

Establishment Inspection Report
Gambol Pet Products (Liaocheng) Co.,
Ltd.
Liaocheng, China

FEI: 3006781697
EI Start: 04/11/2012
EI End: 04/13/2012

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SUMMARY

The inspection of this pet treat manufacturer was conducted in accordance with DFFI FACTS assignment #1395232, OP ID #6054251 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. Reports of illness were 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 hepatic disease, renal disease and Fanconi like syndrome in dogs associated with the consumption of CJT and non-chicken-based jerky treats. As of March 1, 2012, CVM had received over (b) 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.

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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). Gambol Pet Products (Liaocheng) 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 chicken jerky, duck jerky and chicken jerky wrapped combination products. Firm management estimated that over 95% of their products are exported to the United States for the (b) (4) only. The firm exports approximately (b) (4) of their products to Canada. The firm also sells a small amount of jerky domestically.

An evaluation was conducted on 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 various steps which are used to manufacture the jerky products. Records were also reviewed relating to manufacturing, quality control, ingredient and product testing among others.

No FDA-483 was issued although one GMP deficiency was discussed with the firm's owner. Cracked bases and rough welds which contacted product were observed on the bottoms of a number of stainless steel totes that were used to hold product prior to drying operations. The cracked bases and rough welds make it difficult to properly clean the totes.

A review of the firm's food facility registration prior to the inspection found the firm was registered as a low acid canned food/acidified canned food (LACF/ACF) manufacturer and a pet food manufacturer. The inspection found the firm only manufactures pet food for export to the U.S. The firm's owner was requested to update their food facility registration in order to identify the firm's true operation. The firm's food facility registration was confirmed to have been updated following the inspection.

A review of FDA's Online Reporting Analysis Decision Support System (ORADSS) database prior to the inspection found no lines of entry into the U.S. for product shipped by the firm after June 2008. The inspection found the firm's products were exported to the U.S. under an unrelated Chinese broker/shipper's food facility registration (FFR) number prior to January 2012. Since January 2012 the firm's products have been exported to the U.S. under the FFR number of a related Chinese shipper/broker, (b) (4). The firm's owner was informed that shipping records should identify the FFR number for the true manufacturer of these products rather than using the registration number of the shipper/broker and identifying the shipper/broker as the manufacturer. A review of the ORADSS database on 5-13-12 continued to find no lines of entry into the U.S. for

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Gambol Pet Products; however, shipments of pet products have entered the U.S. under the FFR number for (b) (4) identified as a manufacturer.

(b) (4)

The firm's owner provided a written response to the observations following the inspection.

The AQSIQ representative who observed the inspection stated that samples could not be collected during the inspection 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. 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: Gambol Pet Products (Liaocheng) Co., Ltd.
Location: No.38 Liaotang Road, Liaocheng City
Shandong, China.
Liaocheng,
China
Phone: 86-6358428608
FAX: 86-6358428608
Mailing address: No.38 Liaotang Road, Liaocheng City
Shandong, China.
Liaocheng,
China 252000
Dates of inspection: 4/11/2012, 4/12/2012, 4/13/2012
Days in the facility: 3

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Participants: Dennis L. Douppnik, Investigator
Evid Liu, Medical Research Scientist

In a letter to AQSIQ dated 3-13-12, FDA's Beijing office identified five firms including Gambol Pet Products (Liaocheng) Co, Ltd 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.

On arrival at the firm on 4-11-12, credentials were shown to Mr. Hua Qin, president and primary owner of Gambol Pet Products (Liaocheng) Co, Ltd (Gambol Pet Products).

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.

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

HISTORY

Gambol Pet Products was established as a newly built firm in September 2006. The firm is owned by the following individuals:

Mr. Hua (Luke) Qin – President (70% ownership)
Mr. Lawrence K. Lin – (30% ownership)

According to Mr. Qin, he and Mr. Lin have owned the firm since it was established in 2006. Mr. Qin stated that Mr. Lin is a U.S. citizen living in Chicago, IL. All correspondence should be directed to Mr. Hua Qin at the firm's physical address.

Mr. Qin stated that he is the sole owner of one other company which manufacture jerky treat products and one company which exports the jerky treat products to the U.S. These firms are:

- Shandong Petswell Food Co., Ltd (Shandong Petswell) (jerky treat manufacturer)
No 2 North Binhu Road, Gaotang County,
Liaocheng City, Shandong Province, PRC 252000

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FEI: 3009426105, **3009495188**

FFR: 125xxxxxxxx

- Shandong Burton Industry Corp., Ltd (shipper/broker)

Room 251, Phoenix Building #2, Huanghe Road,
Liaocheng Development Zone,
Liaocheng, Shandong Province, 252000

FEI: **3008547072**, 3008765507

FFR: 104xxxxxxxx

(Note: DFFI has been requested to merge the FEI numbers for each firm. The FEI numbers in bold are the FEI numbers which will remain.)

Shandong Petswell is a manufacturer of jerky treat products. This firm was identified as the fifth firm to be inspected by FDA relating to the CJT issue. In preparation for the Shandong Petswell inspection, a query of FDA's Food Facility Registration database (FURLS) found that Shandong Petswell had not registered with FDA in accordance with the Bioterrorism Act of 2002. Since Mr. Qin was the owner of Shandong Petswell and he was previously notified that FDA would inspect his firm the next week, this issue was discussed with him during the inspection of Gambol Pet Products. Mr. Qin subsequently registered Shandong Petswell with FDA in accordance with the Bioterrorism Act of 2002. The registration of Shandong Petswell was completed prior to the completion of the Gambol Pet Foods inspection.

According to Mr. Qin, Shandong Burton Industry Corp. Ltd (Shandong Burton) was established in December 2010. Since January 2012, Shandong Burton has acted as the shipper/broker/exporter for jerky pet treats which are manufactured by Gambol Pet Products and Shandong Petswell. A query of FDA's Online Reporting Analysis Decision Support System (ORADSS) database prior to the inspection found no lines of entry into the U.S. for products shipped by Gambol Pet Products after June 2008. This issue was discussed with Mr. Qin during this inspection. Mr. Qin acknowledged that all products which were manufactured by Gambol Pet Products and Shandong Petswell were identified on shipping records under the food facility registration number for Shandong Burton. Mr. Qin was informed that shipping records should identify the food facility registration number of the true manufacturers of these products rather than identifying Shandong Burton as the manufacturer of the jerky treat products.

A query of the ORADSS database on 5-13-12 continues to find no lines of entry into the U.S. for products shipped by Gambol Pet Products and Shandong Petswell. This database continues to show products entered into the U.S. as recent as 5-10-12 under the name of Shandong Burton as the manufacturer.

According to Mr. Qin, Gambol Pet Products' QC Department provides quality control oversight for an unrelated firm that also manufactures jerky treats which are exported to the U.S. by (b) (4)

(b) (4)

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(b) (4) Mr. Qin stated that the QC manager at (b) (4) reports to Mr. Jun Xue, the QC manager for Gambol Pet Products. Mr. Qin stated that (b) (4) purchases their own raw materials and auxiliary materials and no ingredients or finished products are exchanged between the companies.

Gambol Pet Products generally manufactures jerky treat products seven days per week throughout the year. The firm operates three production shifts which run as follows:

- 8:00AM – 4:00PM (lunch break from 12:00PM to 1:00PM)
- 4:00PM – 12:00AM (dinner break from 6:30PM – 7:30PM)
- 12:00AM – 8:00AM (dinner break from 12:00AM – 1:00AM)

The firm employs a total of (b) employees with some employees living on site.

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

Gambol Pet Products has registered with FDA in accordance with the Bioterrorism Act of 2002 although the firm's food facility registration was in need of updating to reflect the firm's true operations at the time of the inspection. The firm updated their food facility registration following the inspection.

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 also 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 that 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. Qin, the firm exports in excess of (b) of their jerky treats to the U.S. The firm exports approximately (b) of their products to Canada. The firm also sells a small amount of jerky domestically.

Mr. Qin stated that the firm began exporting products to the U.S. approximately April 2007. Until January 2012, the firm's products were exported to the U.S. through one unrelated Chinese exporter, (b) (4). Since January

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2012 the firm's products have been exported to the U.S. through Shandong Burton Industry Corp. Ltd, Liaocheng, Shandong Province, PRC. Mr. Qin stated that he is the sole owner of Shandong Burton.

JURISDICTION

According to Mr. Qin, Gambol Pet Products manufactures the following types of jerky products:

- Chicken jerky (b) (4)
- Duck jerky (b) (4)
- Chicken jerky wraps (b) (4)
 1. Chicken and biscuit (b) (4)
 2. Chicken and sweet potato (b) (4)
 3. Chicken and apple (b) (4)
 4. Chicken and banana (b) (4)

Mr. Qin stated that until approximately 1 ½ years ago the firm also manufactured a sushi-type product consisting of fish skin, chicken jerky and glycerin for the (b) (4). Mr. Qin stated that this line of products has been discontinued to the best of his knowledge.

Mr. Qin stated that the firm's only U.S. customer is the (b) (4). Mr. Qin stated that the firm exported approximately (b) (4) of jerky pet treats to the U.S in 2011.

All of the firm's products are packaged under the (b) (4). Mr. Qin stated that the firm began exporting the jerky treat products to the U.S. for the (b) (4) in September 2010.

Mr. Qin estimated that (b) (4) of the jerky treats they manufacture are packaged under the (b) (4) brand. Identified as Exhibit #4/4a is a product list with translation which identifies each of the products manufactured by the firm for the (b) (4) the brands these products are packaged under and package size.

Examples of the labels for (b) (4) jerky treats which are exported to the U.S. are identified as Exhibits #5-19.

According to Mr. Qin, the (b) (4) is responsible for the labeling information on all products which are exported to the U.S.

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INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Gambol Pet Products is owned by Mr. Hua Qin (70% ownership) and Mr. Lawrence K. Lin (30 % ownership). Mr. Qin stated that both he and Mr. Lin have owned the firm since it was established in September 2006.

(b) (4)



Mr. Qin stated that he is the most responsible individual at this firm. All managers at the firm report directly to Mr. Qin. Identified as Exhibit #20/20a is a copy of an organizational chart for the firm with translation. Identified as Exhibit #21/21a is a copy of a document with translation which identifies the duties and responsibilities of the firm's managers.

Mr. Qin stated that he is the owner of two other related firms. These firms are:

- Shandong Petswell Food Co., Ltd
Gaotang Co, Liaocheng City, Shandong Province, PRC
A manufacturer of jerky treat products which are sold to the Purina Co.
- Shandong Burton Industry Corp., Ltd
Liaocheng, Shandong Province, PRC
A shipper and export of jerky treats for Gambol Pet Products and Shandong Petswell for the Purina Co.

Mr. Qin estimated that he spends approximately 1/3 of his time at each of his firms throughout the course of the year.

An opening meeting was held with Mr. Hua Qin, his staff and representatives from AQSIQ and CIQ. A sign-in sheet for the persons who were present at the start of this meeting with translation is identified as Exhibit #22/22a. Identified as Exhibit #23 are the business cards which were received from Mr. Qin, his staff and representatives of the Liaocheng CIQ at this opening meeting. Also included with Exhibit #23 are copies of business cards which were previously received from the AQSIQ and Shandong CIQ officials who were present.

A closing meeting was held with Mr. Hua Qin, president, his staff and representatives from AQSIQ and CIQ at the conclusion of the inspection. A sign-in sheet for the persons who were present at this meeting with translation is identified as Exhibit #24/24a.

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Information for this report was provided by Mr. Hua Qin; Mr. Changwen Liu, vice general manager; Mr. Jun Xue, QC manager; and other managers and staff from the firm. We were accompanied during the inspection by Mr. Qin; Mr. Liu; Mr. Xue and other members of the firm's staff; Dr. Shulong 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 Gambol Pet Products 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 leases warehouse space from an outside firm for the storage of frozen meats which are used in the production of jerky. Identified as Exhibit #25 are photos which were taken to document manufacturing operations at the firm.

According to Mr. Qin, the (b) (4) has a person on site to oversee production operations whenever the firm is manufacturing jerky that is intended to be exported to the U.S. We were told this individual was not at the firm during the inspection.

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 treats. According to Mr. Qin, the firm developed their own HACCP plan. The HACCP plan was verified by the China Quality Certification Center (CQC).

The firm has identified three 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

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and the Ministry of Health (MOA) quarantine certificate. According to Mr. Qin, the firm performs scheduled audits at the suppliers to ensure the quality of the meat they receive.

CCP 2: (b) (4)

CCP 3:

Ingredient Suppliers:

Meat Suppliers:

According to Mr. Qin, the firm purchases raw meat from a large number of suppliers. These suppliers are primarily located in Shandong Province; however, some of the firm's meat suppliers are located in Liaoning Province, Fujian Province, Jilin Province, Henan Province, Shanxi Province, Hebei Province, Jiangsu Province, Heilongjiang Province, Inner Mongolia and Beijing. Identified as Exhibit #26/26a is a list of the firm's suppliers of meat from April 2010 to date with translation.

Mr. Qin estimated that the closest suppliers are located approximately (b) (4) from the firm. The farthest suppliers are located approximately (b) (4) from the firm. Mr. Qin stated that all meat is delivered frozen primarily using third party logistics trucks.

Auxiliary Ingredients:

The firm uses a limited number 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 #27/27a is a list of the firm's auxiliary ingredient suppliers which have been used since April 2010 with translation.

Besides the raw meat, the most common ingredient used in the manufacture of jerky is glycerin which is added as a softening agent. The firm uses (b) (4) in the manufacture of the jerky treats. According to Mr. Qin, the firm has used (b) (4) in the manufacture of jerky treats since April 2007 when the firm began exporting products to the U.S.

The firm had 65 – 250 kg drums of (b) (4) in the ingredient warehouse during this inspection. Identified as Exhibit #25, Photo #1 is a picture of the drums of glycerin which were found in the firm's ingredient warehouse during the inspection.

The firm documents the receipt and usage of glycerin using an Ingredient Input and Output Record. An example of this record is identified as Exhibit #28.

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A review was made of the firm's glycerin receiving and usage records for 2010 to date. These records were compared against Chinese customs taxation forms (fapiao) for 2010, 2011 and 2012. Glycerin usage records were also compared with randomly selected production records for weeks during January through April 2012. As best determined, the firm has only used (b) (4) during at least the past several years as Mr. Qin 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.

Product Formulation:

According to Mr. Qin, the firm uses only one formulation for chicken jerky and duck jerky. Mr. Qin stated that the formula for chicken jerky which is used for the wrapped products is the same as the formula for the plain chicken jerky.

Mr. Qin stated that the (b) (4) originally developed the formulation for these products. When (b) (4) (b) (4) became the responsible firm for product formulation.

According to Mr. Qin, the amounts of glycerin used in the jerky products have changed over the years. Mr. Qin was requested to provide information on jerky formulation changes which have occurred since January 2009. According to Mr. Qin, the firm only keeps records for two years and therefore could only provide this information since January 2010.

From information provided by Mr. Qin and our observation of the mixing operations, we determined the following:

(b) (4)



Glycerin amounts used in the manufacture of duck jerky were understood to be the same as above for chicken jerky.

According to Mr. Qin, the firm has made the following changes in jerky formulation in the past two years. These are:

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(b) (4)



Processing of Chicken Jerky:

The firm was processing (b) (4) brand chicken jerky during the inspection. Photographs were taken to document portions of the firm's chicken jerky operations. These photographs are identified as Exhibit #25.

Raw Material (Meat) Receiving:

Ingredient receiving is CCP1 of the firm's HACCP program. Raw meat purchased from suppliers is initially received at the firm's on-site, temporary frozen storage warehouse. According to Mr. Qin, all meat is received frozen.

At the time of receipt the firm verifies the supplier's Ministry of Agriculture (MOA) quarantine certificate, the supplier's certificates and the temperature of the meat. Mr. Qin stated that the internal temperature of the meat is checked by sampling five cases from each lot received. The temperature of the meat is required to be below (b) (4) at the time of receipt.

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(b) (4)

(b) (4)

A visit was made to the firm's off-site freezer on 4-12-12. The off-site freezer is leased from (b) (4) (b) (4). According to Mr. Qin, the firm has used this freezer since January 2012. Mr. Qin stated that prior to this date, the firm leased freezer space from another company's freezer which was located approximately 30 – 40 minutes from the firm. Mr. Qin stated that the company felt this was too long a time for the loading and unloading of the meat and so the firm leased the current freezer which was closer to the firm.

The firm uses one dedicated freezer at this facility which has a capacity of (b) (4). The temperature in the freezer was observed to be (b) (4). The firm documents the freezer temperature.

An examination of the products on hand on 4-12-12 found the freezer contained five lots of chicken breasts from five different suppliers. According to the receiving tags, these shipments were received by the firm on 4-10-12.

Each lot of meat is identified with a tag with contains the following information:

- Name of ingredients (i.e. frozen chicken breast)
- Supplier's name
- Dimensions of the packages (i.e. 10 kg x 2)
- Quantity (i.e. 70 bags/pallet)
- Weight of lot
- Arrival date
- Remarks

Thawing:

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Prior to processing, the bags of meat are moved from the leased freezer or the firm's temporary frozen storage room to one of two thawing rooms. The suppliers ship the frozen meat to the firm in plastic weave bags. The meat is sealed within the plastic weave bags in 2 kg, 4 kg, 10 kg or 20 kg plastic bags.

(b) (4)

Each thawing rack is identified with a tag which allows the firm to trace the meat to the supplier. Each tag contains the following information:

- Lot #
- Date of thawing
- Tracing code
- Size of product bag
- Time thawing starts
- Weight of product on a rack
- Person responsible for completing tag
- Remarks

(b) (4)

(b) (4)

Ingredient Weighing:

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The firm has a separate weighing room which is located next to the semi-clean processing area where ingredients are weighed. Glycerin drums are brought into the ingredient weighing room. The glycerin is then gravity fed into stainless steel containers that are weighed and set aside for the next batch of jerky produced. Identified as Exhibit #25, Photo #4 is a picture of a glycerin drum, stainless steel containers and scale in the ingredient weighing room.

Water is used to dilute the glycerin before it is added to the meat in the mixer/tumbler. Other ingredients which are used in the manufacture of jerky are also weighed in this room.

Each container of glycerin, water, or ingredients is identified with a tag containing the following information:

- Date and number of containers weighed
- Product lot #
- Ingredient tracing #
- Batch weight of meat (i.e. 800 kg of chicken breast meat)
- Name of auxiliary ingredient weighed (i.e. glycerin)
- Lot # of auxiliary ingredient weighed (i.e. (b) (4))
- Standard weight (in formula) (i.e. 24 kg)
- Actual weight (24 kg)
- Responsible person who weighed ingredient
- Remarks

(b) (4)



(b) (4)



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(b) (4)

(b) (4)

An examination of the mixer after unloading found the mixer contained an estimated several kilograms of chicken breast meat. We observed that the firm's employees made no attempt to completely clean out all chicken breast meat between mixer batches. Identified as Exhibit #25, Photo #8 is a picture of chicken breast meat remaining in the mixer after mixing operations were completed and the mixer was emptied.

We were told that any chicken breast meat would be cleaned from the mixer after the last lot of glycerin or lot of meat was used. We were also told that at the end of the shift, any chicken in the mixer would be washed out and this material would be placed in a waste receptacle as would any meat which fell onto the floor. This waste would be picked up the next day for use as fertilizer.

After the mixers are unloaded and the chicken breast meat is emptied into the stainless steel totes, the totes are moved to the semi-clean processing area of the workshop where the chicken breast are laid onto metal screens prior to drying. Identified as Exhibit #25, Photo #9 is a picture of the semi-clean workshop where employees lay out the chicken breasts onto metal screens prior to the drying operations.

The temperature in the semi-cleaning processing area was stated to be maintained at (b) (4). I determined the temperature in this area to be (b) (4) when this area was evaluated on 4-11-12.

Screening and Racking:

(b) (4)

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(b) (4)



Each rack is identified with a tag 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):

- Time of bag opening
- Shift and date
- Tracing code and lot #
- Time of input of product into mixer
- Tumbling lot #
- Rack #

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

(b) (4)



(b) (4)



(b) (4)



(b) (4)



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(b) (4)

(b) (4)

Should any temperature or time deviation occur during the sterilization stage, the firm completes a deviation form entitled "Deviation Correction Record (CCP2)". A copy of this form with translation is identified as Exhibit #32/32a.

The design and construction of the firm's ovens are the same for both the drying and "sterilizing ovens". Heating in both types of 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.

(b) (4)

Moisture readings are recorded on a Moisture Content Test Record. A copy of this record is identified as Exhibit #33. According to this record, moisture readings for jerky products should be as follows exiting the drying ovens:

- Chicken jerky tenders and duck jerky tenders: (b) (4)
- Chicken & biscuits/PBJ: (b) (4)
- Chicken & apple: (b) (4)
- Chicken & yam: (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.

De-screening and Metal Detection:

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(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

The firm documents the challenge to the metal detector using a Metal Detection Record for each line. A copy of this record is identified as Exhibit #34. Should metal be found the firm's procedure is to run all of the jerky which falls into plastic totes at the end of the conveyor line for a total of three times in order to verify all metal is detected. Any jerky found to contain metal is then placed in a sealed metal box and QC analyzes the product in a segregated area at the end of the shift.

The firm documents any deviations to metal detection by means of a record entitled "Deviation Correction Record (CCP3)". A copy of this record with translation is identified as Exhibit #35/35a.

Packaging:

The jerky falls into plastic totes at the end of the conveyor lines where the metal detectors are located. These totes are weighed and are moved to any of three packaging lines where the jerky is hand packaged into consumer sized bags. Approximately nine employees are stationed at each packaging line.

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Located next to the packaging area is a bag coding room. The firm uses two lines for the ink coding of empty product bags. The firm was coding (b) (4) brand chicken jerky tenders when we observed packaging operations on 4-12-12. The code used for chicken jerky packaged on 4-12-12 was "(b) (4) /BEST BEFORE : OCT 2013/OKC8 APR 2012".

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.

Following packaging, employees place desiccants into each bag prior to heat sealing in order to remove the oxygen from the sealed bags. According to Mr. Qin, the firm has used the same two firms to supply desiccants for the jerky packages. Identified as Exhibit #36/36a is a list of the two firms which supply this firm with desiccants along with an identification of the materials in these desiccants.

(b) (4)



Irradiation:

All jerky treats which are produced by this firm undergo irradiation before the product is exported to the U.S. Products are shipped to the irradiator firms from Gambol Pet Products by means of third party logistics trucks.

(b) (4)



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The firm initially used this firm to irradiate products beginning in February 2009 but has most recently begun using this firm on a regular basis in December 2011

Mr. Qin estimated that (b) (4)

(b) (4)

(b) (4) According to Mr. Qin, he felt the firm received better service from Zhejiang (b) (4) however, if that firm is unavailable, the firm will use (b) (4) to perform the irradiation of the products. Mr. Qin stated that his firm has also worked with the (b) (4) to determine which irradiator firm to use.

Mr. Qin stated that the firm had routinely used (b) other irradiation firms to perform product irradiation before 2011. These firms were:

(b) (4)

(b) (4)

According to Mr. Qin, these (b) irradiators were verified by their customers and by their exporter at the time (b) (4) as being capable of irradiating products; however, Mr. Qin stated that they stopped using these (b) firms because they could not handle the capacity needed.

According to Mr. Qin, each of the above (b) (4)

Mr. Qin stated that the dosage limits for irradiation of the jerky treats is 7.5 kG. Mr. Qin stated that the (b) (4) was responsible for setting the dosage irradiation specifications. Mr. Qin stated that the firm receives a copy of the certificates for each lot irradiated.

(b) (4)

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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. Jun Xue, QC manager, no physical or chemical testing is performed on raw materials (meats). The firm performs moisture analysis on the finished product. Moisture specifications for the finished products are as follows:

- Plain chicken and duck jerky tenders: (b) (4)
- Chicken wrapped biscuits: (b) (4)
- Chicken wrapped apple and banana: (b) (4)
- Chicken wrapped sweet potato: (b) (4)

Microbiology Laboratory:

Three employees work in the firm's micro laboratory.

The firm has performed micro testing on chicken and duck received from their suppliers on a quarterly basis following the national standard for frozen chicken since February 2012 according to Mr. Jun Xue, QC manager. Prior to February 2012, this testing was performed every six months.

Testing limits are as follows:

(b) (4)



According to Mr. Xue, the firm performs micro testing of the auxiliary ingredients used in the chicken wrapped products as follows:

(b) (4)



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(b) (4)



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

According to Mr. Xue, the firm performs micro testing on the finished product prior to irradiation. Five samples are tested from each day's production run. The following micro tests are performed on the finished product:

(b) (4)



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

Third Party Testing:

A variety of third party testing is performed when the firm does not have equipment to perform specified analysis of products or customers request test verification.

- Raw Materials (Meat):

(b) (4)



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(b) (4)



(b) (4)



(b) (4)



• (b) (4)



(b) (4)



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(b) (4)

Testing of chicken wrapped jerky treats also included aflatoxin.

(b) (4)

Mr. Xue stated the firm also submitted two samples of chicken jerky to the Comprehensive Test Center of CAIQ for EG, PEG and DEG testing in March 2012. The results of this testing are as follows:

(b) (4)

(b) (4)

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 #25, Photo #12 is a picture of apparel required to be worn in the semi-clean and clean workshops.

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Prior to entering the workshop, persons are required to wash their hands with soap and water followed by hand sanitizing using a (b) (4) hypochlorite solution in a hand dip station. According to the firm, the sanitizer is changed in the hand dip station every two hours. The solution in the hand dip station is reportedly maintained at (b) (4). The strength of the hand dip solution when tested by me on 4-11-12 was found to be (b) (4).

Prior to entering the workshop, persons are required to step through a sanitizing boot dip containing (b) (4). We were informed that the boot dip solution is also changed every two hours. The strength of the boot dip solution when tested by me on 4-11-12 was found to be over (b) (4).

Upon entering the processing areas, hands are sprayed with (b) (4). Every two hours a siren sounds in the workshop and employees and visitors are required to wash and sanitize their hands. The hand dip chlorine solution in the workshop was stated to be maintained at (b) (4). The strength of the hand dip solution when tested by me on 4-11-12 was found to be (b) (4).

Employees are required to wear clean uniforms each day. Uniforms are cleaned by the firm at the end of each shift. 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. The firm has a separate cleaning crew to perform equipment cleaning. Quality control persons verify that cleaning has been performed adequately.

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

- Floors:

Floors are cleaned at the end of each shift using cold water followed by detergent cleaning and cold water rinse. (b) (4) followed by a cold water rinse.

- Work Stations:

Semi-Clean Area:

Work stations are cleaned every two hours and at the end of the shift using a cold water wash followed by detergent cleaning, cold water rinse, (b) (4) and cold water rinse.

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Clean Area:

Work stations are cleaned every two hours and at the end of the shift using a dry cloth to wipe the conveyor belts and equipment. The conveyor belts and equipment are then sprayed with (b) (4)

- **Stainless Steel Totes:**

Semi-Clean Area:

The totes are washed with cold water followed by detergent cleaning, cold water rinse and washing with at least (b) (4) hot water for at least 2 minutes.

Clean Area:

Totes and containers are washed with a chlorine solution and rinsed with cold water followed by hot air drying.

- **Mixers/Tumblers:**

Every 24 hours or before a formulation change, the mixers/tumblers are washed with cold water followed by a detergent wash with warm water. The equipment is then rinsed with cold water followed by the use of a (b) (4) chlorine sanitizer and cold water rinse.

- **Trays:**

Trays are washed with cold water after every use followed by brushing with detergent, a cold water rinse and washing with (b) (4) water for 2 minutes.

The following cleaning compounds were noted to be used by the firm:

(b) (4)



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(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 glue strips and screens on windows. No sprays or fumigants are allowed inside the workshop.

MANUFACTURING CODES

According to Mr. Qin, the firm had implemented a new coding system for their products as of 2-15-12 on the request of the (b) (4). An example of the firm's new coding system is as follows:

(Example) 2103T026 0101WG1

BEST BEFORE OCT 2013

OKC8 APR 2012

2 = year (2012) (3 = 2013, etc)

103 = Julian date of packaging

T026 = Gambol plant ID

01 = workshop # (1 for Gambol)

01 = product ID (01 = chicken and duck, 00 = mixed package, 02 = wraps, 03 = cut jerky

04 = shaped products, 05 = IQF products, 06 = for repacker

WG1 = chicken jerky

BEST BEFORE DATE: 18 month for (b) (4) and 24 months for (b) (4)

(b) (4)

OKC8 = order #

APR 2012 = month and year of packing

Old coding system:

(Example) G1CA6113A

BEST BEFORE 100213

G = plant ID (Gambol)

1 = Initial order number to Gambol (2 = revised order, etc)

CA6113 = Order #

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A = If container holds 1 product = A (if container holds 2 products = B

Mr. Qin stated the firm never used "C".

BEST BEFORE = 10 (month)

02 (day)

13 (year)

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. Depending on the nature of the complaint, the corresponding department (i.e. production, packaging, etc) would be responsible for correction of the issue.

According to the firm, they have received (b) complaints in the past two years. Each of these complaints was reviewed during the inspection. (b) of these complaints involved the consumer finding dark spots in the jerky. (b) complainant reported finding a piece of chicken bone in the jerky. (b) complainants reported the jerky was too dry or small pieces of jerky were found in the packages.

According to the firm, they have received no complaints relating to illness or dead of 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 (b) complaint in this database was received on 11-25-11. The last complaint was received on 3-27-12. (b) of the complaints involved the (b) (4) brand of chicken jerky treats. (b) complaints involved the (b) (4) brand of chicken jerky.

RECALL PROCEDURES

The firm has a written recall procedure. Mr. Qin stated that the firm conducts a mock recall once per year.

The firm has identified a recall group which consists of the following management staff members:

- QC Department: Mr. Jun Xue – QC Manager
- General Manager: Mr. Changwen Liu
- Production Department: Mr. Jingling Liu – Production Manager
- Warehouse and Logistics Manager

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- Procurement Manager

According to Mr. Qin, the firm has not had any recalls or import rejections to date.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No FDA-483, Inspectional Observations form, was issued at the conclusion of the inspection although four issues were discussed with Mr. Hua Qin, president. These were:

- 1) Cracked bases and rough welds which contacted product were observed on the bottoms of a number of stainless steel totes that were used to hold product prior to drying operations.
- 2) The firm's food facility registration should be updated to reflect the true operations of the firm. At the time of the inspection, the firm's food facility registration identified the firm as an LACF/ACF processor and pet food manufacturer.
- 3) Shipping records should identify the food facility registration number for Gambol Pet Products Co., Ltd as the true manufacturer of jerky treat products rather than using the registration number of Shandong Burton Industry Corp., Ltd, a shipper/export company also owned by Mr. Qin.
- 4) A review of some of the firm's production records documenting the drying of the jerky products appeared to have been falsified based on the uniformity of the writing. These records were reportedly completed by three persons over three production shifts.

A review of the firm's production records found a number of instances where the handwriting on the records appeared to be the same across all three shifts on one jerky production day even though the records identified different teams of employees had completed these records. For example, the first entry on Drying Tunnel Temp Monitoring Record dated 3-7-12 (Exhibit #45, page #1) documented jerky drying in drying tunnel (oven) #2 began at 3:33 AM with the last entry on this page documented jerky drying in drying tunnel #17 began at 22:03 (10:33 PM). This page of the Drying Tunnel Temp Monitoring Record identified the entries were "Recorded By" (b) (4) (b) (4) (translated). Exhibit #45, page #2 of the Drying Tunnel Temp Monitoring Record dated 3-7-12 documents jerky drying in tunnel #21 began at 18:53 (6:53 PM) with the last entry on this page documented jerky drying in drying tunnel #36 began at 13:23 (1:23 PM). This page of the Drying Tunnel Temp Monitoring Record identified the entries were "Recorded By" (b) (4) (b) (4) (translated).

Our review of the information written on these two records for the three production shifts on 3-7-12 found the writing appeared similar if not identical. This can be seen in the writing of the numbers "3" and "8" (under start time) and the letter "A" (under lot no.) for example.

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Mr. Liu stated that the stainless steel totes would be repaired immediately.

Mr. Qin stated that the firm's food facility registration would be updated immediately. It was observed following the inspection that the firm's food facility registration was updated as promised.

Mr. Qin made no comment regarding the completion of shipping records and the food facility registration number identified on these records.

With respect to the possible falsification of production records, Mr. Qin stated that he had discussed this issue with his colleagues. Mr. Qin stated that these records were made up jointly with customer input. Mr. Qin denied any falsification of records had taken place although he stated the possibility that someone had transferred information onto the official records from some unofficial records. Mr. Qin stated that the firm had attempted to do away with handwritten records by using automated records when possible. In any event, Mr. Qin stated that the staff checks and verifies the accuracy of the records every day.

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 laboratory 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 on the first day of this inspection in order 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 and FDA would not be allowed to collect samples during this inspection unless FDA agreed to AQSIQ's conditions and concerns. 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. Hua Qin, president, at the conclusion of the inspection. Also on hand for the closing discussion were members of Mr. Qin's staff; Dr Dou, the AQSIQ

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representative; and representatives from the Shandong CIQ and Liaocheng CIQ. Identified as Exhibit #24/24a is a sign-in sheet with translation for all persons who were present during the closeout meeting.

Although no FDA-483 was issued at the conclusion of the inspection, several issues were discussed with Mr. Qin. These were:

- Cracked bases and rough welds which contacted product were observed on the bottoms of a number of stainless steel totes that were used to hold product prior to drying operations.

Response: Mr. Qin stated that the stainless steel totes would be repaired immediately.

- The firm's food facility registration should be updated to reflect the true operations of the firm. At the time of the inspection, the firm's food facility registration identified the firm as an LACF/ACF processor and pet food manufacturer.

Response: Mr. Qin stated that the firm's food facility registration would be updated immediately.

- Shipping records should identify the food facility registration number for Gambol Pet Products Co., Ltd as the true manufacturer of jerky treat products rather than using the registration number of Shandong Burton Industry Corp., Ltd, a shipper/export company also owned by Mr. Qin.

Response: Mr. Qin made no specific comments on how this would be corrected or handled in the future.

(b) (4)



Dr. Dou, the AQSIQ representative, provided comments on behalf of AQSIQ. Dr. Dou stated that AQSIQ and FDA shared the same goal of ensuring the firm's products were safe. Dr. Dou suggested that Mr. Qin respond in writing to FDA regarding the repair of the stainless steel totes. Dr. Dou suggested the firm submit photos to document how these totes were repaired.

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(b) (4)



Mr. Qin stated that he would consider the suggestions. Mr. Qin stated that the firm would provide a written response to FDA as Dr. Dou suggested.

ADDITIONAL INFORMATION

The final CJT inspection was conducted at Shandong Petswell Food Co., Ltd the following week. As previously stated, this firm is also owned by Mr. Qin.

Mr. Qin provided us with a written response dated 4-20-12 to the Gambol Pet Products inspection. Identified as Exhibit #46/46a is a copy of the firm's response with translation. According to the firm's response letter:

- Repair of the stainless steel totes

Corrective measures:

The firm checked all totes and repaired and replaced those which had broken bottoms and rough welds. Ten totes were replaced on 4-16-12. Included with the firm's response letter are photographs of the new totes.

- Update to the firm's food facility registration and use of the firm's food facility registration on shipping records.

Corrective measure:

The firm's food facility registration was updated on 4-18-12 (Verified)

After communication with the (b) (4) the Gambol food facility registration would be identified on new entries into the U.S.

- Issue regarding drying records

Corrective measure: The firm installed automated temperature recorders on the sterilizer ovens to provide assurance of the accuracy of temperature recordings for this operation. Attached with the firm's response are photographs and an example of a temperature recording chart which was installed.

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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

One issue was discussed with Mr. Hua Qin, president, during the inspection relating to the firm's need to update their food facility registration to reflect the firm's current operation. At the time of the inspection, the firm's food facility registration identified the firm as a manufacturer of LACF/ACF products and pet food. Mr. Hua Qin stated that the firm would update their food facility registration. An examination of the firm's food facility registration following the inspection found the firm's food facility registration has been update as promised by Mr. Qin.

One GMP deficiency was noted during the inspection relating to broken bottoms and rough welds on the stainless steel totes used to hold raw meat prior to drying. Mr. Qin provided photos of new totes which replaced the damaged totes.

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 (16 pages)
- 4/4a) List of firm's products sold to the U.S. with translation (2 pages)
- 5-19) Examples of firm's product labels (16 pages)
- 20/20a) Organizational chart with translation (2 pages)
- 21/21a) Individual responsibilities of department managers with translation (2 pages)
- 22/22a) List of attendees of opening meeting with translation (2 pages)
- 23) Business cards received (1 page)
- 24/24a) List of attendees of closing meeting with translation (2 pages)
- 25) Photographs taken of firm's operations (12 pages)
- 26/26a) List of meat suppliers with translation (12 pages)
- 27/27a) List of auxiliary ingredient suppliers with translation (2 pages)
- 28) Ingredient Input and Output Record (Glycerin Usage) (1 page)
- 29/29a) List of third party logistics trucking companies used by firm with translation (2 pages)
- 30) Drying Tunnel Temp Monitoring Record (1 page)
- 31) The heating temperature verification record of dried pet products (CCP2) (1 page)
- 32/32a) Deviation Correction Record – CCP2 (2 pages)
- 33) Moisture Content Test Record (1 page)

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- 34) Metal Detection Record (1 page)
- 35/35a) Deviation Correction Record – CCP3 (2 pages)
- 36/36a) List of desiccant suppliers with translation (2 pages)
- 37/37a) Central Laboratory of Fambros test report, report date 12-3-11, for meat supplier (2 pages)
- 38) CAIQ test report dated 4-1-12 for glycerin lot #20180388-GC (1 page)
- 39) Central Laboratory of Fambros test report, sampling date 3-5-12 for glycerin lot # (b) (4) (1 page)
- 40) Sino Analytica Certificate of Analysis for chicken jerky tenders lot # (b) (4) dated 4-12-12 (3 pages)
- 41) Sino Analytica Certificate of Analysis for chicken yam good jerky lot # (b) (4) dated 3-7-12 (3 pages)
- 42) CAIQ test report dated 4-1-12 for chicken jerky lot (b) (4) (1 page)
- 43) CAIQ test report dated 4-1-12 for chicken jerky lot (b) (4) (1 page)
- 44/44a) CIQ surveillance sampling plan for Gambol Pet Products with translation (8 pages)
- 45) Drying Tunnel Temp Monitoring Record dated 3-7-12 (2 pages)
- 46) Firm's response letter with translation dated 4-20-12 (8 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. Douppnik, Investigator


Evid Liu, Medical Research Scientist