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SUMMARY

The inspection of this pet treat manufacturer was conducted in accordance with DFFI FACTS assignment #1395253, OP ID #6054350 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 to be reported to CVM in the following years. A variety of tests were performed on the jerky treats without a determination made of the causative agent. Following a notice which was put out by the Canadian Veterinary Medical Association relating to jerky treats imported from China, CVM issued a CVM Update in November 2011 which led to the receipt of a significant number of consumer complaints reporting severe GI signs, hepatic disease, renal disease and Fanconi like syndrome in dogs associated with the consumption of CJT. As of March 1, 2012, CVM had received over (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). Shandong Petswell Food Co., Ltd was one of the five firms recommended for inspection. FDA also questioned whether AQSIQ would be interested in observing these inspections. Representatives of AQSIQ and the Chinese Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China (CIQ) observed these inspections. This inspection was pre-announced.

This inspection found the firm is a manufacturer of chicken jerky, duck jerky and chicken wrapped jerky treats. Firm management estimated that (b) (6) of their products are exported to the United States only for the (b) (4). The firm also sells a small amount of their jerky treats domestically.

An evaluation was conducted 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 and product testing among others.

No FDA-483 was issued although several issues were discussed with the firm's owner at the conclusion of the inspection. These were:

- Several automatic timers used to time the length of time persons sanitized their hands in the hand sanitizer solution prior to entering the workshop did not function properly.
- Firm's procedure calls for testing each supplier's raw materials (meat) once per year. Instances were noted where raw materials were received during the year and no testing was performed.

The firm's owner stated that clocks were installed as back-up to the automatic timers in the hand sanitizing areas and management would discuss revising the firm's procedure for the yearly testing of meat samples from their suppliers.

It was AQSIQ's position during the previous CJT inspections that FDA would not be allowed to collect samples unless certain sampling conditions were agreed to by FDA. These conditions included having the samples analyzed in a Chinese laboratory although FDA representatives could observe the analysis. The AQSIQ representative who observed this inspection confirmed that samples could not be collected during the inspection unless certain sampling conditions were agreed to by FDA. No samples were collected during the inspection.

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

The firm was manufacturing plain chicken jerky during the inspection.

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ADMINISTRATIVE DATA

Inspected firm: Shandong Petswell Food Co., Ltd.
Location: No. 2 North Binhu Road, Gaotang County
Liaocheng,
China
Phone: 086-6353961366
FAX: 086-6353693866
Mailing address: No. 2 North Binhu Road, Gaotang County
Liaocheng,
China

Dates of inspection: 4/19/2012, 4/20/2012
Days in the facility: 2
Participants: Dennis L Doupnik, Investigator
Clotia C. Abbey Mensah, Investigator
Evid Liu, Medical Research Scientist

In a letter to AQSIQ dated 3-13-12, FDA's Beijing office identified five firms including Shandong Petswell Food 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. This was the initial FDA inspection of this firm.

On arrival at the firm on 4-11-12, credentials were shown to Mr. Hua Qin, owner of Shandong Petswell Food Co, Ltd (Shandong Petswell).

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. Doupnik.

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HISTORY

Shandong Petswell Food Co., Ltd was established as a newly built firm in August 2010. The firm is owned by Mr. Hua Qin. All correspondence should be addressed to Mr. Qin at the firm's physical address.

Mr. Qin stated that he is the sole or primary 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:

- Gambol Pet Products (Liaocheng) Co., Ltd. (jerky treat manufacturer)
No.38 Liaotang Road, Liaocheng
Shandong Province, PRC
FEI: 3006781697
FFR: 130xxxxxxxx
- Shandong Burton Industry Corp., Ltd (shipper/broker)
Room 251, Phoenix Building #2, Huanghe Road,
Liaocheng Development Zone,
Liaocheng, Shandong Province, 252000
FEI: 3008547072
FFR: 104xxxxxxxx

Gambol Pet Products was the third firm inspection during the chicken jerky treat investigation. The firm was inspected on 4-11/13-12.

Shandong Burton currently ships products to the U.S. which are manufactured by Shandong Petswell and Gambol Pet Products. Mr. Qin stated that he spend approximately 1/3 of his time at each of his firms:

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

- 8:00AM – 4:00PM (lunch break from 11:00PM to 12:00PM)
- 4:00PM – 12:00AM (dinner break from 6:00PM – 7:00PM)
- 12:00AM – 8:00AM (no lunch break)

The firm employs a total of (b) employees. Some of the employees live in off-site dormitories.

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

A query of FDA's Food Facility Registration database (FURLS) prior to the inspection found that Shandong Petswell had not registered with FDA in accordance with the Bioterrorism Act of 2002.

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This issue was discussed with Mr. Qin during the inspection of Gambol Pet Products on 4-11/13-12. Mr. Qin stated that Shandong Petswell would register with FDA immediately. It was confirmed prior to this inspection that Shandong Petswell had registered with FDA in accordance with the Bioterrorism Act of 2002.

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

The firm has 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 (b) (4) of their jerky treats to the U.S for one customer, the (b) (4). Mr. Qin stated the firm exported (b) (4) of jerky to the U.S. in 2011. The firm also sells a small amount of jerky domestically.

Mr. Qin stated that the firm began exporting plain jerky treats to the U.S. in February 2011. In November 2011, the firm began exporting chicken jerky wrapped products to the (b) (4). (b) (4) is the only shipper/broker used by Shandong Petswell to export products to the U.S. Until Shandong Petswell registered with FDA in accordance with the Bioterrorism Act of 2002, all products had been exported to the U.S. under the food facility registration number for Shandong Burton.

JURISDICTION

Mr. Qin stated that Shandong Petswell manufactures the following products for export to the U.S.:

- Plain chicken jerky (b) (4)
- Plain duck jerky (b) (4)
- Jerky wrapped products (b) (4)
 1. Chicken and biscuit (b) (4)
 2. Chicken and apple (b) (4)
 3. Chicken and banana (b) (4)

Mr. Qin stated that the firm's only U.S. customer is the (b) (4). All products are sold under the (b) (4) brands. Identified as Exhibit #4/4a is a list of products by brand name and package size with translation which are manufactured

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by the firm. Examples of the labels for (b) (4) jerky treats which are exported to the U.S. are identified as Exhibits #5 - 13. According to Mr. Qin, the (b) (4) is responsible for the labeling information on all products exported to the U.S.

Mr. Qin estimated that (b) (4) of the products the firm manufactures is sold to the (b) (4). Mr. Qin stated that the firm exported (b) (4) of jerky pet treats to the U.S in 2011.

Less than (b) (4) of the firm's jerky treat products are sold domestically under the firm's own (b) (4) brand name.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Shandong Petswell Food Co., Ltd is owned by Mr. Hua Qin. Mr. Qin is responsible for any decisions affecting the firm. All managers at the firm report directly to Mr. Qin.

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

- Gambol Pet Products (Liaocheng) Co., Ltd.
Liaocheng, 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.

Mr. Qin stated that Mr. Shouquan Xue, deputy general manager, is responsible for the firm's day to day operations when Mr. Qin is away from the firm. All department managers would then report directly to Mr. Xue.

Mr. Jun Xue, QC manager at Gambol Pet Products, oversees QC operations at Shandong Petswell and an unrelated jerky treat manufacturer, (b) (4). Reporting to Mr. Xue is Mr. Guo, Shandong Petswell QC manager.

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 #14/14a. Identified as Exhibit #15 is the business card which was received from Mr. Shouquan Xue, deputy general manager, at the start of the inspection. Also identified with Exhibit #15 are copies of business cards which were previously received from Mr. Qin; Mr. Jun

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Xue, quality general manager at Gambol Pet Products; and officials from AQSIQ and the Liaocheng CIQ and Shandong CIQ who were present.

A closing meeting was held with Mr. Hua Qin, 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 closing meeting with translation is identified as Exhibit #16/16a.

Information for this report was provided by Mr. Hua Qin; Mr. Jun Xue, Gambol QC manager; Mr. Guo, Shandong Petswell QC manager; and other managers and staff from the firm. We were accompanied during the inspection by Mr. Shouquan Xue; Mr. Jun Xue; Mr. Guo; other members of the firm's staff; Dr. Dou, AQSIQ representative; Dr. Congping Huang, Shandong CIQ; Dr. Ting Yu, Shandong CIQ, and other representatives from the Liaocheng CIQ.

Conversation with (b) (4)

We were informed that the firm's (b) (4) representative was at the plant and that she would be willing to meet with us during our inspection. On 4-20-12 we met with (b) (4) (b) (4) representative who is assigned to the Shandong Petswell plant.

According to (b) (4), she has worked for the (b) (4) since August 2011 when she answered an advertisement for this position. (b) (4) was assigned to the Shandong Petswell plant at the time of her hiring. (b) (4) stated that the Shandong plant is the only plant she has been assigned to oversee. (b) (4) (b) (4) stated that prior to working for the (b) (4) she had two years experience in the food industry in Jinan, Shandong Province, PRC.

(b) (4) stated that her duties are as follows:

(b) (4) works from 8:00AM to 5:00PM five days per week. (b) (4) stated that the firm is allowed to process jerky treats when she is not on site.

(b) (4) oversees jerky processing operations from raw material receiving to the loading of finished products onto trucks for irradiation. Another (b) (4) representative is stationed at the irradiator firm to oversee the irradiation of jerky treats.

Raw Materials (Meat):

Ms. Tian stated that the firm notifies her when a shipment of meat is received. (b) (4) stated that the firm generally receives two shipments or more of meat per week.

Although the firm follows their own HACCP plan and CCP1 for the receipt of meat, (b) (4) verifies the temperature of the meat and the truck (minimum of -12°C (10.4°F) for the meat and -18°C (-0.4°F) for the truck). (b) (4) stated that she verifies the meat is received from a qualified supplier. (b) (4) stated she also checks the sanitation of the truck.

In the time she has been stationed at the firm, (b) (4) has never seen any instances where meat shipments were outside of the minimal receiving temperature. (b) (4) stated that she has never seen any shipments of meat which were not received on refrigerated trucks. (b) (4) has never seen any instances where any meat shipments were rejected.

Auxiliary Ingredients:

(b) (4) stated she visually examines all shipments of auxiliary ingredients received. (b) (4) stated that she reviews test reports for the shipments of auxiliary ingredients received. (b) (4) stated that she reviews the analytical reports although she did not know if these reports were completed by the supplier or a third party laboratory.

According to (b) (4) she has only seen the firm use the (b) (4) was not aware whether the (b) (4) requires the firm to use (b) (4).

Finished Products:

(b) (4) (b) (4) requires the collection of samples of each finished product lot prior to and after irradiation. If (b) (4) requests a sample, (b) (4) is the person responsible for collecting the sample.

(b) (4) was questioned whether (b) (4) had requested (b) (4) to collect any sample for analysis. (b) (4) stated that this happened one time when she first began working for (b) (4). That sample was collected by the (b) (4) representative who is assigned to the Gambol facility. The (b) (4) representative at Gambol had come to the Shandong Petswell facility in this case in order to help train (b) (4). (b) (4) stated that she did not know what the sample was analyzed for.

CJT Issue:

(b) (4) stated that she is aware of the CJT issue through (b) (4). (b) (4) stated that she receives specific information from (b) (4) regarding sick animals; however, she did not remember whether any of the complaints specifically involved product from the Shandong Petswell plant.

(b) (4) stated that she has not seen anything at the plant which she felt could lead to the illness or death of dogs eating jerky treats. (b) (4) stated that it is her perception that the firm is making a good product.

(b) (4) stated that since the Chinese New Year (end of January 2012), (b) (4) has asked the representatives to check glycerin usage at the firms at least three times per week. This is done by reviewing the glycerin receiving records, glycerin lot numbers and the usage of glycerin in the workshop and warehouse.

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When questioned, (b) (4) stated that she does not verify product formulation or mixing procedures; however, she stated that she would start doing this in the future.

(b) (4)

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.)

Shandong Petswell operates in a leased facility on a campus which is shared with other processors. According to Mr. Qin, there is no business relationship between Shandong Petswell and the other processors on this campus. According to the Liaocheng CIQ, none of the other processors on this campus export products to the U.S.

According to Mr. Qin, Shandong Petswell uses one workshop to produce jerky treats. This workshop is (b) (4). The firm has a freezer on site which is used for the storage of frozen meat. Identified as Exhibit #17 are photographs taken to document the firm's operations.

According to Mr. Qin, the Purina Co. 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 met with this individual 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 firm has identified three critical control points (CCPs) in their HACCP plan. These are:

- CCP 1: The inspection of incoming raw materials (meat products) received from suppliers. Each shipment of raw materials is checked for temperature to ensure the product is received frozen. The firm verifies that each shipment includes the supplier's animal health certificate
- CCP 2: Drying of the jerky. The jerky is required to undergo an additional heating or "sterilization"

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step beyond the normal drying process. The critical limit for the sterilization step is (b)

(b) (4)

CCP 3: Metal detection for the jerky prior to packaging

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 and neighboring provinces. Identified as Exhibit #18/18a is a list of the firm's suppliers of meat from 2011 to date with translation.

Mr. Qin estimated that the closest suppliers of chicken 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 using third party logistics refrigerated trucks.

Mr. Qin was questioned whether the firm had seen any price fluctuations for the purchase of chicken over the past several years. According to Mr. Qin, he had seen big fluctuations in the price of chickens around October 2010 although he did not explain the reason. Mr. Qin was asked whether recent reports of bird flu were affecting the price of chicken meat in 2012. According to Mr. Qin, this was a more localized issue which did not affect prices in the Shandong area. Mr. Qin stated that the price of chicken has been stable for 2012 and for the past several years.

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. The list of base material suppliers is included with Exhibit #18/18a. Identified as Exhibit #19/19a is a list of the firm's auxiliary ingredient suppliers with translation which have been used since 2011.

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) (b) (4) in the manufacture of the jerky treats. According to Mr. Qin, the firm has used (b) (4) (b) (4) in the manufacture of jerky treats since February 2011 when the firm began exporting products to the U.S.

(b) (4)

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(b) (4)

A review was made of the firm's glycerin receiving and usage records from 2011 to date. These records were compared against Chinese customs taxation forms (fapiao) for 2011 and 2012. Glycerin usage records were also compared with randomly selected production records for weeks during December 2011, January 2012 and February 2012. As best determined, the firm has only used (b) (4) (b) (4) since February 2011 as Mr. Qin stated. Glycerin usage also appeared to approximate the quantities observed during this inspection.

Some slight price fluctuations were seen in the firm's purchase of glycerin during our review of the fapiao taxation forms for glycerin. The issue of price fluctuation for the purchase of glycerin was discussed with Ms. Fang Li, procurement manager. Ms. Li stated that the price of food grade glycerin may vary to some small degree between suppliers but she has not seen a large fluctuation in the price of glycerin very often in the past several years.

(b) (4)

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. (b) (4) (b) (4) became the responsible firm for product formulation.

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

(b) (4)

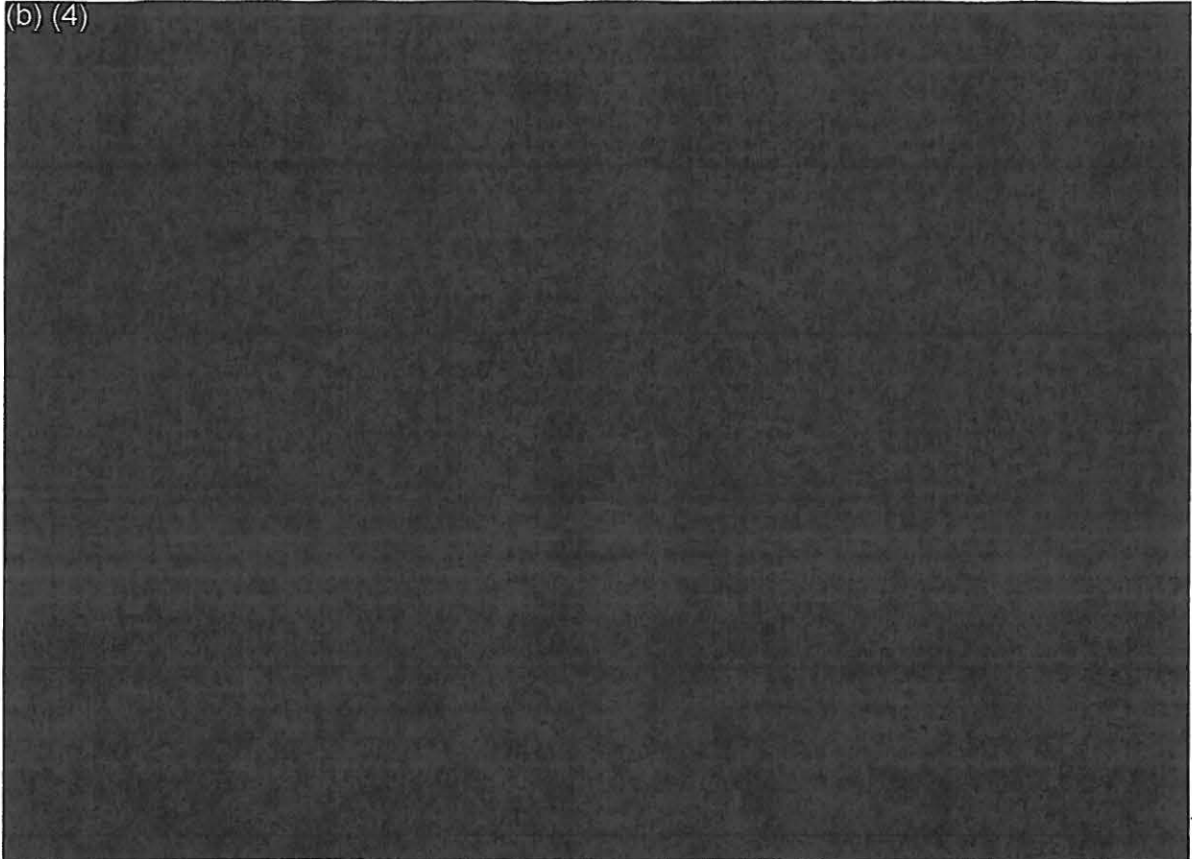
(b) (4)

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

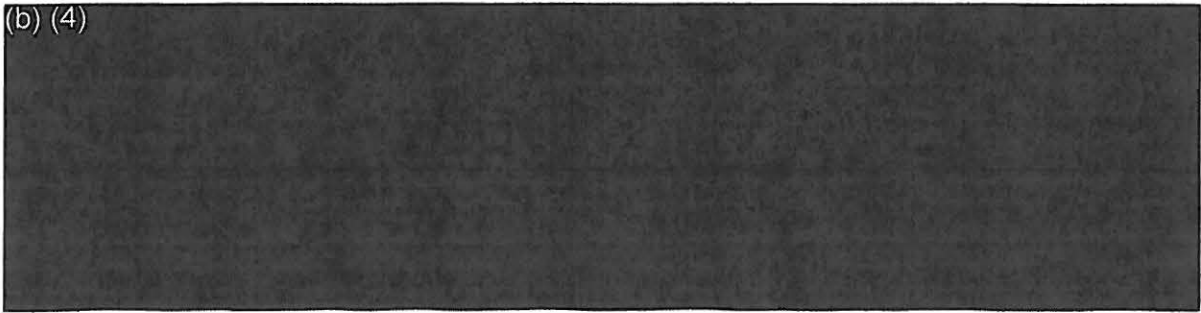
(b) (4)



(b) (4)



(b) (4)



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(b) (4)



An examination of the firm's temporary freezer storage room found two lots of chicken breast meat on hand. These lots were received on 4-17-12 and 4-18-12. Identified as Exhibit #17, Photo #3 is a picture of two lots of frozen chicken breast meat stored in this room on 4-19-12.

If the meat will not be processed within 72 hours, the meat is placed in the long term storage freezer. This freezer was not being used during our examination of this freezer on 4-19-12.

(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)



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Each tote of meat is identified with a tracing card after the meat is added to the tote. Information on a tracing card includes:

- Lot #
- Date
- Tracing #
- Time when thawing was completed
- Time when meat bags are opened
- Weight
- Responsible individual
- Remarks

(b) (4)

(b) (4)

(b) (4)

(b) (4)

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

- Name of auxiliary ingredient weighed (i.e. glycerin)
- Lot # of auxiliary ingredient weighed (b) (4)
- Date of usage

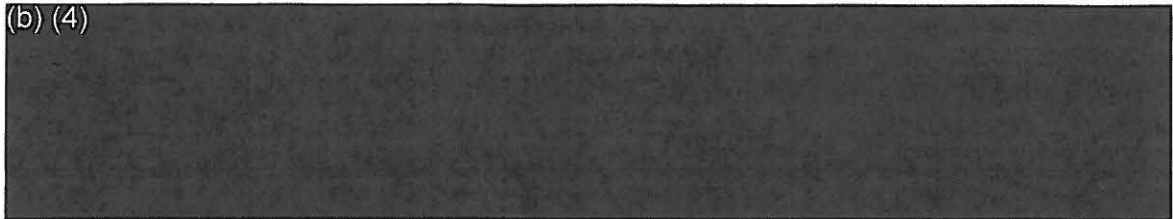
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- Weight of material
- Responsible person who weighed ingredient
- Remarks

In addition, the weigh-out of glycerin is documented on an Ingredient Input Record for each batch of jerky which is mixed.

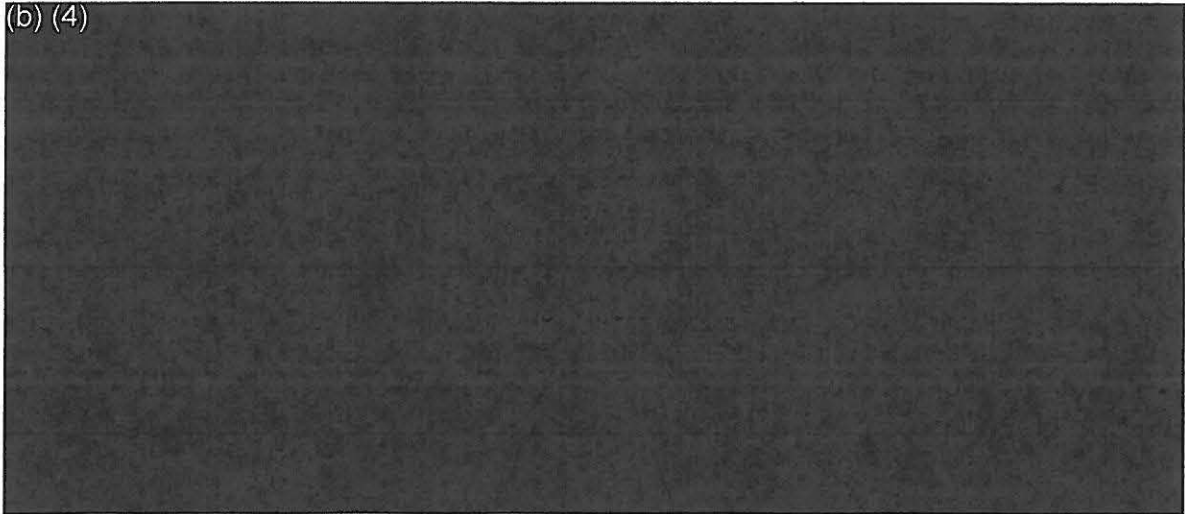
(b) (4)



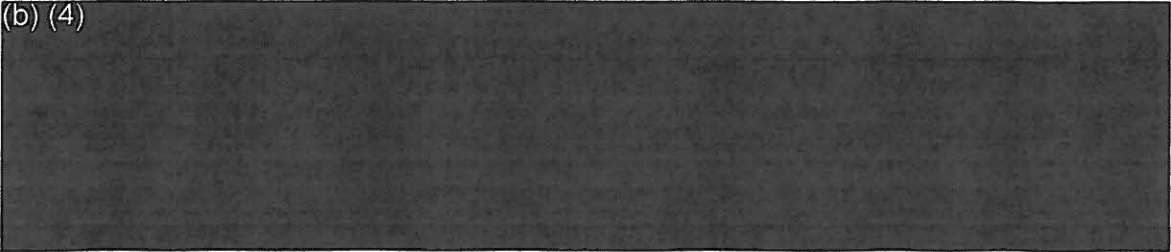
(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(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 #

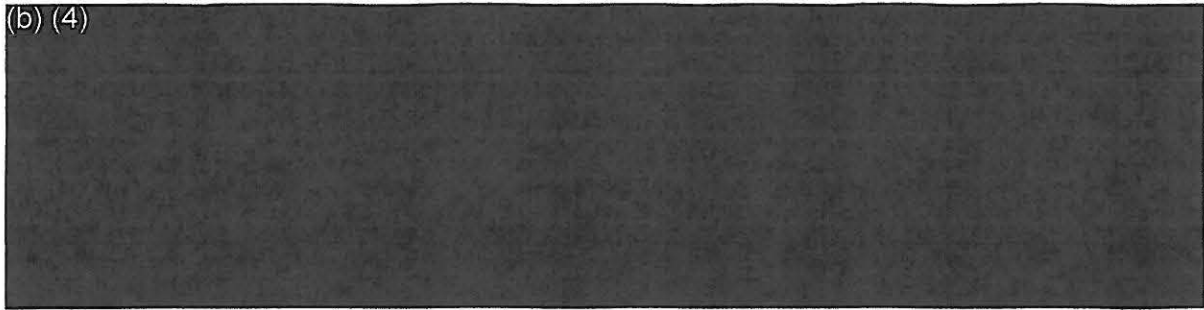
(b) (4)



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(b) (4)



(b) (4)



(b) (4)



(b) (4)



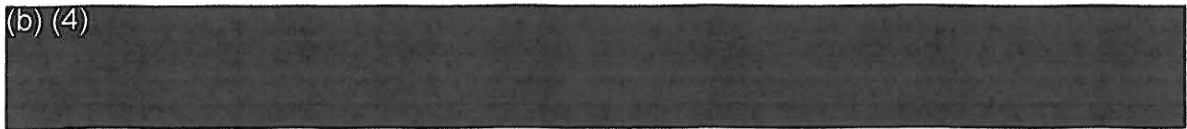
(b) (4)



(b) (4)



(b) (4)



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(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



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(b) (4)



(b) (4)



(b) (4)



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

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



Mr. Qin stated that (b) (4) is the primary firm used to irradiate products. (b) (4) is the back-up firm used to irradiate products.

(b) (4)



(b) (4)



(b) (4)




(b) (4)



(b) (4)



(b) (4)



Water test results were reviewed for 2011 and 2012. No problems were noted.

(b) (4)



Third Party Testing:

A variety of third party testing is performed on raw materials, auxiliary ingredients and finished products.

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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 #17, Photo #20 is a picture of apparel required to be worn in the semi-clean and clean workshops.

Prior to entering the workshop, persons are required to wash their hands with soap and water followed by hand sanitizing using a sodium hypochlorite (bleach) solution for 20 seconds in a hand dip station. The solution in the hand dip station is reportedly maintained at (b) (4) The strength of the hand dip solution was found to be (b) (4) when tested by me on 4-19-12.

The firm uses automatic timers to time the length of time hands are to remain in the hand dip station. It was observed that several of the timers did not work. This deficiency was discussed with Mr. Qin at the conclusion of the inspection.

Prior to entering the workshop, persons are required to step through a sanitizing boot dip containing (b) (4) The strength of the boot dip solution was found to be 300 ppm when tested by me on 4-19-12.

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 have their hands sprayed with (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 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. All cleaning is documented.

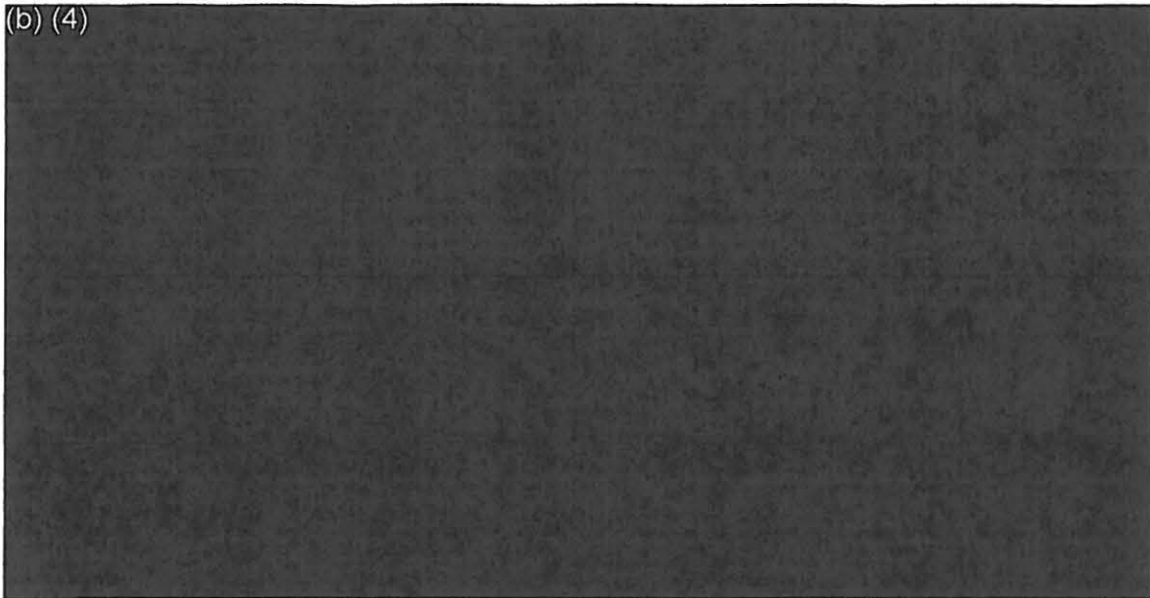
The firm uses procedures for workshop and equipment cleaning as follows:

- Small utensils:
 - Cold water wash with detergent, rinsed with (b) (4)
- Trays:

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(b) (4)

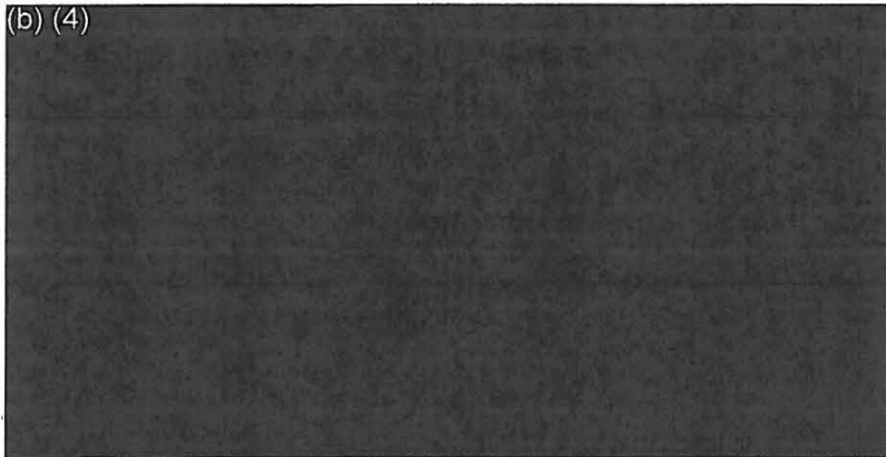


(b) (4)



is used.

(b) (4)



(b) (4)



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

Insects are controlled using insecticutors, plastic strips in doorways and screens on windows. No sprays or fumigants are allowed inside the workshop.

MANUFACTURING CODES

Mr. Qin stated that the (b) (4) changed the firm's manufacturing coding system in February 2012. An example of the firm's coding system is as follows:

(Example) 2110T028 0101WG1
BEST BEFORE OCT 2013
DEN6 APR 2012

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

110 = Julian date of packaging

T028 = Petswell plant ID

01 = workshop # (1 for Petswell)

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)

Determined by the (b) (4)

DEN6 = order #

APR 2012 = month and year of packing

An example of the firm's old coding system before February 2012 is as follows:

(Example) B1CA5000A
BEST BEFORE 100213

B1 = plant ID (Petswell)

CA5000 = Order # (If order couldn't be filled by Petswell, the order could be finished by another manufacturer which would continue with this order number)

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

BEST BEFORE = 10 (month)

021 (day)

3 (year)

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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 no complaints relating to illness or death 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 first complaint in this database was received on 1-19-12. The last complaint was received on 5-4-12. All of the complaints involved the (b) (4) brand of chicken jerky treats.

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 with their responsibilities:

- General Manager (oversees recall)
- QC Director (coordinator for recall)
- Sales Manager (contact customers)
- Production Manager (assist with recall investigation)
- Procurement Manager (assist with recall investigation)

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 was issued although several issues were discussed with Mr. Hua Qin, owner, at the conclusion of the inspection. These were:

- Several automatic timers used to time the length of time persons sanitized their hands in the hand sanitizer solution prior to entering the workshop did not function properly.
- Firm's procedure calls for testing each supplier's raw materials (meat) once per year. Instances were noted where raw materials were received during the year and no testing was performed.

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Persons entering the semi-clean and clean processing areas of the workshop are required to wash and then sanitize their hands in a (b) (4) Time is monitored using an automatic timer. It was observed that several of these timers were not functioning when we sanitized our hands prior to entering the workshop.

The firm's procedures call for testing meat from each supplier which is received each year. A review of meat testing records found approximately half of the suppliers who provided meat to the firm in a year's time did not have any shipments of the meat tested as required.

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 in an attempt to resolve the sampling issue. (See the Yantai Aska Food Co., Ltd. EIR dated 3-28/30-12 for further information on this issue.)

I met with Dr. Dou during 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, owner at the conclusion of the inspection. Also on hand during this closing discussion were individuals from the firm's staff and representatives from AQSIQ and CIQ. A sign-in sheet for the persons who were present at this closing meeting with translation is identified as Exhibit #16/16a.

Although no FDA-483 was issued, several issues were discussed with Mr. Qin. These were:

- Several automatic timers used to time the length of time persons sanitized their hands in the hand sanitizer solution prior to entering the workshop did not function properly.

Mr. Qin stated that clocks were installed in the washing area in the event that automatic timers used to time hand sanitizing did not function properly.

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- Firm's procedure calls for testing each supplier's raw materials (meat) once per year. Instances were noted where raw materials were received during the year and no testing was performed.

Mr. Qin agreed that each supplier's meat may not be tested each year due to the fact that a supplier may only ship meat to the firm once a year. Mr. Qin suggested that the firm could revise their procedure to test the first shipment of meat received from each supplier each year. I agreed that this would correct the problem of testing each supplier's shipment of meat to the firm.

Dr. Dou, the AQSIQ representative, felt that it may not be prudent to test the first shipment of meat received from each supplier in a year as the suppliers could be aware of this and the firm would have not be aware of the quality of the meat received the remainder of the year. Dr. Dou suggested that the firm, should determine a better way to write their procedure for testing each supplier's meat during a year.

Mr. Qin stated the firm would discuss this issue and devise a better procedure for ensuring each supplier's shipment of meat was tested at least once per year.

ADDITIONAL INFORMATION

None

SAMPLES COLLECTED

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

VOLUNTARY CORRECTIONS

Mr. Qin stated that the firm had installed four clocks in the wash areas as back-ups to the automatic times. In the event the times were not functioning, the clocks could be used to ensure times were met for person to sanitize their hands in the hand dip stations.

The addition of clocks to the wash areas was not verified during the inspection.

EXHIBITS COLLECTED

- 1/1a) Copy of firm's business license with translation (2 pages)
- 2/2a) Copy of firm's CIQ export certificate with translation (2 pages)
- 3/3a) Copy of firm's presentation made at the start of the inspection with translation (16 pages)
- 4/4a) List of firm's products sold to the U.S. with translation (2 pages)
- 5-13) Examples of firm's product labels (9 pages)

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- 14/14a) List of attendees of opening meeting with translation (2 pages)
 - 15) Business cards received (1 page)
 - 16/16a) List of attendees of closing meeting with translation (2 pages)
 - 17) Photographs taken of firm's operations (20 pages)
 - 18/18a) List of meat suppliers with translation (13 pages)
 - 19/19a) List of auxiliary ingredient suppliers with translation (2 pages)
 - 20) Copy of Raw Material Inspection Report (1 page)
 - 21) Copy of Drying Tunnel Temp Monitoring Record (1 page)
 - 22) Copy of Moisture Content Test Record (1 page)
 - 23/23a) List of desiccant suppliers with translation (2 pages)
 - 24) Copy of Ingredient Inspection Report for glycerin (b) (4) GC dated 4-13-12 (1 page)
 - 25) CAIQ test report dated 4-1-12 for glycerin (b) (4) (1 page)
 - 26) (b) (4) Analytica Certificate of Analysis (b) (4) dated 4-2-12 for Chicken Jerky Tenders WT (b) (4) Irradiated 40 oz (4 pages)
 - 27) (b) (4) Analytica Certificate of Analysis (b) (4) dated 4-13-12 for Duck Jerky Tenders WT lot (b) (4) Irradiated 16 oz (4 pages)
 - 28) (b) (4) Analytica Certificate of Analysis (b) (4) dated 4-2-12 for Wrapples WT lot (b) (4) Irradiated 3.5 oz (4 pages)
 - 29) (b) (4) Analytica Certificate of Analysis (b) (4) dated 4-10-12 for Chik'n Biscuits Recipe WT (b) (4) Irradiated 5 oz (4 pages)
 - 30) (b) (4) Analytica Certificate of Analysis (b) (4) dated 4-2-12 for PBJ CCR lot (b) (4) Irradiated 16 oz (4 pages)
 - 31/31a) CIQ surveillance sampling plan for Shandong Petswell with translation (5 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)

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