaction box covering the majority of the page content.

(b) (4)

A large black rectangular redaction box covering the majority of the page content.

(b) (4)

A large black rectangular redaction box covering the majority of the page content.

(b) (4)

(b) (4)

Other Manufacturing Equipment Used:

Shandong Honva manufactures a variety of jerky products which require different manufacturing equipment. Among the equipment which the firm uses to manufacture formulated or other forms of jerky products are:

- Large Chopper (Exhibit #44, Photo #15) (NOTE: Photo was taken on 4-17-12. Camera used incorrectly identifies that photo was taken on 4-18-12.)
- Small Chopper (Exhibit #44, Photo #16) (NOTE: Photo was taken on 4-17-12. Camera used incorrectly identifies that photo was taken on 4-18-12.)
- Mincer/Meat Grinder (Exhibit #44, Photo #17) (NOTE: Photo was taken on 4-17-12. Camera used incorrectly identifies that photo was taken on 4-18-12.)
- Mixer for formulated products (Exhibit #44, Photo #18) (NOTE: Photo was taken on 4-17-12. Camera used incorrectly identifies that photo was taken on 4-18-12.)

The firm manufactures formulated products by using mixers, shapers, and conveyor belts. Identified as Exhibit #44, Photo #19 is a picture of this equipment in the semi-clean processing area. (NOTE: Photo was taken on 4-17-12. Camera used incorrectly identifies that photo was taken on 4-18-12.)

(b) (4)

We initially reviewed production records showing the product contained (b) (4)

(b) (4)

We eventually were informed that the product contains approximately 75%

(b) (4)

(b) (4)

#44, Photo #20 is a picture of the interior of one of these steam chambers. (NOTE: Photo was taken on 4-17-12. Camera used incorrectly identifies that photo was taken on 4-18-12.)

(b) (4)



(b) (4)



After cutting, the product passes a metal detector before being packaged.

Screening and Racking:

(b) (4)



Exhibit #44, Photo #22 is a picture of an employee laying out chicken breast meat onto a metal screen. (NOTE: Photo was taken on 4-17-12. Camera used incorrectly identifies that photo was taken on 4-18-12.)

(b) (4)



Each rack is identified with a "Placing on Plate Process Tracking Record Card" containing the following information for the semi-clean processing portion of the operation (Note: This tag also contains additional information which is completed for the drying portion of the operation):

- Processing date
- Order #
- Product name/Customer name
- Raw material lot #
- Material name
- Material lot #

- Start of time (first screen on rack)
- Operator's name
- This card contains other information documenting the drying operation.

The racks of chicken breast meat are then moved to the drying ovens.

Drying:

The firm has a total of (b) (4) which are used for drying jerky. Each of the ovens can hold (b) (4) racks. Identified as Exhibit #44, Photo #24 is a picture of a portion of the firm's drying ovens. (NOTE: Photo was taken on 4-17-12. Camera used incorrectly identifies that photo was taken on 4-18-12.)

(b) (4)

Heating in the ovens is by means of hot air. Filtered air is pulled into the ovens from the outside by a fan and passes over a heat exchanger (steam/air) in order to heat the air. The heated air circulates from one end of the ovens and exhausts through an overhead cavity at the other end of the oven or a portion of the heated air can be diverted back into the oven.

The firm documents the drying temperatures using the (b) (4) Records (CCP2). Identified as Exhibit #49 is a copy of this form.

After the initial drying period has been completed, an employee collects three pieces of jerky from the top, middle and bottom screens on a rack. (b) (4)

(b) (4)


Moisture readings are recorded on a Moisture Testing Record. A copy of this record is identified as Exhibit #50. According to Mr. Xu, moisture readings for jerky products range from (b) (4) depending on the product. Mr. Xu stated that the moisture range for plain chicken jerky produced on 4-17-12 was (b) (4)

If the moisture limits are not met, the racks of jerky are returned to the drying ovens for additional drying before the product would be retested for the moisture level.

---

The water activity limit for jerky is (b) Mr. Xu stated that the water activity for the jerky being produced on 4-17-12 was (b)

(b) (4)



(b) (4)



(b) (4)



Packaging:

The firm generally uses (b) (4) for the manual packaging of jerky. Identified as Exhibit #44, Photo #27 is a picture of the firm's packaging stations.

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

Located next to the packaging area is a bag coding room. The firm ink codes the empty product bags in this room. The firm was coding (b) (4) brand chicken jerky when we observed packaging operations on 4-17-12. The code used for chicken jerky packaged on 4-17-12 was "BEST IF USED BY/ 10 10 13/ 2108HV B".

We were informed that in the event more bags are coded than are packaged for the run; the code on the bags is wiped off. A new code would be printed on the bags for the next run.

(b) (4)



(b) (4)



Irradiation:

Product is shipped from the firm to the irradiator firms in third party logistics trucks.

(b) (4)



According to Mr. Bai, the firm has only used two irradiation firms since they began exporting jerky treats to the U.S. These firms are:

(b) (4)





(b) (4)

According to Mr. Bai, the radiation source used to irradiate the firm's jerky products is (b) (4). Mr. Bai stated that the dosage limits for irradiation of the jerky treats is (b) (4). Mr. Bai stated that the firm's customers and the irradiators were responsible for setting the radiation dosage specifications. According to Mr. Bai there have been no changes to the radiation source or dosage limits since the firm began using these irradiators.

Mr. Bai stated that the firm receives copies of the irradiation certificates for each lot of jerky irradiated. Irradiation certificates were reviewed for 2012.

According to Mr. Bai, after the jerky has been irradiated, the product is loaded for sea shipments to the U.S. Shipments to the U.S. are generally made from the port of Shanghai.

Product Testing:

The firm has both a physical/chemistry laboratory and a microbiology laboratory on site. Visits were made to both laboratories during the inspection.

Physical/Chemistry Laboratory:

According to Mr. Xu, no physical or chemical testing is performed on raw materials (meats). The firm performs moisture analysis on the finished product. Mr. Xu stated the firm analyzes one sample from each lot of jerky produced. Moisture limits for finished products is (b) (4) depending on the product.

(b) (4)

(b) (4)

Water test results were reviewed for February, March and April 2012. No problems were noted.

(b) (4)

Finished product micro test records were reviewed for February 2012 and March 2012. No problems were noted.

**Third Party Testing:**

A variety of third party testing is performed on the firm's raw materials (meats), auxiliary ingredients and finished products.

- **Raw Materials (Meat):**

Once per year meat from each active supplier is tested for pesticides, select drugs/antibiotics and melamine. Mr. Xu stated that the firm collects and submits the samples to the third party laboratory for testing. Testing is performed by the (b) (4)

(b) (4)

Raw material testing records were reviewed for 2010 through 2012. No problems were noted.

- **Glycerin:**

The firm requested the testing of their (b) (4) (b) (4) in March 2012. One sample of glycerin was randomly collected from (b) (4). This sample was submitted to the (b) (4). Results of this testing were as follows:

(b) (4)

(b) (4)

- **Other auxiliary ingredients:**

Mr. Xu stated that there is no third party testing on other auxiliary ingredients.

- Finished Products:

According to Mr. Xu, some of the firm's customers require testing of the finished products prior to irradiation. This testing is as follows:

1. (b) (4)

Each lot of finished product is tested prior to irradiation. Samples of finished products are also tested after irradiation. Samples collected at the firm prior to irradiation are sent to the laboratory by the (b) (4) representative who is on site.

Testing is performed by (b) (4).  
(b) (4) According to Mr. Xu, (b) (4) provides the firm with e-copies of the test results. Finished product test records were reviewed for March 2012. Random finished product test records were also reviewed for 2010 and 2011. A total of (b) (4) test reports were reviewed. No problems were noted.

2. (b) (4)

3.

Only two samples of finished products have been tested since Shandong Honva began manufacturing jerky products for the firm. This testing was performed by (b) (4) in December 2011 and March 2012. The following testing was performed with no problems found:

December 2011:

March 2012:

4.

Mr. Xu stated that no testing has been performed on non-irradiated finished products

(b) (4) performs the yearly testing of meat based pet foods at the firm for select drugs, select chemicals and salmonella. Identified as Exhibit #53/53a is a summary of the (b) (4) surveillance testing plan for Shandong Honva for 2012. Also included with this exhibit are the (b) (4) test results for the jerky treats sampled at Shandong Honva in 2011 and 2010 with translations for the 2012 and 2011 documents.

Sanitation:

Employees:

Employees and visitors to the workshop are required to wear hair covers, mouth and nose covers, captive outerwear and captive boots. Identified as Exhibit #44, Photo #28 is a picture of apparel required to be worn in the semi-clean and clean workshops.

Prior to entering the semi-clean and clean areas of workshop, persons are required to wash their hands with soap and water followed by hand sanitizing using a (b) (4) solution for 30 seconds in a hand dip station. According to the firm, the sanitizer is changed hourly in the hand dip station although this is not documented. The solution in the hand dip station is reportedly maintained at (b) (4). The strength of the hand dip solution in the semi-clean area when tested by me on 4-17-12 was found to be (b) (4). The strength of the hand dip solution in the clean area of the workshop when tested by me on 4-17-12 was found to be (b) (4).

Persons are required to step through a sanitizing boot dip containing sodium hypochlorite which is maintained at (b) (4). We were informed that the boot dip solution is also changed hourly but is not documented. The strength of the boot dip solution in both the semi-clean and clean areas of the workshop when tested by me on 4-17-12 was found to be over (b) (4).

Persons entering the workshop are required to spray their hands with (b) (4).

Employees are required to wear clean uniforms each day. Uniforms are cleaned by the firm.

Employees handling the exposed product in the workshops are not required to wear gloves although they are not allowed to work on these lines if they have any cuts or injuries. The firm's QC department is responsible for ensuring employees meet the firm's sanitation requirements.

Equipment Cleaning:

The firm has procedures in place for the cleaning of the workshop, equipment and utensils which are used in the manufacture of jerky products. Equipment cleaning is performed by a separate cleaning crew and/or the equipment operators. Quality control persons verify that cleaning has been adequately performed.

The firm follows the following procedures for workshop and equipment cleaning:

- Equipment (mixers, grinders, choppers):

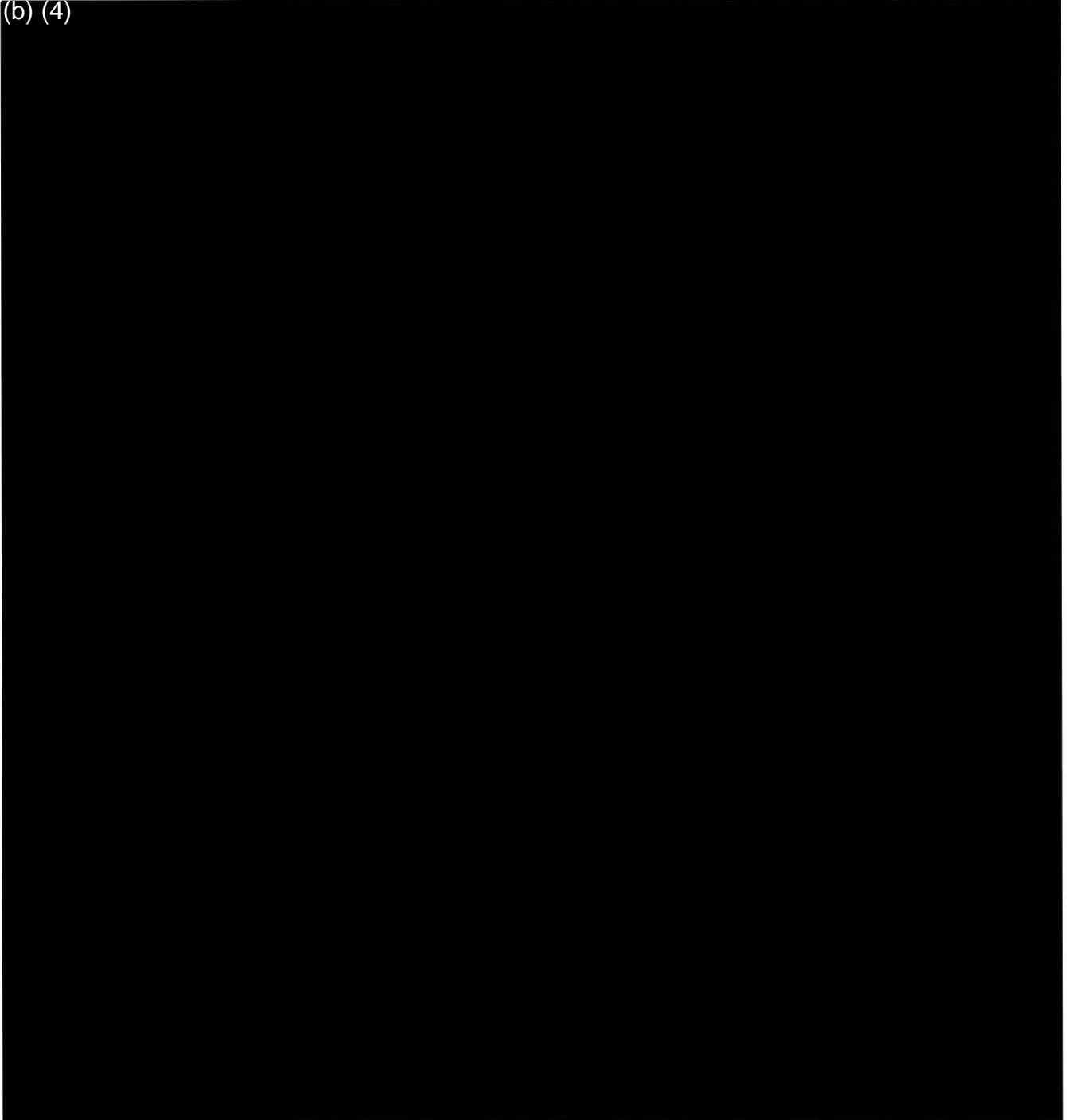
Separate cleaning of this equipment is performed between 5:00 AM and 8:00 AM each day of production by a separate cleaning crew and the equipment operators. The equipment is given a cold water wash followed by a detergent wash with ambient water. If heavy fats or oils were used in the equipment, the equipment will be cleaned with detergent and (b) (4).

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

(b) (4)



(b) (4)

Rodent control is by means of wind-up traps, bait stations, and barrier boards in entryways outside the plant. Glue boards are used in the plant.

Insects are controlled using insecticutors in the plant and screens on windows. No sprays or fumigants are allowed inside the workshop.

### MANUFACTURING CODES

The firm codes the finished products based on a coding system provided by the customers. Identified as Exhibit #54 is a coding documented which identifies the coding system for each customer.

An example of the firm's coding system for (b) (4) products is as follows:

(example) BEST IF USED BY  
10 10 13  
2108HV B

Best Buy Date = October 10, 2013 (10 10 13)

2108 = Del Monte provided lot number

HV = plant ID (Shandong Honva)

B = Packaging shift (A = 1<sup>st</sup> shift, B = 2<sup>nd</sup> shift, C = 3<sup>rd</sup> shift)

(b) (4) products are identified with an 18 month use by date.

(b) (4) products are identified with a 24 month use by date for dogs and an 18 month use by date for cats.

(b) (4) products are identified with a 24 month use by date.

(b) (4) were identified with an 18 month use by date.

Mr. Xu stated that the customers were responsible for developing the product use by dates.

## COMPLAINTS

The firm has a written procedure for complaint handling. Complaints are initially received by the firm's sales department. Complaints are then forwarded to the firm's QC department for any follow-up investigation.

According to Mr. Xu the firm has received a total of (b) complaints from 2010 to date. Two complaints have been received in 2012. (b) complaint involved a customer finding dark spots on chicken jerky. The (b) (4) complaint concerned fish jerky which was not of uniform size.

(b) complaints were received in 2011. (b) of the complaints involved (b) brand lamb and rice jerky. These complaints reported pieces of plastic film in the product. The subsequent investigation found the plastic film was from bags of rice which was used during product formulation.

The firm did not receive any complaints in 2010.

According to the firm, they have received no complaints relating to illness or dead dogs relating to chicken jerky. According to a CVM database query dated 3-9-12, CVM has received (b) CJT complaints involving this firm's products.

A check of FDA's FACTS database found a total of (b) complaints involving this firm's products. All related to the CJT issue. The first complaint in this database was received on 9-9-11. The last complaint was received on 5-9-12. (b) (4) of the complaints involved the (b) (4) brand of chicken jerky treats. (b) complaints involved the (b) brand of chicken jerky.

## RECALL PROCEDURES

Mr. Bai stated that the firm has a written recall procedure. Mr. Bai stated that the firm performs a mock recall yearly. Any product recalls would be overseen by Mr. Bai and executed by the firm's QC department. The firm's sales department would be responsible for contacting each customer.

Mr. Bai stated that the firm has not had any product recalls or import detentions to date.

## OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No FDA-483, Inspectional Observations, form was issued at the conclusion of the inspection although one deficiency was discussed with Mr. Mingcun Bai, general manager. This was:

- On the second day of the inspection, a torn door gasket was observed on mixer #1.

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

Mr. Bai stated that this would be corrected immediately. This gasket was verified as having been replaced by the conclusion of the inspection.

## REFUSALS

Meetings were held with Dr. Dou, the AQSIQ representative, during the first CJT inspection relating to AQSIQ's refusal to allow FDA to sample unless certain conditions were met or concerns addressed. This included a requirement that all samples be tested in a CIQ or third party Chinese laboratory. I was informed that FDA would not be allowed to ship any samples outside of China for testing in an FDA laboratory due to the issue of national sovereignty among other reasons. I informed the FDA Beijing office of AQSIQ's concern and conditions regarding product sampling.

At the time of this inspection, FDA and AQSIQ had met or were attempting to arrange a meeting to attempt to resolve the sampling issue. (See the Yantai Aska Food Co, Ltd EIR dated 3-28/30-12 for further information on this issue.)

I met with Dr. Dou during the previous inspections to determine whether AQSIQ's position had changed relating to that agency's position on the refusal to allow sampling unless AQSIQ conditions were met and concerns addressed. Dr. Dou stated that AQSIQ's position had not changed. A Shandong CIQ representative who observed the Shandong Honva and was representing AQSIQ when Dr. Dou, the AQSIQ representative was absent on one day of this inspection, also confirmed that samples could not be collected during the inspection unless certain sampling conditions were agreed to by FDA.

I did not ask firm management if I could collect samples during this inspection. No samples were collected during the inspection.

## GENERAL DISCUSSION WITH MANAGEMENT

A closing discussion was held with Mr. Mingcun Bai, general manager, at the conclusion of the inspection. Also on hand for the closing discussion were members of Mr. Bai's staff; Dr Dou, the AQSIQ representative; and representatives from the Shandong CIQ and Liaocheng CIQ. Identified as Exhibit #43/43a is a sign-in sheet with translation for all persons who were present during the closeout meeting.

Although no FDA-483, Inspectional Observation, form was issued; one GMP deficiency was discussed with Mr. Bai concerning a torn door gasket was observed on mixer #1 on 4-17-12.

Mr. Bai stated that this gasket had been replaced and he requested that we verify this correction was made. On 4-18-12, we verified the door gasket on mixer #1 had been replaced.



No other issues were discussed at this close-out meeting.

#### **ADDITIONAL INFORMATION**

None

#### **SAMPLES COLLECTED**

No samples were collected during the inspection based on the refusal of AQSIQ to allow FDA sampling unless conditions set forth by AQSIQ were met.

#### **VOLUNTARY CORRECTIONS**

A torn gasket was observed on the door cover for mixer #1 on the second day of the inspection. The gasket on this door cover was verified as having been replaced by the last day of the inspection.

#### **EXHIBITS COLLECTED**

- 1/1a) Copy of firm's business license with translation (2 pages)
- 2/2a) Copy of firm's CIQ export certificate with translation (2 pages)
- 3/3a) Copy of firm's presentation made at the start of the inspection with translation (12 pages)
- 4/4a) List of traders used to export products to the U.S. with translation (2 pages)
- 5/5a) List of firm's products exported to the U.S. with translation (3 pages)
- 6-38) Examples of product labels (32 pages)
- 39/39a) Organizational chart with translation (2 pages)
- 40/40a) Responsibilities of department managers with translation (2 pages)
- 41/41a) Sign-in sheet for persons present during the opening meeting with translation (2 pages)
- 42) Business cards (1 page)
- 43/43a) Sign-in sheet for persons present during the closing meeting with translation (2 pages)
- 44) Photographs (28 pages)
- 45/45a) List of meat suppliers with translation (10 pages)
- 46/46a) List of auxiliary ingredient suppliers with translation (5 pages)
- 47) Copy of auxiliary Material Inspection Record and COA for (b) (4)  
(b) (4) received 3-20-12 (3 pages)
- 48) Copy of auxiliary Material Inspection Record and COA for (b) (4)  
(b) (4) received 2-12-12 (3 pages)
- 49) Drying Pet Food Heating Parameters Record (CCP2) (1 page)
- 50) Moisture Testing Record (1 page)

**Establishment Inspection Report**  
SHANDONG HONVA FOOD CO. LTD.  
LIAOCHENG, China

FEI: 3007420579  
EI Start: 04/16/2012  
EI End: 04/18/2012

---

- 51/51a) List of desiccant suppliers with translation (2 pages)  
52) Copy of Comprehensive Test Center of CAIQ test report dated 4-1-12 for the testing of (b) (4) (1 page)  
53/53a) Copy of (b) (4) surveillance sampling plan for Shandong Honva for 2012 and results of testing for 2011 and 2010 with translations for the 2012 and 2011 documents (12 pages)  
54) Copy of manufacturing code breakdown (3 pages)

#### ATTACHMENTS

1. Letter dated 3-13-12 from Cory Bryant, FDA Acting Assistant Country Director – Foods to Dr. Dou, AQSIQ Deputy Director identifying the five firms FDA recommended for inspection regarding the CJT issue (1 page)



Dennis L. Doupnik, Investigator

Clotia Abbey-Mensah, Investigator



Evid Liu, Medical Research Scientist