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SUMMARY

The inspection of this pet treat manufacturer was conducted in accordance with DFFI FACTS assignment #1395223, OP ID #6054173 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 subsequent 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.

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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), FDA identified five firms for inspection. Yantai Aska Foods Co, Ltd (Yantai Aska) 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 Yantai Aska is a manufacturer of a variety of chicken jerky, duck jerky, other meat jerky products, jerky wrapped vegetable and fruit products and other chew type products. Firm management estimated that (b) (4) of their products are exported to the United States. The firm primarily exports these products to the United States under a variety of private label brands including (b) (4)

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, ingredient, product testing and shipping among others.

The inspection found one of the main constituent of the jerky treats is glycerin. The glycerin on hand at the time of the inspection was noted to be (b) (4) brand identified as USP/FCC grade. According to the firm's senior management, the firm had used this particular brand of glycerin for at least the past two years.

(b) (4)

(b) (4)

(b) (4)

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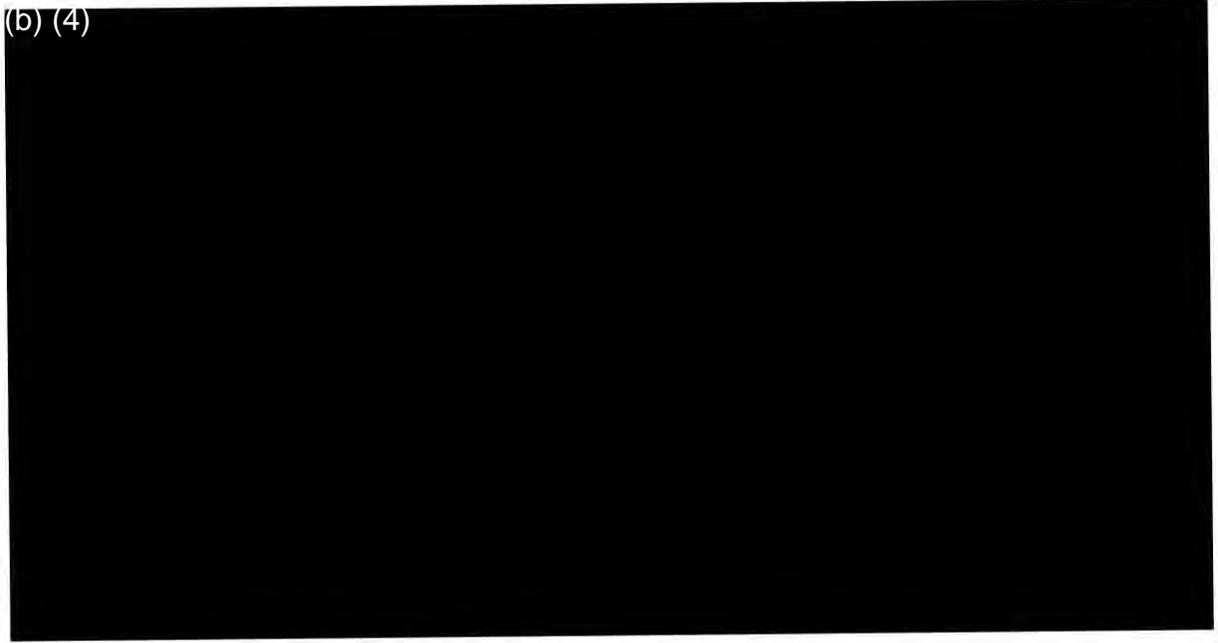
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An FDA-483 was issued to the firm's president and owner at the conclusion of the inspection which identified that until the week prior to the inspection and continuing for approximately the past two years the firm had used in part glycerin labeled as being industrial grade in the manufacture of jerky pet treat products without having assurance or verification of the safety of the glycerin as an ingredient in these products. This individual was informed that the inspection would be considered violative. Firm management was informed of the legal options that FDA could consider as a result of the inspection.

The firm's president and owner acknowledged that the observation was accurate. This individual went on to state that his concern was the impact this would have on his business.

It was suggested that management should consider submitting a written response to FDA to address any corrective actions they would take. Following the inspection, the firm's owner and two other members of the firm's staff requested to meet with us to present the firm's written response. A brief meeting was held on 4-13-12 in Liaocheng, Shandong Province, PRC where subsequent CJT inspections were being conducted. At the conclusion of that meeting, the firm's president decided that more documentation needed to be submitted to FDA. The firm subsequently provided two written responses to the FDA Guangzhou office following the meeting on 4-13-12. Copies of these responses are included with this report. According to the AQSIQ representative, AQSIQ has suspended the firm's export certificate as a result of the inspectional findings.

(b) (4)



An attempt was made to sample these products during the inspection; however, the AQSIQ representative who was present during the inspection refused to allow FDA to collect samples unless

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conditions were met which included analysis of the samples only by a Chinese laboratory and co-sealing the samples by FDA and AQSIQ. As a result of these and other conditions, no samples were collected. Meetings were held between FDA and AQSIQ to discuss the sampling issue both during and following the inspection.

Firm management also refused to provide quantitative formulation for CJT products. Following the inspection, management provided some basic formulation information on a percentage basis.

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

The firm was manufacturing plain chicken jerky and chicken jerky wraps during the inspection.

ADMINISTRATIVE DATA

Inspected firm: Yantai Aska Foods Co, Ltd
Location: No.16 Puchang Road
Laishan Economic Development Zone
Yantai,
China
Phone: 86-0535-6729598
FAX: 86-0535-6727901
Mailing address: No.16 Puchang Road
Laishan Economic Development Zone
Yantai, China

Dates of inspection: 3/28/2012, 3/29/2012, 3/30/2012
Days in the facility: 3
Participants: Dennis L. Douppnik, Investigator
Evid Liu, Medical Research Scientist

FDA's Beijing office in a letter to AQSIQ dated 3-13-12 identified five firms including Yantai Aska Foods 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. The inspection of this firm was pre-announced. This was the initial inspection of this firm.

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On arrival at the firm on 3-28-12, credentials were shown to Mr. Zhongli Hao, president and primary owner of Yantai Aska. 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 Yantai CIQ.

At the conclusion of the inspection the FDA-483 was issued to Mr. Zhongli Hao, president and primary owner, as the most responsible person for the firm.

Dr. Dou requested a pre-meeting with us prior to the start of the inspection in order to provide information on AQSIQ's surveillance program and procedures for the oversight of the Chinese pet food industry and CIQ's export certification program. Others in attendance during this meeting were:

- Dr. Congping Huang – Shandong CIQ
- Dr. Ting Yu – Shandong CIQ
- Xuelian Zheng – Yantai CIQ
- Xiantong Sun – Yantai CIQ
- Hao Wang – Yantai CIQ
- Xiaogang Li – Yantai CIQ

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

HISTORY

According to Mr. Hao, Yantai Aska Foods Co, Ltd was originally formed in 1999 during which time the firm operated as a trading company only. In 2007 the firm formed a Sino –Japanese partnership specializing in the manufacture of pet food products. Mr. Hao stated that there was no change in ownership between 1999 and 2011. Ownership change took place in 2012; however, Mr. Hao has remained the primary owner of the firm since the time the firm was formed in 1999. Identified as Exhibit #1/1a is a list of the owners and ownership changes with translation involving Yantai Aska Food Co, Ltd since the firm was established in 1999.

Mr. Hao stated that he maintains his office at the Yantai Aska facility. Any correspondence should be directed to Mr. Hao at the firm's physical address.

Mr. Hao stated that he also has ownership in the following companies:

- Yantai Zhongli Industrial & Trading Co, Ltd (100% ownership)
- Yantai China Pet Foods Co, Ltd (primary owner)
- Yantai Iris Pet Foods Co, Ltd (minority owner)

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FDA's FACTS MARCS Firm Management Services (FMS) advance database search was not available prior to the start of this inspection. A search of this database after the inspection found the following firms listed:

NAME	ADDRESS	FEI #	FFR
Yantai Aska Foods Co, Ltd.	19 Puchang Road, Laishan Yantai, Shandong Province, PRC	3009033213	none
Yantai China Pet Foods Co, Ltd	No. 8 Puchang Road, Shengquan Industrial Park, Laishan Yantai, Shandong Province, PRC 264003	3004313889	yes
Yantai Iris China Pet Food Co, Ltd	No. 7 Jieaisi Road, Laishan Economic Development Zone, Yantai, Shandong Province, PRC 264003	3007631295	yes

Mr. Hao provided the following information on these firms:

- Yantai Aska Foods Co, Ltd.
No such firm at this address according to Mr. Jiang, vice-president.
- Yantai China Pet Foods Co, Ltd
According to Mr. Hao, this firm is a pet food manufacturer which stopped selling to the U.S. during the first half of 2009. The firm primarily manufactures chicken jerky with mutton and chicken and beef canned pet food. The firm primarily sells its products to Japan, the EU, Australia, and China.
- Yantai Iris China Pet Food Co, Ltd
Mr. Hao stated that the majority investors in this company are Japanese. Mr. Hao stated that this firm has only shipped product samples to U.S customers. The firm primarily produces chicken and some duck jerky for sale in Japan and Hong Kong.

According to Mr. Hao, Yantai Aska has not purchased finished products from any other firms including the pet food processors which he has ownership in.

According to Mr. Hao, Yantai Aska operates year around. The firm operates one production/packaging shift which operates eight to ten hours per day up to seven days per week from 8:00AM until 5:00 PM (one hour for lunch). The firm operates their jerky dehydrating operation using three shifts which operate as follows:

- 12:00 AM to 8:00AM (No break)
- 8:00AM to 4:00PM (1 hour break between 11:00 AM and 12:00PM)
- 4:00PM to 12:00AM (1 hour break between 5:30PM and 6:30 PM)

The firm's office hours are 8:30AM to 5:00PM.

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The firm employs more than (b) persons. Some of these employees live in dormitories on site.

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

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

The firm holds a business license to operate from the Yantai Industry and Commerce Administration. A copy of the firm's business license with translation is identified as Exhibit #2/2a.

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 #3/3a.

INTERSTATE COMMERCE

According to Mr. Hao, the firm exports in excess of 80% of their jerky pet food treats to the U.S. The firm also exports some product to Canada. A small amount of product is also sold in China. Mr. Hao stated that the firm began exporting products to the U.S. in the second quarter of 2009. All products are shipped to the U.S. through the port of Tianjin, PRC.

JURISDICTION

According to Mr. Hao, Yantai Aska manufactures the following types of jerky or pet chew products:

- Chicken jerky (85 – 90%)
- Duck jerky (5%)
- Vegetable or fruit chews with chicken wrap (i.e. sweet potato and chicken jerky wrap) (3%)
- Chews with duck wrap (3 – 5%)
- Miscellaneous other jerky products (i.e. fish, etc) (<1%)
- Mutton and chicken jerky (<1% but never shipped to the U.S.)

Primary customers for products exported to the U.S. with examples of the product labels for each customer are as follows:

(b) (4)



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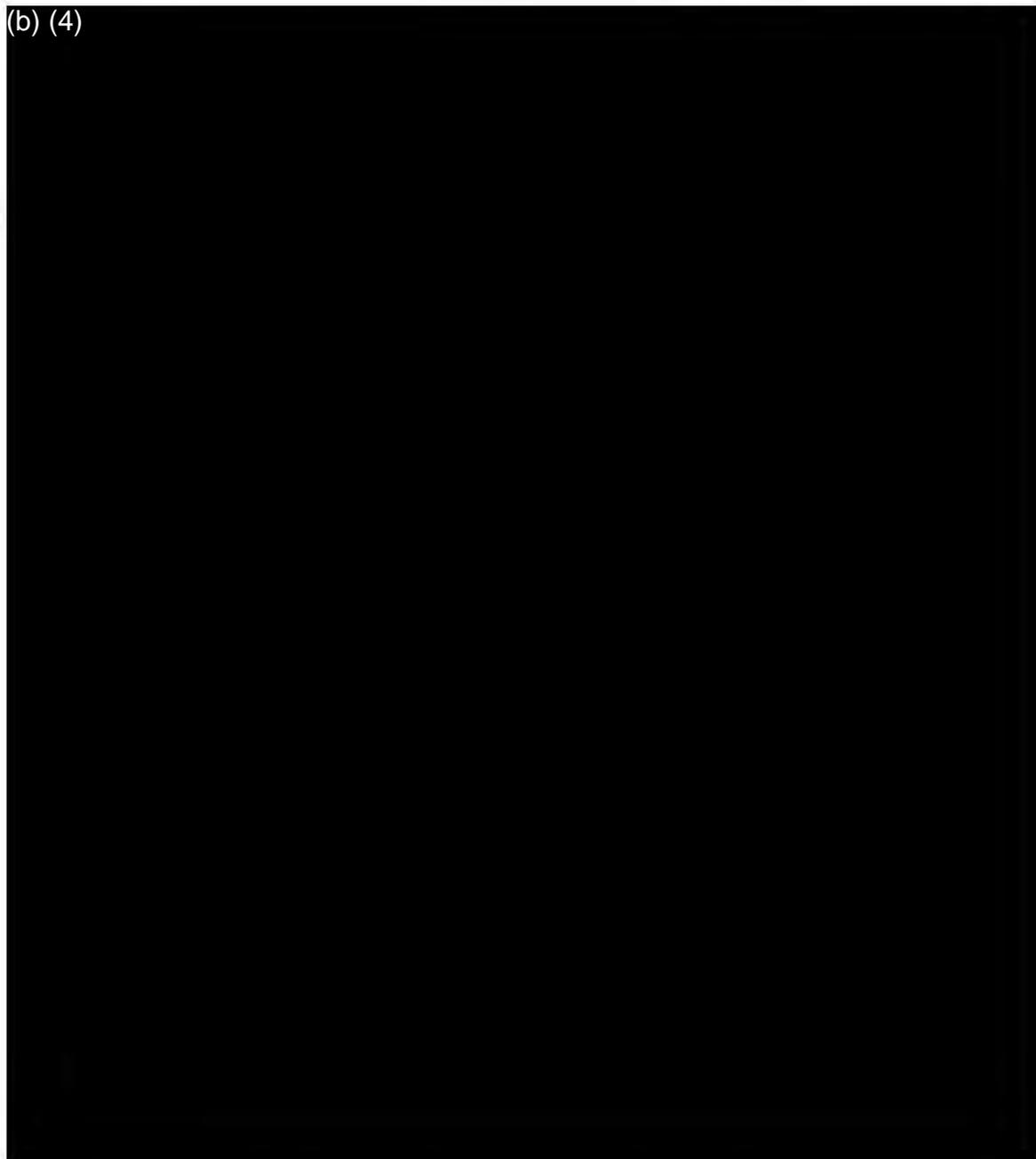
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(b) (4)



Due to the numbers of labels which are packaged by the firm, other labels for these customers will remain at the FDA Guangzhou office unless otherwise requested.

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Identified as Exhibit #27 is a customer list that identifies the labels and package sizes which are produced by this firm.

Information received from CVM prior to the start of the inspection was that this firm also manufactured CJT products under the (b) (4) [REDACTED]. Identified as Exhibit #28/28a is a statement dated 4-11-12 from Mr. Hao with translation which states his firm has not sold any pet treat products to (b) (4) [REDACTED].

All of the brands produced by this firm are private label brands with the exception of the (b) (4) [REDACTED] label which is the firm's own brand. According to Mr. Hao, the firm began marketing and exporting products under their own brand name to the U.S. in the past year.

Mr. Hao stated that all of the formulas are developed by the firm with approval of the customers. Mr. Hao stated that the firm has variations on the formulas for different brands. The reason for the different formulas is customer preference and product shape. Mr. Hao stated that there are two or three basis formulas for chicken jerky, duck jerky, chews and wrapped products. Labeling is the responsibility of the firm and the customers.

All of the firm's jerky treat products are irradiated by a contract firm before being exported to the U.S.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The most responsible individual for this firm is Mr. Zhongli Hao, president and primary owner. Mr. Hao estimated that he spends 2/3 of his time at the firm with 1/3 of his time spent traveling and marketing his firm's products. Each of the managers at this firm ultimately report to Mr. Hao. Identified as Exhibit #29/29a is an organizational chart for the firm with translation. Mr. Hao is ultimately responsible for making decisions affecting the firm since he is the primary owner.

Reporting directly to Mr. Hao is Mr. Yishan Jiang, vice president and standing deputy general manager. Mr. Jiang is the most responsible individual at the firm in Mr. Hao's absence. All senior department managers report directly to Mr. Jiang. (b) (4) [REDACTED]
(b) (4) [REDACTED]

Identified as Exhibit #30/30a is a document provided by firm management with translation which details the responsibilities of the various department heads.

An opening meeting was held with Mr. Zhongli Hao, president and primary owner, his staff, and representatives from AQSIQ and CIQ. A sign-in sheet for the persons who were present at the start

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of this meeting with translation is identified as Exhibit #31/31a. Identified as Exhibit #32 are the business cards which were exchanged with individuals at this opening meeting.

A closing meeting with held with Mr. Zhongli Hao, president and primary owner, his staff, and representatives from AQSIQ and CIQ. A sign-in sheet for the persons who were present at the conclusion of this meeting with translation is identified as Exhibit #33/33a.

Information on the firm's operations was primarily provided by Mr. Hao, president and primary owner; Mr. Jiang, vice-president; Ms. Yingbo Liu, QC manager, Ms. Hongxin Zhu, production department manager, and several other department managers. We were accompanied by Mr. Jiang, Ms. Yingbo Liu, Ms. Hongxin Zhu and other department managers and staff. We were also accompanied by Dr. Dou, AQSIQ representative, and CIQ members from the Shandong CIQ and Yantai 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.)

(b) (4)



(b) (4)



HACCP Program:

The firm has a written HACCP program for the production and packaging of jerky treat products. 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 supplier provides a self inspection certificate as to the wholesomeness of the meat and that the supplier has an animal health certificate from the Chinese regulatory authorities.

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(b) (4)

CCP 3: Metal detection for the jerky prior to packaging

Ingredient Suppliers:

Meat Suppliers:

Identified as Exhibit #35/35a is a list of the firm's suppliers of chicken and duck breast meat with translation which are used in the production of jerky. This list also includes the dates when the firm began using these suppliers.

According to Mr. Hao, 70 – 80% of chicken breast meat comes from (b) (4)

(b) (4)

Mr. Hao stated that all of the firm's chicken and duck breast meat suppliers are located in Shandong Province and neighboring Liaoning Province. The closest supplier was estimated to be approximately (b) (4) away.

(b) (4)

(b) (4)

(b) (4)

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(b) (4)



(b) (4)



(b) (4)



(b) (4)



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(b) (4)

Product Formulation:

Mr. Hao and Mr. Jiang initially refused to provide product formulation for the jerky products during the inspection. Eventually we were provided with general information in terms of ingredient percentages which are included in the (b) (4) brand of jerky products. Identified as Exhibit #38/38a is an ingredient list with translation for (b) (4) products which identifies the percentages of ingredients used in this brand of products.

(b) (4)

Mr. Jiang subsequently provided additional information on chicken jerky formulations. (b) (4)

(b) (4)

Processing of Jerky:

Photographs were taken to document the firm's operations from the receipt and storage of raw materials (meats), product mixing, processing, jerky drying and packaging. These photographs are identified as Exhibit #40.

(b) (4)

According to Mr. Jiang, once an order to produce jerky is received from their customers, the firm contacts a supplier informing them when the meat should be delivered. Meat is to be delivered between 8:00 AM and 5:00 PM any day of the week. Generally shipments of meat are received two times per week. Frozen chicken breast meat is generally received in (b) (4)

(b) (4)

Mr. Hao stated that the meat is either delivered in the suppliers' own trucks or by means of third party logistics refrigerated trucks. All meat is reportedly delivered frozen.

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The firm's QC department is notified when a supplier's truck has arrived at the freezer. A visual examination of the product is performed by QC personnel along with a check of paperwork documentation received from the supplier. We were informed that temperature indicators on the truck are examined although this is not documented. All meat received must be frozen at the time of receipt as required by the firm's HACCP program. The firm has a procedure for the routine sampling and testing of the meat by their in-house laboratory.

Following receipt of a shipment and QC confirmation, the frozen meat is moved to one of two freezers. Freezer 1 was stated to have a capacity of (b) (4) Freezer 2 was stated to have a capacity of (b) (4) Temperatures in the freezers are monitored and recorded every 4 hours according to Mr. Jiang. The critical temperature storage limit in the freezers was stated to be under - (b) (4) The temperature noted in freezer 1 and freezer 2 during our inspection on 3-29-12 (b) (4) respectively. We were informed that in the event of a power outage the firm would keep the doors of the freezers closed to prevent warming. If a power outage was greater than two hours the firm would use their back-up generator to maintain power.

Identified as Exhibit #40, Photo #1 is a picture of cartons of frozen chicken breast stored in freezer 1. According to Mr. Jiang, the cartons of meat remain in a freezer around one week. Mr. Jiang stated the longest meat would remain in the freezers is around three weeks.

Thawing:

Prior to processing into jerky, the cartons of meat are removed from the freezers and are taken to a room at Yantai Aska for temporary frozen storage in the firm's own trucks. According to Mr. Jiang, the firm's uses refrigerated trucks to move the product from the freezers to their temporary frozen storage room. We asked to see the firm's trucks but were told they were not at the firm during our inspection.

The meat remains in the temporary frozen storage room for (b) (4) hours for tempering. The temperature in this room at the time of our visit on 3-29-12 was noted to be (b) (4) Identified as Exhibit #40, Photo #2 is a picture of cartons of chicken breasts which were stored in the tempering room during our inspection.

Following tempering, the cartons of chicken or other meat products are moved to an adjoining room. The cartons are opened and the center temperature of the packages of meat within these cartons is checked. The temperature of the meat (b) (4)

(b) (4)

(b) (4)

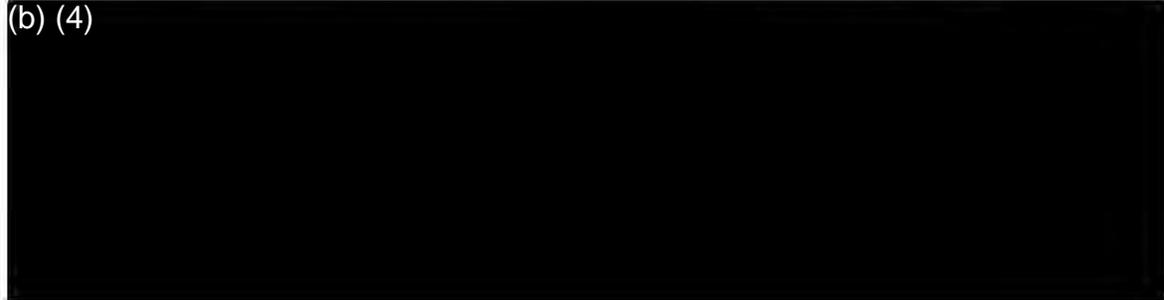
Mr. Jiang declined to provide us with the name of the microwave unit manufacturer citing this information as a trade secret. Identified as Exhibit #40, Photo #3 is a picture of bags of chicken tenders (b) (4)

(b) (4)

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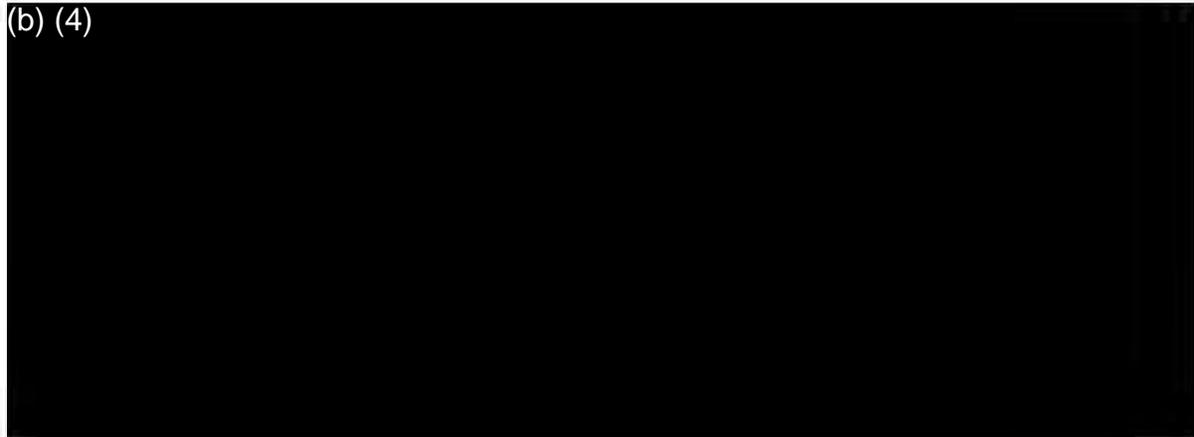
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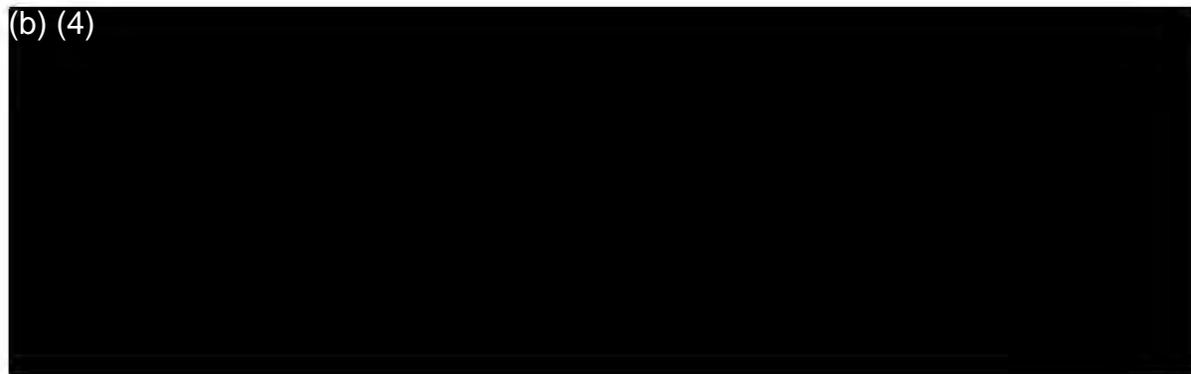
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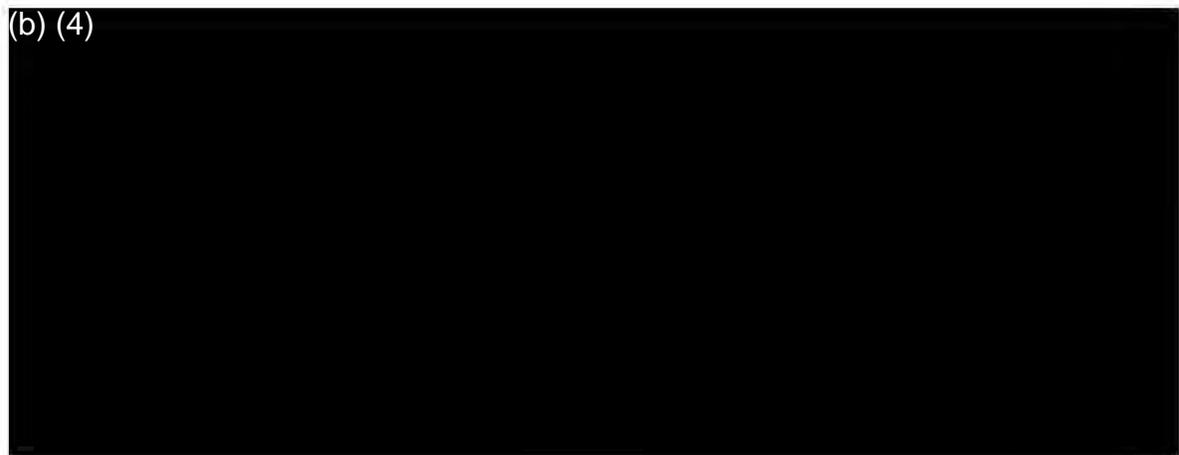
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(b) (4)



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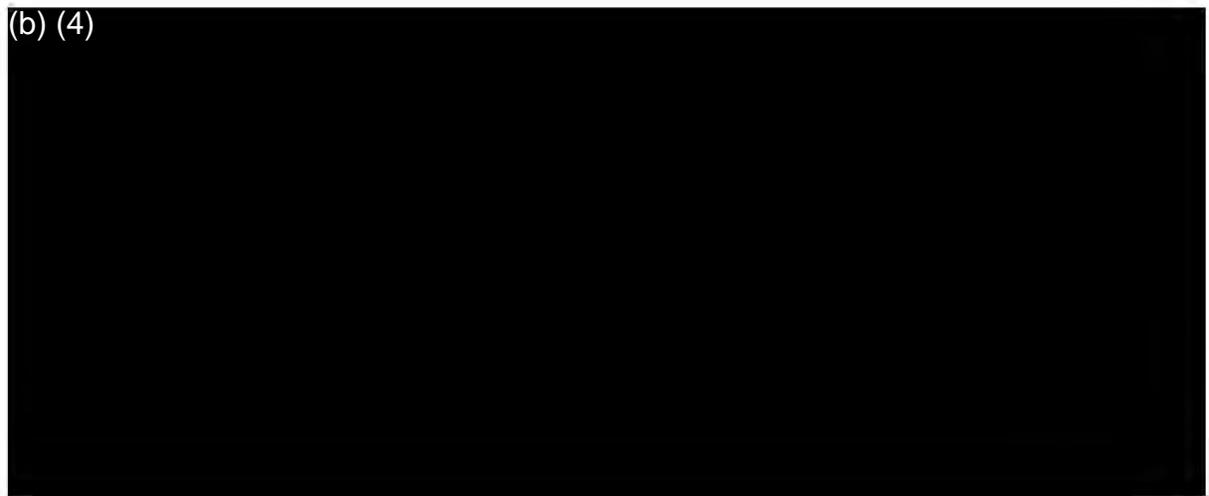
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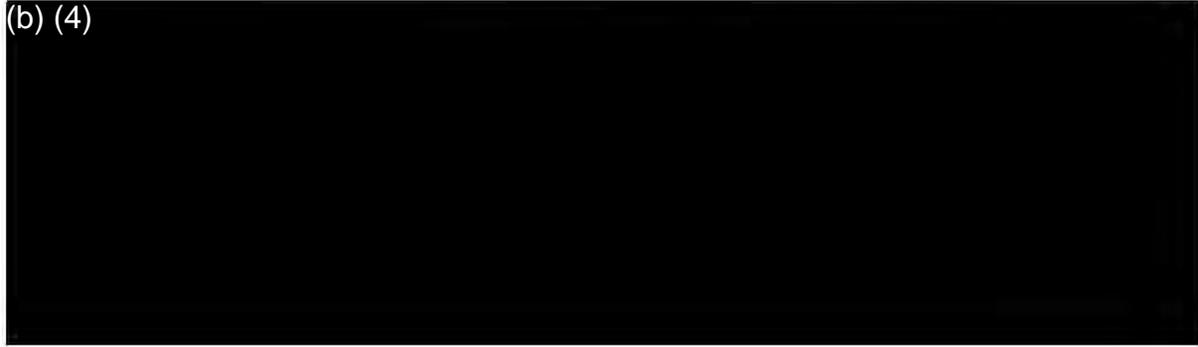
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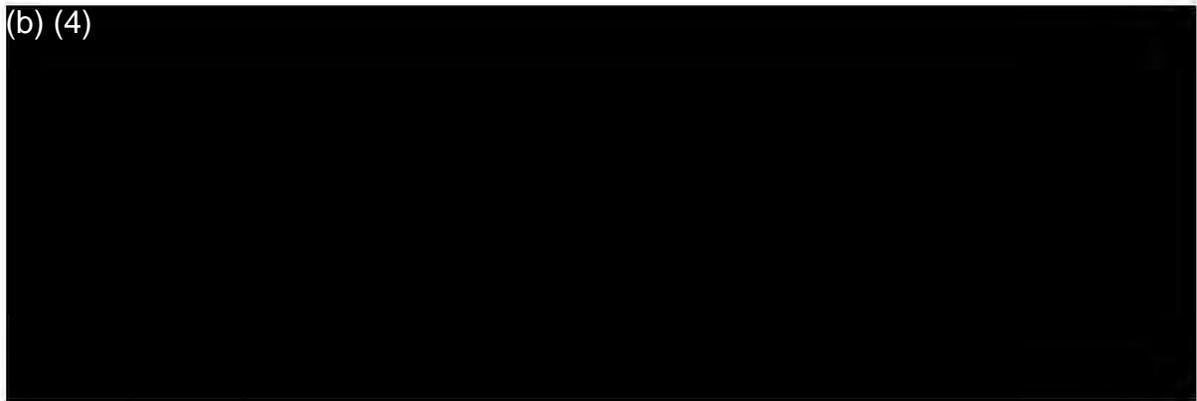
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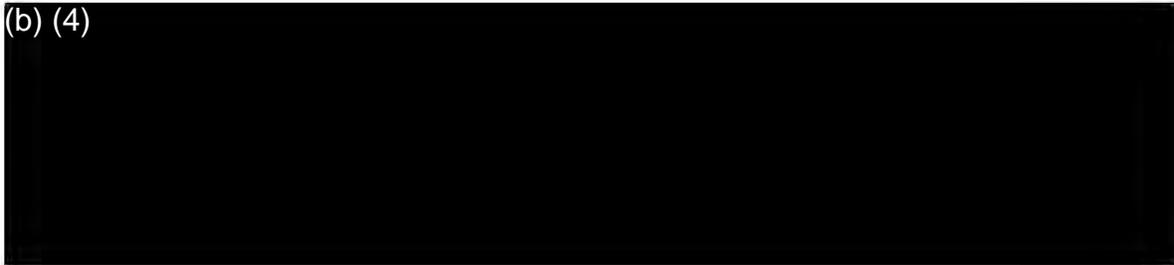
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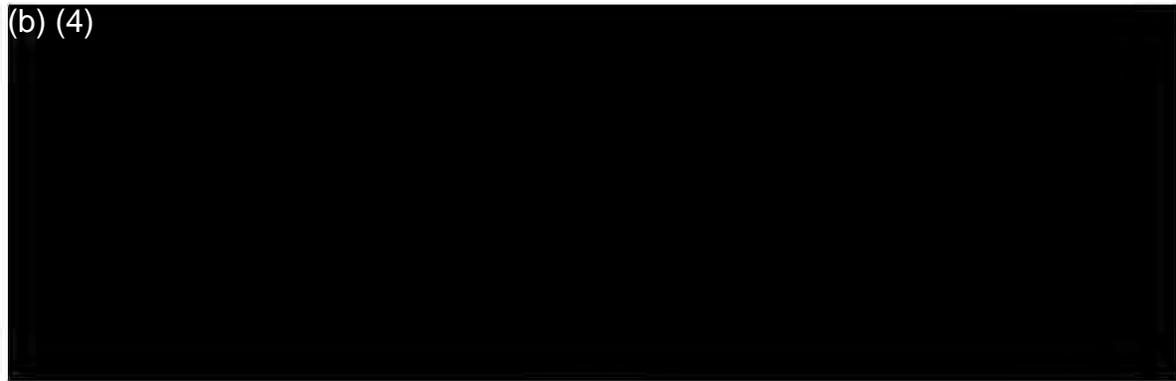
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We were informed that these testing specifications are based on the Chinese national standards.

We verified that the firm had finished product test records available from at least January 2011 to February 2012 in the laboratory. Testing records for March 2012 remained at the QC department at Yantai Aska.

We reviewed finished product microbiological testing records for January 2011 and December 2011 during the inspection. No problems were noted.

Physical and Chemistry Laboratory:

We were informed that the firm tests some of the auxiliary ingredients (no raw meats) as well as the finished product. Finished products are tested for crude protein, fiber, lipid content (fat), ash and moisture. The firm also tests finished jerky products for water activity on customer request. Testing records were reviewed for January 2011 during the inspection. No problems were noted.

(b) (4)

Third Party Testing:

Management was requested to provide any records which they had for the testing of glycerin which was used in the manufacture of the jerky. According to Mr. Jiang, the firm had one report documenting the testing of glycerin for heavy metals; however, no testing was ever performed on the glycerin for glycol analysis. Identified as Exhibit #44 is a copy of a test report from (b) (4) dated 7-12-10 documenting heavy metal testing of glycerin which was manufactured by (b) (4). As noted on this report, testing was performed for lead (b) (4)

(b) (4)

To Mr. Jiang's memory, the firm had provided around 10 finished product samples to (b) (4) (b) (4) starting in November 2011. Mr. Jiang provided two such reports for the finished product testing of chicken jerky (b) (4). These reports were dated 11-18-11 (Exhibit #45) and 12-15-11 (Exhibit #46) respectively. Results were as follows:

Report dated 11-18-11 (Exhibit #45)

(b) (4)

Report dated 12-15-11 (Exhibit #46)

(b) (4)

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Mr. Jiang stated that he would look for other reports of finished product testing; however, he did not provide any other test reports for our review by the conclusion of the inspection.

Mr. Jiang stated that he heard that FDA was looking at glycerin use in the jerky products as a possible cause for the illnesses and deaths in dogs. Mr. Jiang stated that the firm had looked for third party testing laboratories which could test the finished product for glycol levels. Mr. Jiang stated that the firm did not find any such laboratories that were able to perform this testing.

Sanitation:

The firm has procedures in place for the cleaning of the workshop, equipment and utensils which are used in the manufacture of jerky products. Employees working in the semi-clean and clean processing areas of the workshop are required to comply with sanitation procedures.

Employees and visitors to the workshop are required to wear hair covers, mouth and nose covers, captive outerwear and captive boots. Identified as Exhibit #40, Photo #25 is a picture of the garments which must be worn prior to entering the workshop.

Prior to entering the workshop, persons are required to wash their hands with soap and water followed by hand sanitizing using sodium hypochlorite (i.e. bleach) solution for 30 seconds in a hand dip station. According to the firm, the hand dip sanitizer is changed in the hand dip station every two hours. The solution in the hand dip station is reportedly maintained at 50 – 100 ppm. The strength of the sodium hypochlorite when tested by me on 3-29-12 was found to be 100 ppm.

Prior to entering the workshop, persons are required to step through a sanitizing boot dip containing sodium hypochlorite which is maintained at 200 ppm. The strength of the sanitizing solution when tested by me on 3-29-12 was found to be 200 ppm. We were informed that the boot dip solution is changed twice per day at the beginning of each shift and the lunch break,

Upon entering the processing area, persons are required to spray their hands with 75% alcohol.

Employees handling the product are not required to wear gloves. We were informed that a production supervisor checks employees' hands for any cuts or scraps. Employees having cuts, scraps or other issues which could compromise the product are assigned to another job where they do not handle the product or they are required to take the time off until they have healed.

We were informed that cleaned uniforms are provided to the employees by the firm each day. Employees' uniforms are cleaned by the firm.

The firm has a separate cleaning crew who perform cleaning operations. Workstations are cleaned and sanitized with sodium hypochlorite every two hours. Trays, racks and other utensils are cleaned

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throughout the day. Floors, walls, and other workshop areas are cleaned and sanitized at the end of each shift.

MANUFACTURING CODES

The firm has developed their own coding system for products which can be used to trace products back to their suppliers. This includes the coding of incoming raw materials (meats) and auxiliary ingredients as well as finished products. Identified as Exhibit #47/47a is a breakdown of the firm's coding system for ingredients and finished products with translation.

All of the firm's products are identified with both a customer code as well as a production code. An example of the firm's coding for finished products is as follows:

AJ08812 H088E2B3

AJ08812: customer code

H: year (year ending in 5 = F; years ending in 1 and 6 =G; year ending in 2 = H; years ending in 3 and 8 = K; years ending in 4 and 9 = L)

088: Julian date of packaging

E2B3: code combination for chicken/duck suppliers

- E: meat supplier ID
- 2: type of main ingredient (2 = large chicken breast)
- B: year received (1,6 = A; 2,7 = B; 3,8 = C; 4,9 = D; 5,0 = E)
- 3: number of shipments in year from that supplier

We were informed that the majority of product containers also include a use-by-date of 18 months which is based on microbiological testing performed on the products by the firm.

COMPLAINTS

The firm has a procedure in place for the receipt and investigation of complaints. The firm's sales department is responsible for documenting any complaints which are received from customers. Complaints are then forwarded to the firm's QC department for any investigation performed. According to Yingbo Liu, QC Manager, the firm has received one complaint relating to the CJT issue.

The firm received a complaint involving an illness in a dog dated 12-6-11 from (b) (4) (b) (4) which was produced and packaged in July 2011. According to the complaint investigation, the firm reviewed processing and testing records and found no problems. The firm's investigation records identified reserve samples for the suspect lot were available; however, another lot which used the

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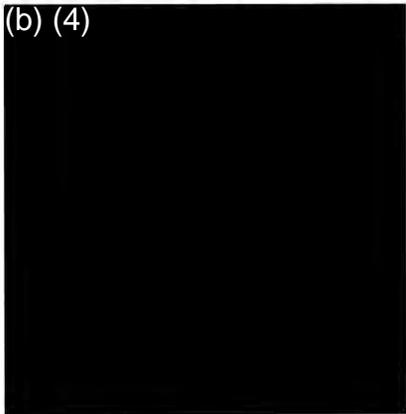
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same formula was tested and no problems were found. The investigation concluded that excessive feeding was the cause of the problem.

According to a CVM database query dated 3-21-12, the following numbers of complaints have been received relating to the CJT product issue:

(b) (4)



It is not known whether all of the products under these brands were produced by Yantai Aska or other firms.

A check of FDA's FACTS database found a total of (b) (4) complaints involving this firm. All related to the CJT issue. The first complaint in this database was received on 11-9-11. The last complaint was received on 4-17-12. (b) (4) of the complaints involved the (b) (4) brand involving chicken jerky treats (b) (4) and sweet potato and chicken jerky (b) (4) (chicken fillet jerky treats).

RECALL PROCEDURES

According to management, the firm has not been involved in any recalls to date. The firm stated that they have not had any import refusals to their knowledge.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

One observation was identified on the FDA-483 which was issued to Mr. Zhongli Hao, president and primary owner of the firm.

- 1) **Your firm acknowledged that until last week and continuing for approximately the past 2 years your firm used in part glycerin labeled as being industrial grade in the manufacture of jerky pet treat products. Your firm has no assurance or verification of the safety of this glycerin as an ingredient in jerky pet treat products.**

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Supporting Documentation:

We visited the firm's ingredient storage room on the first day of the inspection in order to document the ingredients which were being used in the manufacture of jerky products. One of the ingredients in this storage room was observed to be (b) (4)

(b) (4) manufacturing date: FEB 2, 2012. The labeling on the drums identified the country of origin as Kuantan, Malaysia. Identified as Exhibit #40, Photo #26 is a picture of the 13 drums of (b) (4) which were in the firm's storage room. Identified as Exhibit #40, Photo #27 is a picture of the labeling for the glycerin. According to Mr. Jiang, the firm had used (b) (4) in the manufacture of jerky products for at least the past two years.

On the second day of the inspection, we asked Mr. Jiang to provide us with the receiving records for glycerin for the past two year in order to verify the source of the glycerin used by the firm. In addition, we requested to be taken to the location at the firm where these records were kept in order to review them.

Mr. Jiang expressed reluctance to take us to this office. When pressed as to the reason for his hesitation, he initially stated that the employees were on lunch break. When we continued to request to go to this office, Mr. Jiang stated that the person in charge of procurement, Mr. Xuejing Cui – Manager of Procurement who handled these records, was traveling and was unable to be contacted. Mr. Jiang went on to state that others in the procurement department did not know where Mr. Cui kept these records.

We then pointed out that Mr. Jiang oversaw the firm's procurement department and it seemed unlikely that neither he nor others would have access to or knowledge of these records when Mr. Cui was away. Shortly thereafter Mr. Jiang returned and provided us with records which he said were the receiving records for the lots of glycerin we requested.

The records provided by Mr. Jiang identified the firm's receipt of (b) (4) which were received on seven different dates from 2-9-11 to 3-15-12. Documents provided by Mr. Jiang for each shipment of glycerin received included a receiving record, a record identifying the results of testing performed by the firm and a corresponding COA. Copies of these records are identified with the EIR as follows: (Note: Only the first copy of the receiving record and testing record dated 2-9-11 have been translated, all other receiving records and testing records have not been translated since the headings are the same on all of these documents.)

- Date of receipt: 2-9-11
 - Receiving record dated 2-9-11 (Exhibit #48a)
 - Translated copy of the receiving record (Exhibit #48b)
 - Testing record dated 2-9-11 (Exhibit #48c)
 - Translated copy of testing record dated 2-9-11 (Exhibit #48d)
 - COA for glycerin lot received on 2-9-11 (Exhibit #48e)

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-
- Date of receipt: 3-9-11
Receiving record dated 2-9-11 (Exhibit #49a)
Testing record dated 2-9-11 (Exhibit #49b)
COA for glycerin lot received on 2-9-11 (Exhibit #49c)
 - Date of receipt: 3-31-11
Receiving record dated 2-9-11 (Exhibit #50a)
Testing record dated 2-9-11 (Exhibit #50b)
COA for glycerin lot received on 2-9-11 (Exhibit #50c)
 - Date of receipt: 4-28-11
Receiving record dated 2-9-11 (Exhibit #51a)
Testing record dated 2-9-11 (Exhibit #51b)
COA for glycerin lot received on 2-9-11 (Exhibit #51c)
 - Date of receipt: 6-3-11
Receiving record dated 2-9-11 (Exhibit #52a)
Testing record dated 2-9-11 (Exhibit #52b)
COA for glycerin lot received on 2-9-11 (Exhibit #52c)
 - Date of receipt: 9-2-11
Receiving record dated 2-9-11 (Exhibit #53a)
Testing record dated 2-9-11 (Exhibit #53b)
COA for glycerin lot received on 2-9-11 (Exhibit #53c)
 - Date of receipt: 3-15-12
Receiving record dated 2-9-11 (Exhibit #54a)
Testing record dated 2-9-11 (Exhibit #54b)
COA for glycerin lot received on 2-9-11 (Exhibit #54c)

As we reviewed these records we noticed that the glycerin lot number identified on the COA's for each shipment was the same for each of the firm's (b) (4) shipments which were supposedly received from 2-9-11 through 3-15-12. This was lot (b) (4). Although lot # (b) (4) was identified on each of the (b) (4), the COA's identified four different dates of manufacturing for this lot. In addition, each of the COA's for glycerin lot (b) (4) identified that the lot consisted of a total of (b) (4) while the total weight identified on the firm's receiving records for these (b) (4) shipments of glycerin was in excess of (b) (4) (4).

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Date of Receipt	Amount Received	COA lot#	Date of lot manufacture
	(b) (4)		
2-9-11			January 31, 2011
3-9-11			January 31, 2011
3-31-11			January 31, 2011
4-28-11			February 27, 2011
6-3-11			February 27, 2011
9-2-11			July 17, 2011
3-15-2012			February 02, 2012

These discrepancies were pointed out to Mr. Jiang and he was requested to explain how this could be. At the same time, these discrepancies were also pointed out to Dr. Dou, the AQSIQ representative, and he also asked Mr. Jiang for an explanation.

(b) (4)

(b) (4)

(b) (4)

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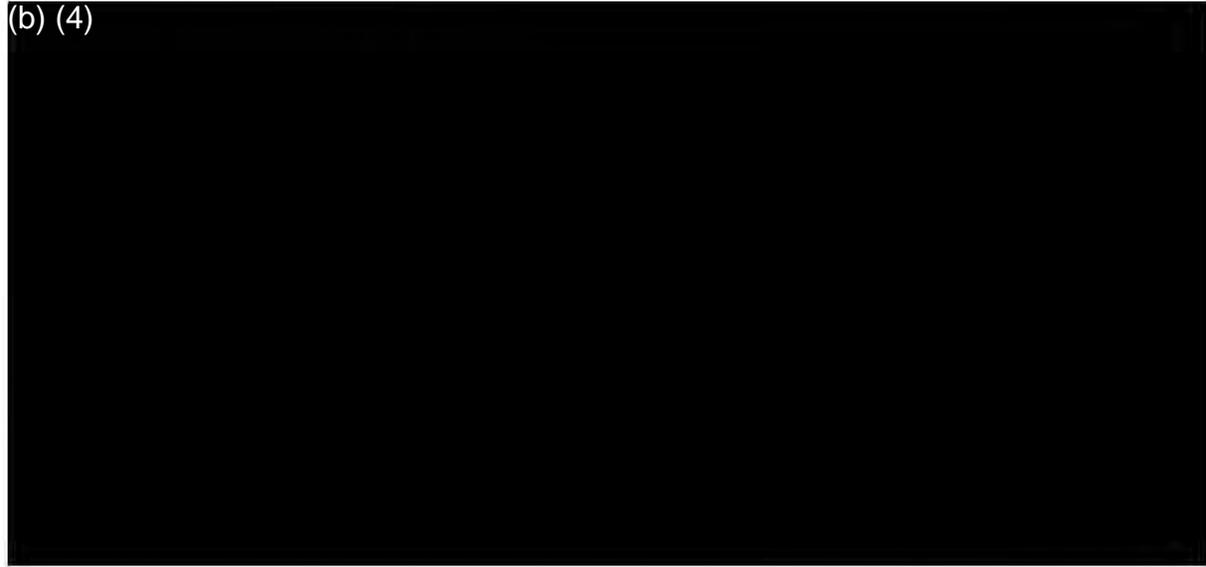
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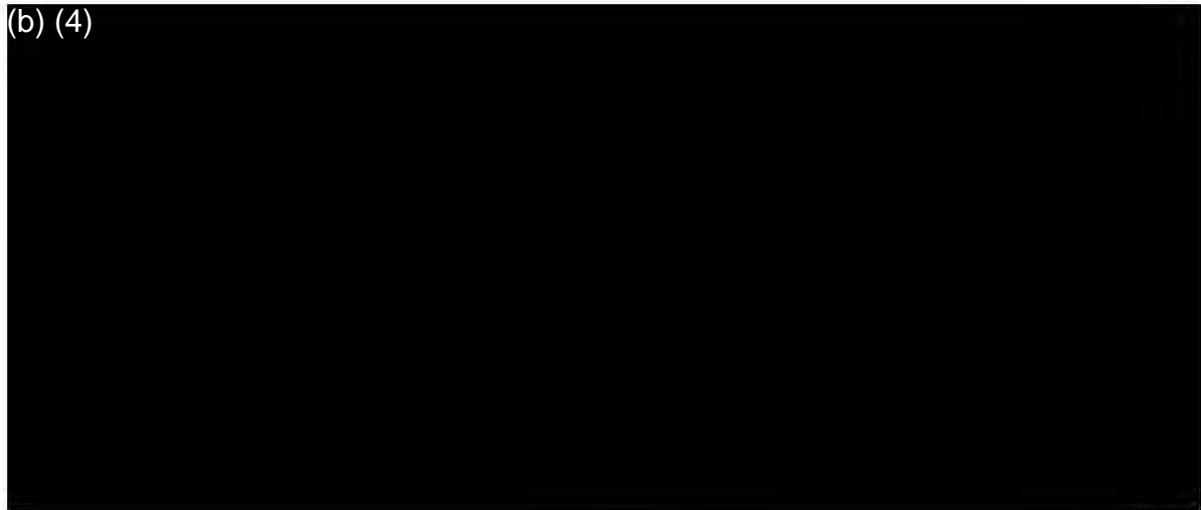
I questioned whether the firm had ever conducted any testing on the glycerin to verify it was food grade. Mr. Jiang acknowledged that the firm had not done any such testing. Mr. Jiang then asked that I not include this incident in my report.

(b) (4)



A meeting was held the next morning which was the last day of the inspection. At that time we were informed that Mr. Hao would be present as he had cancelled his meeting in Japan due to the seriousness of this issue. In attendance during this meeting were Mr. Hao; Mr. Jiang; members of the firm's management staff; Dr. Dou from AQSIQ; and the CIQ representatives.

(b) (4)



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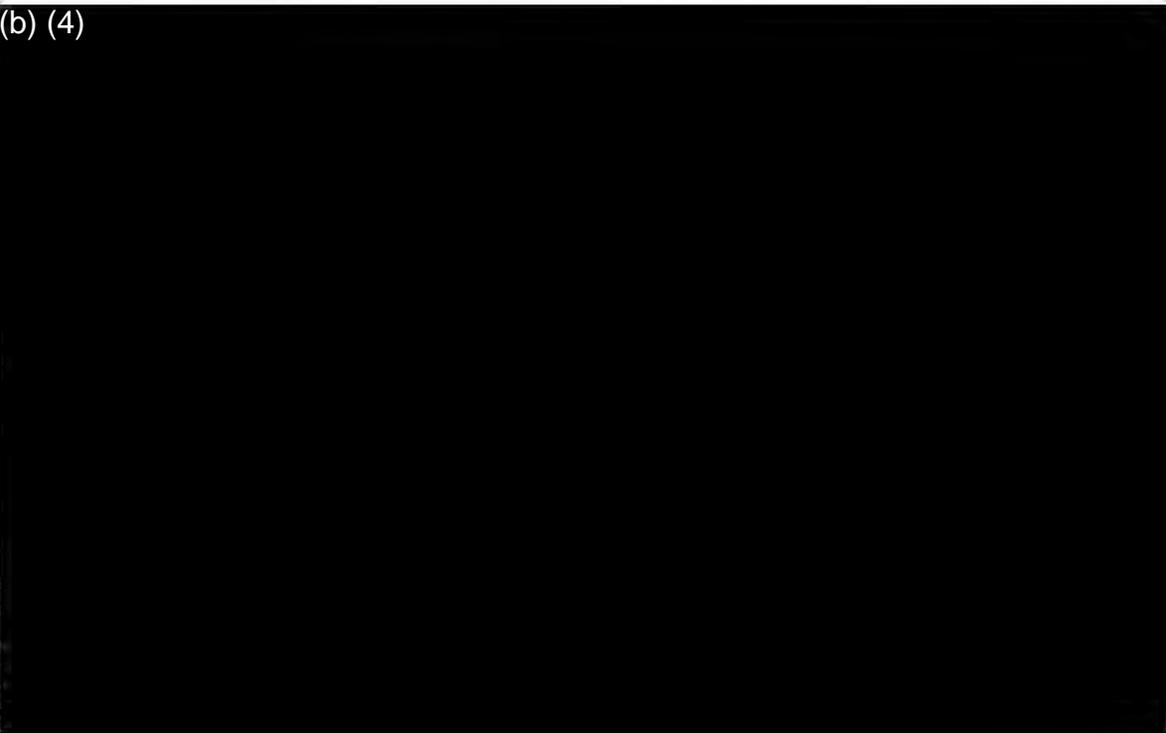
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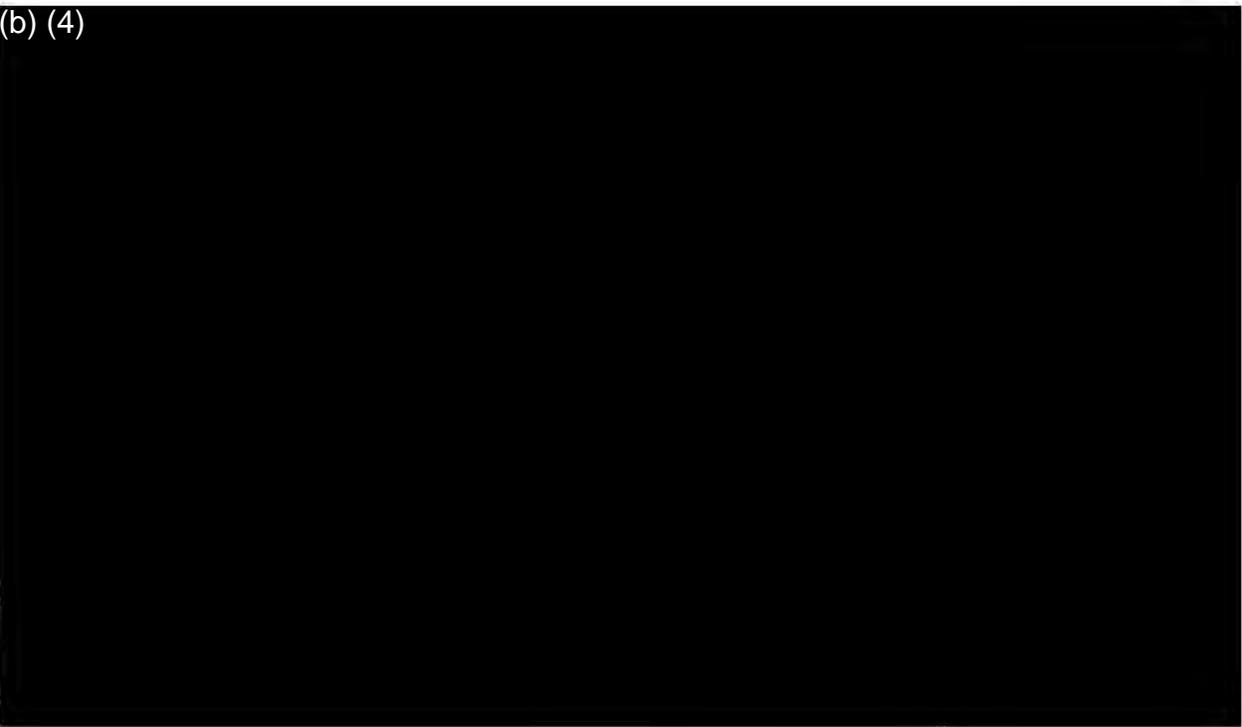
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(b) (4)



(b) (4)



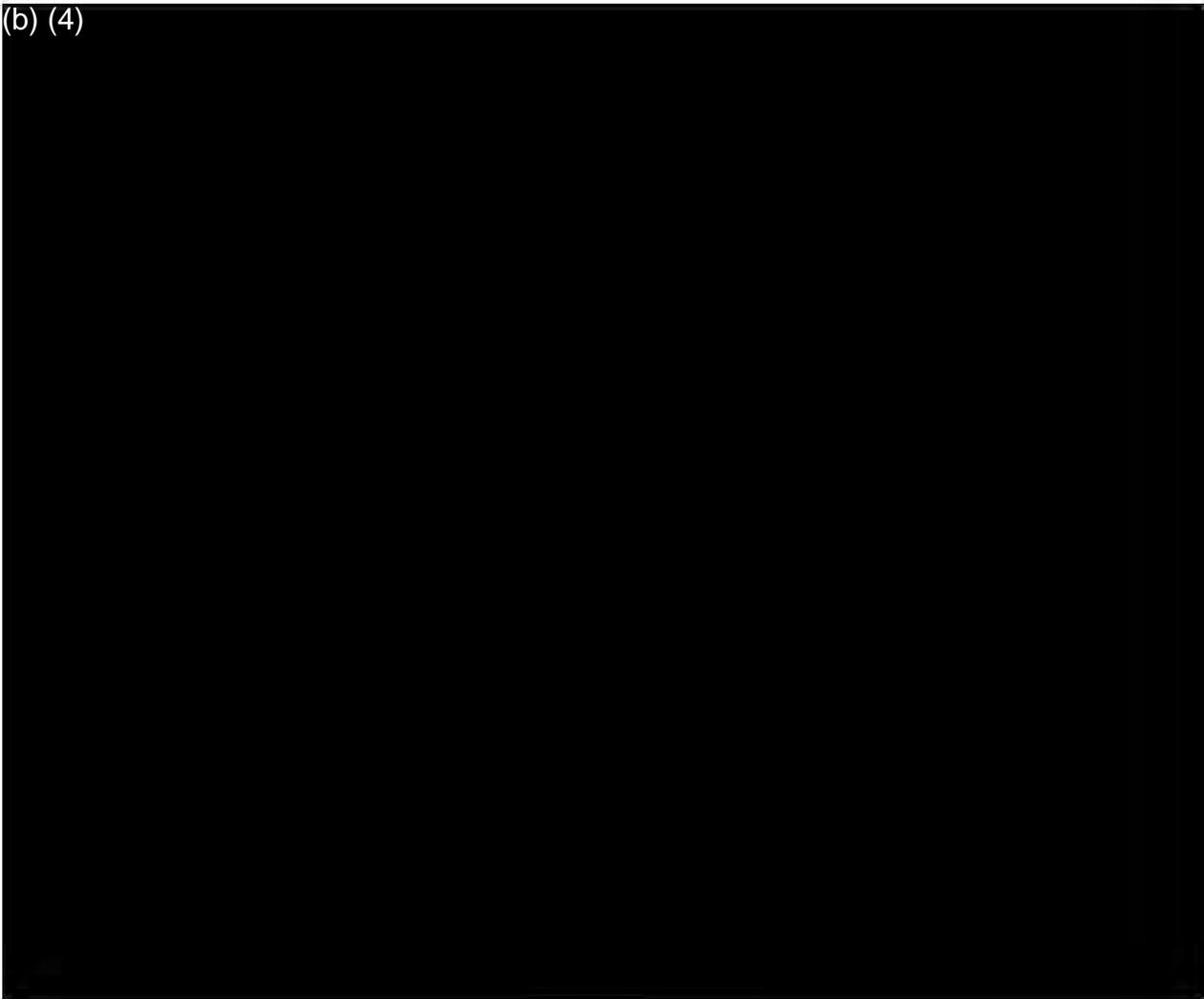
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(b) (4)

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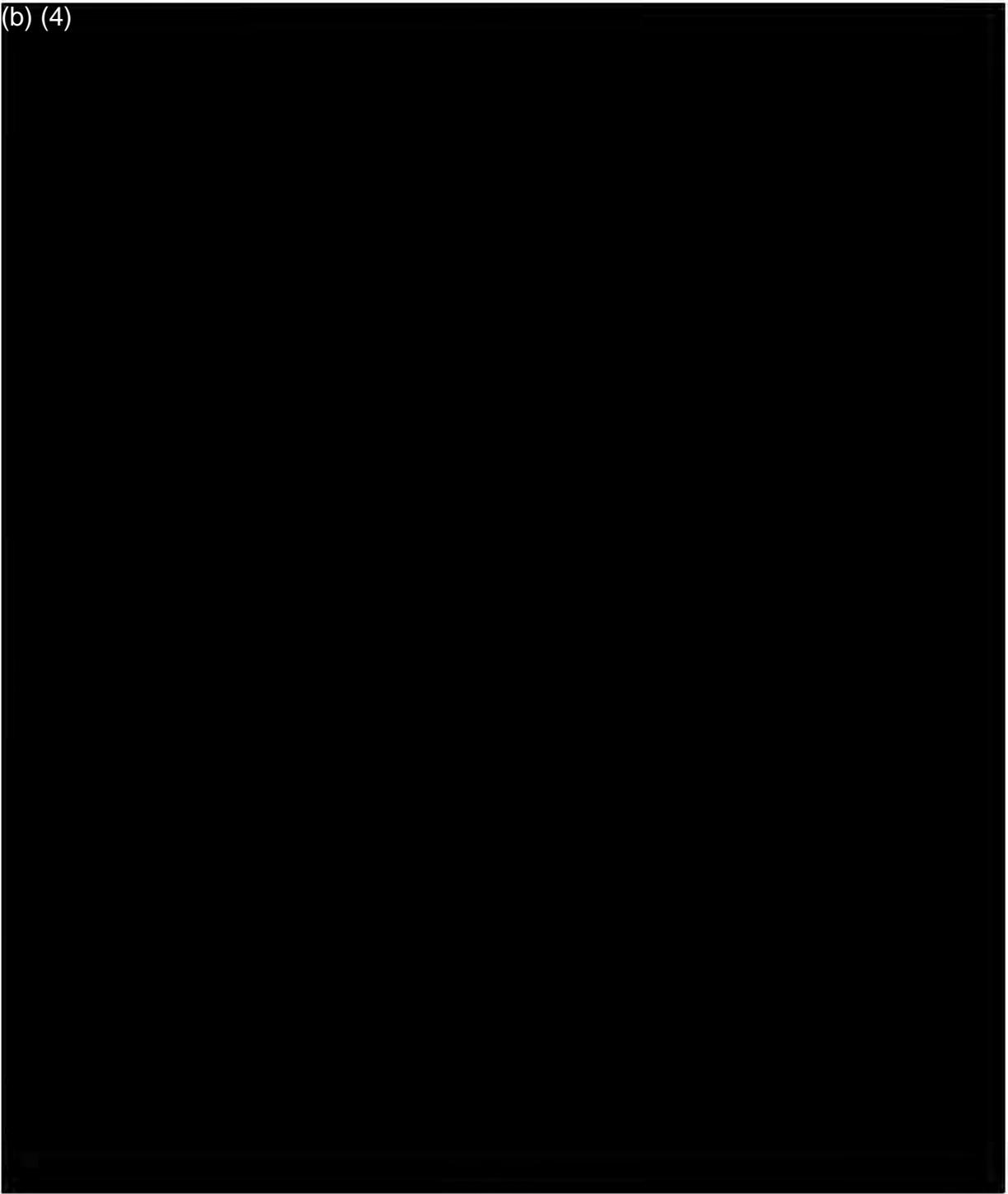
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(b) (4)



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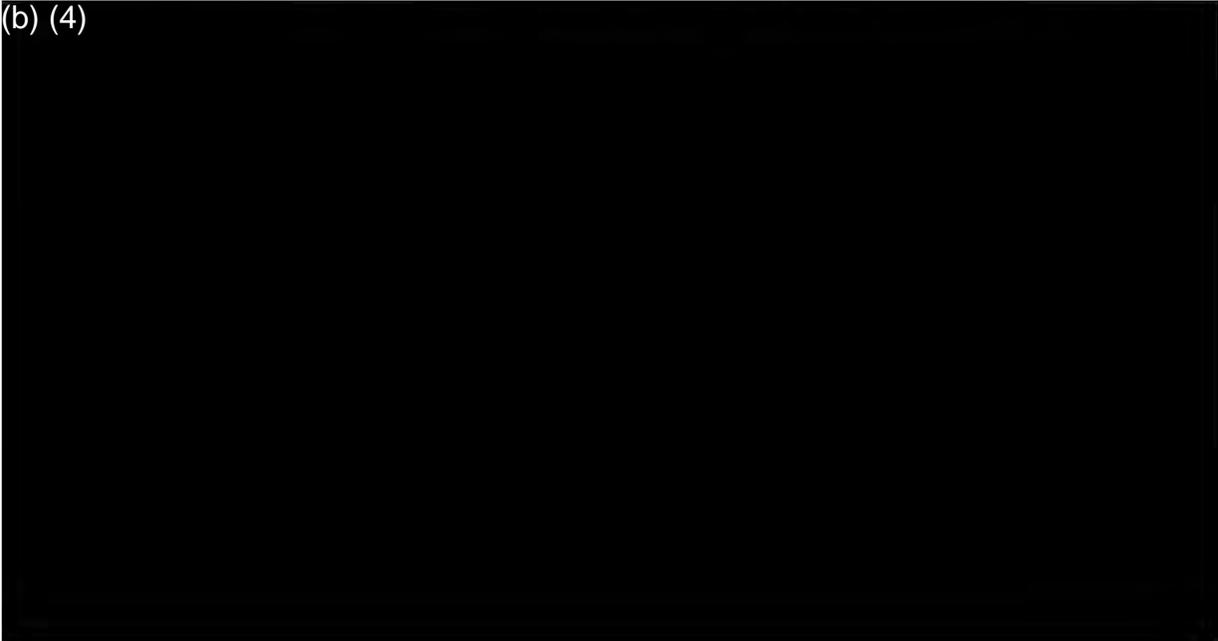
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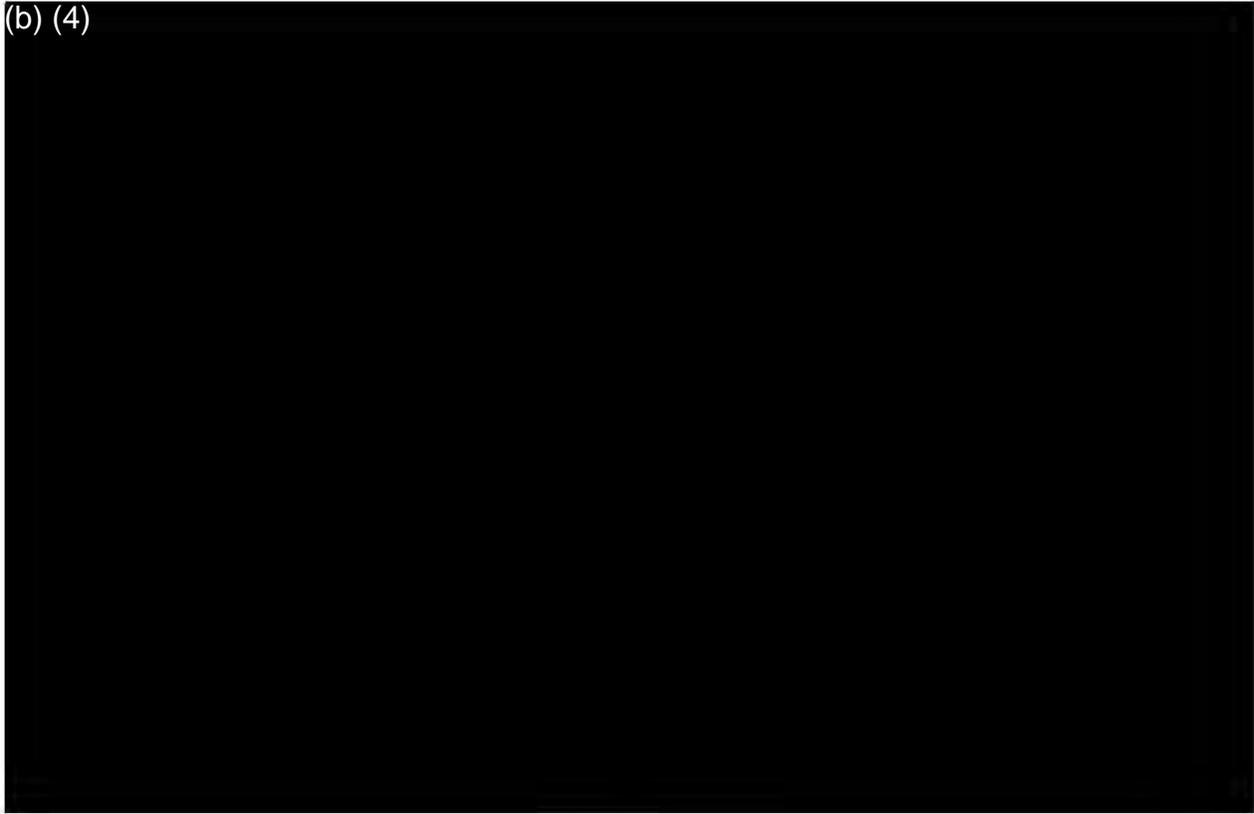
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(b) (4)



(b) (4)



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(b) (4)

(b) (4)

I informed Dr. Dou that my instructions were that AQSIQ could collect and analyze any parallel samples which FDA collected; however, the FDA samples were to be submitted to an FDA laboratory for analysis. I also explained FDA's method for the collection of samples and the chain of custody procedures we use to seal the samples.

Dr. Dou acknowledged that if the samples were analyzed scientifically by both AQSIQ and FDA, the results should match; however, he insisted that the reason that all samples must be analyzed in a CIQ laboratory was the issue of national sovereignty. Dr. Dou then requested that I contact FDA management to explain AQSIQ's proposal.

I subsequently telephoned Dr. Christopher Hickey, FDA's China Country Director in Beijing, and informed him of Dr. Dou's sampling and testing demands. After my conversation with Dr. Hickey, I informed Dr. Dou that others in our agency would decide whether or not FDA would agree to the AQSIQ demands.

Dr. Dou suggested that both AQSIQ and FDA could double seal the samples to ensure the integrity of the samples. Dr. Dou then slightly changed his demand and stated that the samples must be analyzed in China; however, the samples could be analyzed in a CIQ laboratory or a third party laboratory.

Dr. Dou closed our portion of the meeting by stating that he felt AQSIQ and FDQ should collect the finished product samples before the sampling issue was resolved. Dr. Dou stated by later that day, he

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should have some answers as to where the samples could be analyzed. Dr Dou also stated that he would leave it to the firm to decide whether they would allow samples to be collected.

Mr. Hao stated that the firm had confidence of the safety of their products. Mr. Hao's suggestion was that AQSIQ and FDA collect at least five units of the finished product, both agencies' seal the sample collected and then leave the sample at the firm until the issue could be resolved between AQSIQ and FDA.

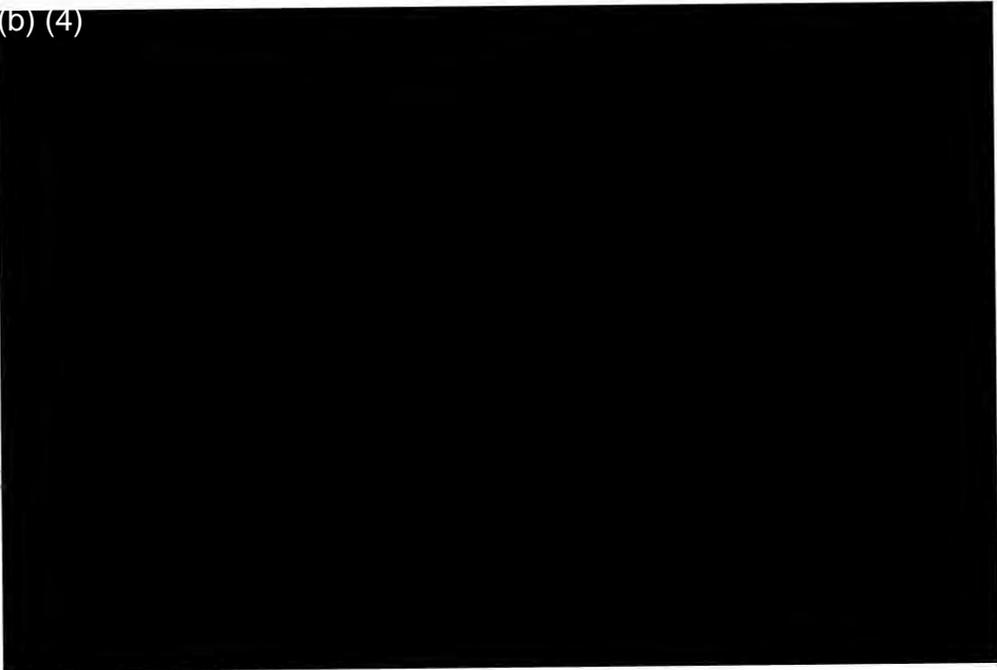
I explained that I could not agree to this proposal. I further stated that I was aware that the FDA China office was meeting with their AQSIQ counterparts in Beijing regarding this issue. It was at this time that I received word to contact Ms. Sema Hashemi, FDA Acting Deputy Country Director in Beijing. During my conversation with Ms. Hashemi, it was agreed that FDA could not agree to the AQSIQ sampling proposal although I would determine what finished products remained in the firm's warehouse which were made in part using the (b) (4)

Finished Products Made in Part Using (b) (4)

Mr. Hao and Mr. Jiang provided me with a list of finished products remaining at the firm which were made in part using the (b) (4). A copy of this list with translation is identified as Exhibit #78/78a.

We subsequently visited the firm's storage room to verify what finished products were on hand that were made using the (b) (4). We took an inventory of the products on hand. These were:

(b) (4)



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(b) (4)

Following the inspection, Dr. Dou reported that AQSIQ had suspended the firm's export certificate and these (b) (4) lots of finished products remain at the firm.

Discussion with Management:

(b) (4)

Mr. Hao stated that the observation identified on the FDA-483 was accurate. Mr. Hao stated his concern was with the impact any legal action taken by FDA as a result of this inspection would have on his business. Mr. Hao stated that he firm had records documenting the analysis of finished product for heavy metals and melamine and he requested that information also be included on the FDA-483.

I informed Mr. Hao that placing that information on the FDA-483 was not appropriate; however, I would include that information in the inspectional report that I would write.

REFUSALS

Two refusals were made during this inspection. These were:

- A refusal made by Mr. Hao, president and owner of the firm, and by Mr. Jiang, vice-president, to provide quantitative formulation for the manufacture of jerky products.
- A refusal to allow the collection of samples unless FDA agreed to specific conditions which was made by Dr. Dou, the AQSIQ representative who observed the inspection.

Refusal to Provide Formulation:

Mr. Hao eventually provided some limited information relating to formulation following the inspection. This information related to percentages of certain ingredients relating to (b) (4) jerky products (Exhibit #38/38a) and formulation changes made to the (b) (4) jerky products

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(Exhibit #39/39a). Mr. Hao and Mr. Jiang also provided some basic information on the percent of glycerin added to all of the firm's products.

Refusal to Allow Sampling:

I had informed Mr. Hao and Dr. Dou near the end of the first day of the inspection that my intent was to collect samples of ingredients on the second day of the inspection. As such, I arrived at the firm on the second day of the inspection with my sampling supplies.

When Dr. Dou saw my sampling supplies, he requested a meeting involving only himself, the CIQ representatives, Evid Liu and me. Dr. Dou began the meeting by stating that sample collection was never discussed between FDA's China office and AQSIQ officials in Beijing during the discussion of FDA's inspections of the CJT manufacturers. Dr. Dou stated that it was AQSIQ's understanding that FDA's evaluations of the CJT firms were to be visits and not inspections. Dr. Dou felt that FDA should pay more attention to AQSIQ's evaluations of these firms. Dr. Dou also stated that his agency did not believe that our sample collection was in accordance with international protocol in that any sampling performed by FDA infringed upon the sovereignty of the Chinese government.

Dr. Dou then made a number of points as to why sampling should not be done by FDA during these inspections. These were:

- Co-operation between our agencies should be based on trust.
- There was no agreement between China and the U.S. to allow FDA to sample during inspections.
- Sample collections would not be helpful to this investigation.
- There was no evidence to link CJT products to the sickness of animals in the U.S.
- Sample collection would be misunderstood as a way of developing evidence against the CJT manufacturers.
- If there was a problem with the CJT products, we should first look for the problem in the finished products when they entered the U.S.
- Even if there was a substance in an ingredient which was causing the problem, we should first verify that it could be detected in the finished product.
- Collecting a sample would not be the most effective way of determining a problem since there were multiple steps in the manufacture of these products.

Dr. Dou finished by stating that if he was investigating this issue, he felt the most effective and efficient method would be to sample the finished product in the marketplace to verify there was an actual problem first. Dr. Dou stated that if FDA sampled an ingredient and something was found, the investigation could lead to another source which could result in misunderstanding by the U.S. public and press.

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I explained to Dr. Dou and the CIQ representatives that I was not present at the meeting between AQSIQ and FDA in Beijing when the inspections of the CJT manufacturers were discussed. However, I explained that sampling is a routine part of any FDA inspection. I stated that I was aware that FDA had collected samples from other countries in the past (and in fact I had collected samples for other countries); although I conceded that I was not aware whether FDA had ever collected samples in China before.

I conceded that FDA has collected and analyzed CJT finished product samples in the past and has not found the cause of these illnesses to my knowledge. I went on to state that even if we continued to collect only finished product samples as Dr. Dou suggested and FDA then found a problem; FDA would not necessarily know the source of the problem without collecting ingredients which went into the manufacture of the finished products. I stated that sampling the ingredients which went into the finished products was a scientifically sound way of determining the source of this problem.

I then asked Dr. Dou who was refusing to allow me to collect samples at the firm; AQSIQ, the firm, or both. Dr. Dou responded that AQSIQ did not want FDA to collect samples during these inspections.

Dr. Dou restated or raised several points including:

- That he (Dr. Dou) had attended two earlier meetings between AQSIQ and FDA and the issue of sampling had never been raised.
- That FDA had not established a solid foundation between sick animals and CJT products. FDA should establish such a foundation first.
- If FDA established a foundation between sick animals and CJT products, FDA should notify AQSIQ and AQSIQ would handle the problem.

Dr. Dou stated that he had come to the inspection in order to develop trust between our agencies. Dr. Dou stated that he was surprised that I had planned to collect samples during my inspection. When Dr. Dou informed AQSIQ leadership of my plans to collect samples during the inspection, Dr. Dou stated that they were also surprised.

Dr. Dou closed by stating that in order to emphasize the aspect of trust and respect, FDA and AQSIQ leadership should first meet to discuss the issue of sample collection. If an agreement was reached, samples could then be collected. In the meantime, Dr. Dou felt the inspection should continue.

Following this meeting I contacted Dr. Hickey and the FDA China office team in order to alert them to the sampling issue which was raised by AQSIQ. It was agreed that the inspection would continue until I received further guidance.

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The issue of sampling came up during a meeting on our arrival on the last day of the inspection. This meeting was held with Mr. Hao and members of his management staff, Dr. Dou, and the CIQ representatives. This meeting was previously described under the heading “**OBJECTIONABLE CONDITIONS AND MANAGEMENT’S RESPONSE**”.

To summarize, at that meeting Dr. Dou gave Mr. Hao the decision as to whether FDA would be allowed to collect samples of the CJT finished products which were manufactured in part using (b) (4) Mr. Hao’s response was to suggest that FDA and AQSIQ both seal any samples which were collected and then leave the samples at the firm until the sampling issue was resolved between FDA and AQSIQ.

No samples were collected during the inspection.

GENERAL DISCUSSION WITH MANAGEMENT

The FDA-483 was issued to Mr. Zhongli Hao, president and primary owner, at the conclusion of the inspection. Members of Mr. Hao’s management staff; Dr. Dou, the AQSIQ representative, and the CIQ representatives were also on hand for the firm. A sign-in sheet with the name and title of all those present at the closing meeting is identified as Exhibit #33.

(b) (4)

Following the discussion of the FDA-483, Mr. Xian Tong Sun, Deputy Secretary for the Yantai CIQ made a statement. Mr. Sun expressed the opinion that this inspection would help the firm in the future.

Dr. Dou, the AQSIQ representative, followed Mr. Sun by making a statement regarding the inspection. Dr. Dou primarily wished to discuss issues relating to sample collection. Dr. Dou stated that:

- Samples should be collected and they should be sealed by both FDA and AQSIQ
- Dr. Dou felt FDA and AQSIQ should reach some agreement on sample size
- FDA should provide information to AQSIQ on the analytical methods which would be used to analyze any samples collected
- FDA and AQSIQ should reach some agreement on how the confirmation of the sample analysis results would be reported

I informed Dr. Dou that I would relay his comments to FDA’s China office which would provide a response to AQSIQ officials.

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ADDITIONAL INFORMATION:

Following the inspection, we were informed by Dr. Dou that Mr. Hao requested to meet with us and present the firm's written response. I informed Dr. Dou that it was not necessary for Mr. Hao to provide us with the firm's response in person. Dr. Dou stated that Mr. Hao felt that due to the seriousness of the findings, it was more appropriate for him to provide the firm's written response in person.

On 4-13-12, Evid Liu and I met with Mr. Hao; Mr. Jiang; and Ms. Yunnuan Zhang, head of the firm's trade department in Liaocheng, Shandong Province, PRC where we were conducting other CJT inspections. Also on hand for this meeting were Dr. Dou; Dr. Congping Huang, deputy director from the Shandong CIQ; and Dr. Ting Yu, veterinarian from the Shandong CIQ.

Mr. Hao initially presented us with the firm's response to the FDA-483 written in Chinese and translated into English. A short discussion followed between Mr. Hao, Dr. Dou and his CIQ colleagues and us. Mr. Hao explained that additional testing had been performed on several lots of (b) (4) which were stored in their supplier's warehouse. Mr. Hao stated additional testing had also been performed on several finished lots of chicken jerky in order to prove the safety of the product.

I thanked Mr. Hao for the information; however, I stated that while the firm may have some documentation on the safety of their product or the glycerin now, they could provide no assurance as to the safety of the glycerin they previously used to manufacture the jerky treat products. After further conversation, Mr. Hao made the decision to not provide the firm's written response to me until the firm had a chance to provide further documentations as to the safety of the (b) (4) (b) (4)

Mr. Hao asked if I had submitted my report on the inspection of his firm to FDA managers. I stated that it would be some weeks before I would be able to submit my report due to the on-going CJT inspections. I stated that all of the CJT inspection would be completed before I would begin to write any reports of the inspections.

Mr. Hao questioned the best way to provide us with the firm's response. I again stated that he could send it to the FDA Guangzhou office and it would be included with the report which I submitted to FDA management.

In the weeks that followed this meeting, Mr. Hao had the firm's response with documentation both submitted to us by the CIQ representatives who accompanied us during the CJT inspections and also sent to the FDA Guangzhou office. A comparison of both of the firm's responses found one was essentially a copy of the other. In addition, some of the documentation provided with the firm's responses was documentation which was collected during the inspection and is identified as exhibits

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with this Establishment Inspection Report (EIR). Rather than submit copies of each response and the duplicate documentation with this EIR, any duplicated materials were left out for ease of review.

The firm's response is included with this EIR as follows:

- Firm's response letter dated 4-19-12 entitled "The reply regarding Form FDA 483 from Yantai Aska Foods Co., Ltd." with translation (Exhibit #79/79a)
- Letter entitled "Commitment Statement by the President" dated 4-19-12 with translation (Exhibit #80/80a)
- CIQ test record #222102012005851 dated 4-5-12 for (b) (4) (b) (4) (Exhibit #81)
- CIQ test record #222102012005852 dated 4-5-12 for (b) (4) (b) (4) (Exhibit #82)
- Old and Revised Procedure ASK-QW-01-23 (Operational Guidance for Raw Material Receiving) with translations of each (Exhibit #83/83a)
- Old and Revised Procedure ASK-QW-01-24 (Operational Guidance for Auxiliary Ingredient Receiving) with translations of each (Exhibit #84/84a)
- Old and Revised Procedure ASK-CX-25 (Evaluation Control Procedure for Raw and Auxiliary Ingredient Suppliers) with translation of each (Exhibit #85/85a)
- Firm's letter dated 4-19-12 entitled "The supplementary on the safety verification of the (b) (4) (b) (4) with translation (Exhibit #86/86a)
- (b) (4) (b) (4) letter dated 3-29-12 entitled "To Whom It May Concern" (Exhibit #87)
- List of (b) (4) (b) (4) shipments which firm received from 2010 to March 2012 (Exhibit #71)

This list was also collected during the inspection and is identified as Exhibit #71. The firm was able to provide (b) (4) (b) (4) which were reportedly received since 2010. These COA's are identified as Exhibits #60/70.

- Copies of COA's for all lots of (b) (4) (b) (4) reportedly received by firm from 2010 to March 2012 (Exhibits #61-68, 88-147)

Included with the firm's responses were COA's for all glycerin shipments reportedly received from 2010 to March 2012 as identified on the firm's (b) (4) (b) (4) receipt list (Exhibit #71) as well as some COA's which aren't identified on this list. These COA's are attached with this EIR as follows: (Note: arranged by date, oldest to most recent.)

Date	Lot Number	Exhibit #
11-19-09	(b) (4)	<u>88</u>
11-19-09	(b) (4)	<u>89</u>
12-19-09	(b) (4)	<u>90</u>
12-19-09	(b) (4)	<u>91</u>

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11-19-09	(b) (4)	<u>92</u>
1-9-10	(b) (4)	<u>93</u>
1-9-10	(b) (4)	<u>94</u>
1-9-10	(b) (4)	<u>95</u>
2-26-10	(b) (4)	<u>96</u>
2-26-10	(b) (4)	<u>97</u>
2-26-10	(b) (4)	<u>98</u>
2-27-10	(b) (4)	<u>99</u>
2-27-10	(b) (4)	<u>100</u>
2-27-10	(b) (4)	<u>101</u>
2-27-10	(b) (4)	<u>61</u>
2-27-10	(b) (4)	<u>102</u>
2-27-10	(b) (4)	<u>103</u>
3-10-10	(b) (4)	<u>104</u>
3-10-10	(b) (4)	<u>105</u>
3-10-10	(b) (4)	<u>106</u>
3-10-10	(b) (4)	<u>62</u>
3-11-10	(b) (4)	<u>63</u>
3-11-10	(b) (4)	<u>107</u>
3-11-10	(b) (4)	<u>64</u>
4-10-10	(b) (4)	<u>108</u>
4-14-10	(b) (4)	<u>109</u>
4-27-10	(b) (4)	<u>65</u>
5-29-10	(b) (4)	<u>110</u>
5-29-10	(b) (4)	<u>111</u>
6-5-10	(b) (4)	<u>112</u>
6-5-10	(b) (4)	<u>113</u>
7-15-10	(b) (4)	<u>114</u>
7-29-10	(b) (4)	<u>115</u>
7-29-10	(b) (4)	<u>116</u>
8-15-10	(b) (4)	<u>117</u>
8-15-10	(b) (4)	<u>118</u>
11-25-10	(b) (4)	<u>66</u>
11-26-10	(b) (4)	<u>119</u>
11-26-10	(b) (4)	<u>120</u>

11-26-10	(b) (4)	<u>121</u>
12-26-10	(b) (4)	<u>122</u>
12-26-10	(b) (4)	<u>123</u>
12-26-10	(b) (4)	<u>124</u>
4-22-11	(b) (4)	<u>125</u>
4-22-11	(b) (4)	<u>126</u>
4-22-11	(b) (4)	<u>127</u>
4-22-11	(b) (4)	<u>128</u>
4-29-11	(b) (4)	<u>129</u>
4-29-11	(b) (4)	<u>130</u>
5-27-11	(b) (4)	<u>131</u>
5-27-11	(b) (4)	<u>132</u>
8-6-11	(b) (4)	<u>133</u>
8-6-11	(b) (4)	<u>134</u>
8-6-11	(b) (4)	<u>67</u>
8-10-11	(b) (4)	<u>135</u>
8-10-11	(b) (4)	<u>136</u>
8-10-11	(b) (4)	<u>137</u>
9-25-11	(b) (4)	<u>138</u>
9-25-11	(b) (4)	<u>139</u>
9-25-11	(b) (4)	<u>140</u>
9-25-11	(b) (4)	<u>141</u>
9-25-11	(b) (4)	<u>142</u>
9-25-11	(b) (4)	<u>143</u>
12-16-11	(b) (4)	<u>144</u>
12-16-11	(b) (4)	<u>145</u>
12-16-11	(b) (4)	<u>146</u>
12-16-11	(b) (4)	<u>147</u>
12-16-11	(b) (4)	<u>68</u>

- (b) (4) with translation (Exhibit #148/148a)
- (b) (4) (Exhibit #149)

The firm selected two lot of ~~Asizhom glycerin~~ at random for testing from their supplier's warehouse according to the firm's supplementary information (Exhibit #86/86a). The above two test reports document the analysis of those (b) (4)

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- (b) (4) test report dated 4-3-12 for chicken jerky batch # (b) (4) with translation (Exhibit #150/150a)
- (b) (4) test report dated 4-3-12 for chicken jerky batch # (b) (4) with translation (Exhibit #151/151a)
- (b) (4) test report dated 4-3-12 for chicken jerky batch # (b) (4) with translation (Exhibit #152/152a)
- (b) (4) test report dated 4-3-12 for chicken jerky batch # (b) (4) with translation (Exhibit #153/153a)
- (b) (4) test report dated 4-6-12 for chicken jerky batch # (b) (4) (Exhibit #154)
- (b) (4) test report dated 4-3-12 for chicken jerky batch # (b) (4) (Exhibit #155)
- (b) (4) test report dated 4-3-12 for chicken jerky batch # (b) (4) (Exhibit #156)
- (b) (4) test report dated 4-3-12 for chicken jerky batch # (b) (4) (Exhibit #157)

(b) (4)

(b) (4)

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(b) (4)

SAMPLES COLLECTED

No samples were collected during the inspection as a result of a refusal from Dr. Dou, the AQSIQ representative who refused to allow FDA sample collection unless certain conditions were met.

VOLUNTARY CORRECTIONS

NA

EXHIBITS COLLECTED

- 1/1a) Owners and ownership changes for Yantai Aska Foods Co, Ltd with translation (2 pages)
- 2/2a) Yantai Aska business license with translation (2 pages)
- 3/3a) Yantai Aska export certificate with translation (2 pages)
- 4) (b) (4) chicken jerky label (1 page)
- 5) (b) (4) chicken and rawhide jerky wraps label (1 page)
- 6) (b) (4) chik 'n breast label (1 page)
- 7) (b) (4) duck fillets label (1 page)
- 8) (b) (4) choice sweet potato with chicken jerky label (1 page)
- 9) (b) (4) chicken fillets label (1 page)
- 10) (b) (4) canine prime duck jerky label (1 page)
- 11) (b) (4) fish jerky label (1 page)
- 12) (b) (4) triple flavor chew label (1 page)
- 13) (b) (4) breast jerky label (1 page)
- 14) (b) (4) chicken mini-bones label (1 page)
- 15) (b) (4) chicken breast jerky label (1 page)
- 16) (b) (4) choice triple flavor twists label (1 page)
- 17) (b) (4) triple-flavor chews medium bone label (1 page)
- 18) (b) (4) beef & chicken bones label (1 page)
- 19) (b) (4) chicken breast fillets label (1 page)
- 20) (b) (4) chicken & biscuits label (1 page)
- 21) (b) (4) chicken chews (1 page)
- 22) (b) (4) chicken breast jerky (1 page)
- 23) (b) (4) duck jerky label (1 page)
- 24) (b) (4) smokehouse BBQ home style treats for dogs label (1 page)
- 25) (b) (4) chicken rawhide label (1 page)

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- 26) (b) (4) chicken jerky label (1 page)
- 27) Product list (7 pages)
- 28/28a) Statement from Yantai Aska Foods regarding last sale of (b) (4) jerky with translation (2 pages)
- 29/29a) Organizational chart with translation (2 pages)
- 30/30a) Individual responsibility with translation (10 pages)
- 31/31a) List of attendees at opening meeting with translation (2 pages)
- 32) Business cards (1 page)
- 33/33a) List of attendees at closing meeting with translation (2 pages)
- 34/34a) Schematic diagram of firm's workshop with translation (4 pages)
- 35/35a) List of meat suppliers with translation (3 pages)
- 36/36a) List of ingredient suppliers with translation (3 pages)
- 37/37a) List of chew and sweet potato suppliers with translation (2 pages)
- 38/38a) Ingredient list for (b) (4) products with translation (2 pages)
- 39/39a) Formulation change for (b) (4) products with translation (2 pages)
- 40) Photographs (30 pages)
- 41) Ingredient list for desiccant (1 page)
- 42) Certificate of irradiation dated 3-6-12 from (b) (4) Ltd (1 page)
- 43/43a) Summary of firm's testing plan with translation (4 pages)
- 44) (b) (4) test report dated 7-12-10 for (b) (4) (1 page)
- 45) (b) (4) test report dated 11-18-11 for chicken jerky strips (1 page)
- 46) (b) (4) test report dated 12-15-11 for chicken jerky (2 pages)
- 47/47a) Breakdown of firm's coding system with translation (13 pages)
- 48a/48e) Falsified receiving and testing records and COA for (b) (4) lot supposedly received on 2-9-11 (6 pages)
- 49a/49c) (b) (4) receiving and testing records and COA for (b) (4) lot supposedly received on 3-9-11 (4 pages)
- 50a/50c) (b) (4) receiving and testing records and COA for (b) (4) lot supposedly received on 3-31-11 (4 pages)
- 51a/51c) (b) (4) receiving and testing records and COA for (b) (4) lot supposedly received on 4-28-11 (4 pages)
- 52a/52c) (b) (4) receiving and testing records and COA for (b) (4) lot supposedly received on 6-3-11 (4 pages)
- 53a/53c) (b) (4) receiving and testing records and COA for (b) (4) lot supposedly received on 9-2-11 (4 pages)
- 54a/54c) (b) (4) receiving and testing records and COA for (b) (4) lot supposedly

- received on 3-15-12 (4 pages)
- 55) (b) (4) COA for lot (b) (4) manufacturing date January 31, 2012 (2 pages)
 - 56/56a) (b) (4) letter dated 4-20-10 with translation (2 pages)
 - 57/57a) (b) (4) letter dated 4-20-10 with translation (2 pages)
 - 58/58a) (b) (4) letter dated 9-22-11 with translation (2 pages)
 - 59/59a) (b) (4) letter dated 20 SPE 2011 with translation (2 pages)
 - 60) (b) (4) glycerin COA dated 12-17-09, lot # (b) (4) (2 pages)
 - 61) (b) (4) glycerin COA dated 2-27-10, lot # (b) (4) (2 pages)
 - 62) (b) (4) glycerin COA dated 3-10-10, lot # (b) (4) (2 pages)
 - 63) (b) (4) glycerin COA dated 3-11-10, lot # (b) (4) (2 pages)
 - 64) (b) (4) glycerin COA dated 3-11-10, lot # (b) (4) (2 pages)
 - 65) (b) (4) glycerin COA dated 4-27-10, lot # (b) (4) (2 pages)
 - 66) (b) (4) glycerin COA dated 11-25-10, lot # (b) (4) (2 pages)
 - 67) (b) (4) glycerin COA dated 8-6-11, lot # (b) (4) (2 pages)
 - 68) (b) (4) glycerin COA dated 12-16-11, lot # (b) (4) (2 pages)
 - 69) (b) (4) glycerin COA dated 2-10-12, lot # (b) (4) (2 pages)
 - 70) (b) (4) glycerin COA dated 2-10-12, lot # (b) (4) (2 pages)
 - 71) List of glycerin shipments received from 2010 through March 2012 (2 pages)
 - 72) (b) (4) dated 8-30-10 (1 page)
 - 73) (b) (4) dated 9-7-10 (1 page)
 - 74) (b) (4) dated 12-3-10 (1 page)
 - 75) (b) (4) dated 3-29-12 (1 page)
 - 76) (b) (4) dated 3-29-12 (1 page)
 - 77) (b) (4) dated 3-29-12 (1 page)
 - 78/78a) List of finished product lots on hand which used (b) (4) with translation (2 pages)
 - 79/79a) Firm response letter dated 4-19-12 entitled "The reply regarding Form FDA 483 from Yantai Aska Foods Co., Ltd." With translation (2 pages)
 - 80/80a) Firm letter dated 4-19-12 entitled "Commitment Statement by the President" with translation (2 pages)
 - 81) CIQ test record #222102012005851 dated 4-5-12 for (b) (4) analysis for diethylene glycol, ethylene glycol and 1,2-propanediol (1 page)
 - 82) CIQ test record #222102012005852 dated 4-5-12 for (b) (4) analysis for diethylene glycol and ethylene glycol (1 page)
 - 83/83a) Old and Revised Procedure ASK-QW-01-23 (Operational Guidance for Raw Material Receiving) with translations of each (4 pages)
 - 84/84a) Old and Revised Procedure ASK-QW-01-24 (Operational Guidance for Auxiliary

- Ingredient Receiving) with translations of each (4 pages)
- 85/85a) Old and Revised Procedure ASK-CX-25 (Evaluation Control Procedure for Raw and Auxiliary Ingredient Suppliers) with translation of each (15 pages)
- 86/86a) Firm letter dated 4-19-12 entitled "The supplementary on the safety verification of the (b) (4) with translation (4 pages)
- 87) (b) (4) letter dated 3-29-12 entitled "To Whom It May Concern" (1 page)
- 88) (b) (4) (b) (4) COA dated 11-19-09, lot # (b) (4) (2 pages)
- 89) (b) (4) COA dated 11-19-09, lot # (b) (4) (2 pages)
- 90) (b) (4) COA dated 12-19-09, lot # (b) (4) (2 pages)
- 91) (b) (4) COA dated 12-19-09, lot # (b) (4) (2 pages)
- 92) (b) (4) COA dated 12-19-09, lot # (b) (4) (2 pages)
- 93) (b) (4) COA dated 1-9-10, lot # (b) (4) (2 pages)
- 94) (b) (4) COA dated 1-9-10, lot # (b) (4) (2 pages)
- 95) (b) (4) COA dated 1-9-10, lot # (b) (4) (2 pages)
- 96) (b) (4) COA dated 2-26-10, lot # (b) (4) (2 pages)
- 97) (b) (4) COA dated 2-26-10, lot # (b) (4) (2 pages)
- 98) (b) (4) COA dated 2-26-10, lot # (b) (4) (2 pages)
- 99) (b) (4) COA dated 2-27-10, lot # (b) (4) (2 pages)
- 100) (b) (4) COA dated 2-27-10, lot # (b) (4) (2 pages)
- 101) (b) (4) COA dated 2-27-10, lot # (b) (4) (2 pages)
- 102) (b) (4) COA dated 2-27-10, lot # (b) (4) (2 pages)
- 103) (b) (4) COA dated 2-27-10, lot # (b) (4) (2 pages)
- 104) (b) (4) COA dated 3-10-10, lot # (b) (4) (2 pages)
- 105) (b) (4) COA dated 3-10-10, lot # (b) (4) (2 pages)
- 106) (b) (4) COA dated 3-10-10, lot # (b) (4) (2 pages)
- 107) (b) (4) COA dated 3-11-10, lot # (b) (4) (2 pages)
- 108) (b) (4) COA dated 4-10-10, lot # (b) (4) (2 pages)
- 109) (b) (4) COA dated 4-14-10, lot # (b) (4) (1 page)
- 110) (b) (4) COA dated 5-29-10, lot # (b) (4) (1 page)
- 111) (b) (4) COA dated 5-29-10, lot # (b) (4) (1 page)
- 112) (b) (4) COA dated 6-5-10, lot # (b) (4) (1 page)
- 113) (b) (4) COA dated 6-5-10, lot # (b) (4) (1 page)
- 114) (b) (4) COA dated 7-15-10, lot # (b) (4) (1 page)
- 115) (b) (4) COA dated 7-29-10, lot # (b) (4) (1 page)
- 116) (b) (4) COA dated 7-29-10, lot # (b) (4) (1 page)
- 117) (b) (4) COA dated 8-15-10, lot # (b) (4) (2 pages)

- 118) (b) (4) COA dated 8-15-10, lot # (b) (4) (2 pages)
119) (b) (4) COA dated 11-26-10, lot # (b) (4) (2 pages)
120) (b) (4) COA dated 11-26-10, lot # (b) (4) (2 pages)
121) (b) (4) COA dated 11-26-10, lot # (b) (4) (2 pages)
122) (b) (4) COA dated 12-26-10, lot # (b) (4) (1 page)
123) (b) (4) COA dated 12-26-10, lot # (b) (4) (2 pages)
124) (b) (4) COA dated 12-26-10, lot # (b) (4) (2 pages)
125) (b) (4) COA dated 4-22-11, lot # (b) (4) (2 pages)
126) (b) (4) COA dated 4-22-11, lot # (b) (4) (2 pages)
127) (b) (4) COA dated 4-22-11, lot # (b) (4) (2 pages)
128) (b) (4) COA dated 4-22-11, lot # (b) (4) (2 pages)
129) (b) (4) COA dated 4-29-11, lot # (b) (4) (1 page)
130) (b) (4) COA dated 4-29-11, lot # (b) (4) (1 page)
131) (b) (4) COA dated 5-27-11, lot # (b) (4) (1 page)
132) (b) (4) COA dated 5-27-11, lot # (b) (4) (1 page)
133) (b) (4) COA dated 8-6-11, lot #E (b) (4) (2 pages)
134) (b) (4) COA dated 8-6-11, lot #E (b) (4) (2 pages)
135) (b) (4) COA dated 8-10-11, lot # (b) (4) (2 pages)
136) (b) (4) COA dated 8-10-11, lot # (b) (4) (2 pages)
137) (b) (4) COA dated 8-10-11, lot # (b) (4) (2 pages)
138) (b) (4) COA dated 9-25-11, lot # (b) (4) (2 pages)
139) (b) (4) COA dated 9-25-11, lot # (b) (4) (2 pages)
140) (b) (4) COA dated 9-25-11, lot # (b) (4) (2 pages)
141) (b) (4) COA dated 9-25-11, lot # (b) (4) (2 pages)
142) (b) (4) COA dated 9-25-11, lot # (b) (4) (2 pages)
143) (b) (4) COA dated 9-25-11, lot # (b) (4) (2 pages)
144) (b) (4) COA dated 12-16-11, lot # (b) (4) (2 pages)
145) (b) (4) COA dated 12-16-11, lot # (b) (4) (2 pages)
146) (b) (4) COA dated 12-16-11, lot # (b) (4) (2 pages)
147) (b) (4) COA dated 12-16-11, lot # (b) (4) (2 pages)
148/148a) (b) (4) test report for (b) (4) dated 4-6-12 with
translation (4 pages)
149) (b) (4) dated 4-18-12 (4 pages)
150/150a) (b) (4) dated 4-3-12 with
translation (2 pages)
151/151a) (b) (4) dated 4-3-12 with

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- translation (2 pages)
- 152/152a) (b) (4) test report for chicken jerky batch # (b) (4) dated 4-3-12 with translation (2 pages)
- 153/153a) (b) (4) test report for chicken jerky batch # (b) (4) dated 4-3-12 with translation (2 pages)
- 154) (b) (4) Analytica test report for chicken jerky batch # (b) (4) dated 4-6-12 (3 pages)
- 155) (b) (4) Analytica test report for chicken jerky batch # (b) (4) dated 4-6-12 (3 pages)
- 156) (b) (4) Analytica test report for chicken jerky batch # (b) (4) dated 4-6-12 (3 pages)
- 157) (b) (4) Analytica test report for chicken jerky batch # (b) (4) dated 4-6-12 (3 pages)
- 158) (b) (4) test report for Acidchem glycerin batch (b) (4) report #222102012005981, dated 4-5-12 (2 pages)
- 159) (b) (4) test report for Acidchem glycerin batch (b) (4) report #222102012005982 dated 4-5-12 (2 pages)
- 160) (b) (4) test report for Acidchem glycerin batch (b) (4) report #222102012005846, dated 4-5-12 (2 pages)
- 161) (b) (4) test report for Acidchem glycerin batch (b) (4) report #222102012005849, dated 4-5-12 (2 pages)

ATTACHMENTS

- FDA-483, Inspectional Observations, issued to Mr. Zhongli Hao, President, (1 page)
- 1) Letter dated 3-13-12 from Cory Bryant, FDA Acting Assistant Country Director – Foods to Dr. Dou, AQSIQ Deputy Director (1 page)

Establishment Inspection Report

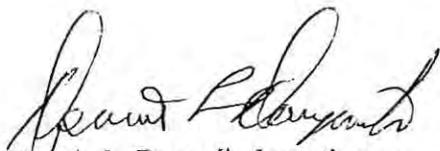
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FEI: 2000045599

EI Start: 03/28/2012

EI End: 03/30/2012



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