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SUMMARY

The inspection of this pet treat manufacturer was conducted in accordance with DFFI FACTS assignment #1395225, OP ID #6054209 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 were reported to CVM in the following years. A variety of tests were performed on the jerky treats without a determination made of the causative agent. Following a notice which was put out by the Canadian Veterinary Medical Association relating to jerky treats imported from China, CVM issued a CVM Update in November 2011 which led to the receipt of a significant number of consumer complaints reporting 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 has received over 1,000 complaints relating to the consumption of imported chicken, duck or sweet potato jerky treats. FDA determined that inspections were warranted for Chinese firms that manufactured jerky treat products and which were identified as having received the bulk of these complaints.

Establishment Inspection Report

Jinan Uniwell Pet Food Co., Ltd
Jinan, China

FEI: 2000027813
EI Start: 04/05/2012
EI End: 04/07/2012

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. Jinan Uniwell Pet Food Co, Ltd (initially identified as Jinan Welcome Food Co, Ltd) was one of the five firms recommended for inspection. FDA also questioned whether AQSIQ would be interested in observing these inspections. Representatives of AQSIQ and the Chinese Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China (CIQ) observed these inspections. This inspection was pre-announced.

This inspection found the firm is a manufacturer of plain chicken jerky, duck jerky and pork jerky products. Firm management estimated that over (b) (4)

(b) (4) The firm also exports approximately (b) (4)

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 one sanitation deficiency was discussed with the firm's owner. Broken metal supports were observed on metal screens. The jerky tenders are placed on these screens during the drying process. In addition, firm management was also requested to update their food facility registration to identify Jinan Uniwell Pet Food Co, Ltd as the true manufacturer of pet treats rather than Jinan Welcome Food Co (the parent company). The firm's owner was also informed that their firm's food facility registration number should be identified on shipping records rather than using the registration number of a Chinese shipper/broker.

Management promised immediate correction. The firm's food facility registration was verified as having been updated following the conclusion of the inspection.

A query of FDA's Online Reporting Analysis Decision Support System (ORADSS) data base on 5-6-12 shows no lines of entry into the U.S. for product shipped by Jinan Uniwell Pet Food Co Ltd to date. The firm's Chinese broker/shipper (b) (4) was identified as the manufacturer on lines of entry into the U.S. for jerky treat products as late as 5-4-12. As best determined (b) (4) (b) (4) is not a manufacturer of jerky pet treats.

The AQSIQ representative who observed the inspection stated that samples could not be collected during the inspection unless certain sampling conditions were agreed to by FDA. These conditions included having the samples analyzed in a Chinese laboratory although FDA could observe the analysis. Meeting between FDA and AQSIQ were held in an attempt to resolve this issue. No samples were collected during the inspection.

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The firm was manufacturing chicken jerky during the inspection.

ADMINISTRATIVE DATA

Inspected firm: Jinan Uniwell Pet Food Co., Ltd
Location: 303 Industry North Road
Jinan, China 250000
Phone: 086-05318896361
FAX: 086-0531889618
Mailing address: 303 Industry North Road
Jinan, China 250000

Dates of inspection: 4/5/2012, 4/6/2012, 4/7/2012
Days in the facility: 3
Participants: Dennis L. Douppnik, Investigator
Lixia Wang, Medical Research Scientist

In a letter to AQSIIQ dated 3-13-12, FDA's Beijing office identified five firms including Jinan Welcome 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.

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

On arrival at the firm on 4-5-12, credentials were shown to Mr. Shengru Liu, Chairman of the Board for Jinan Uniwell Pet Food Co, Ltd and President of Jinan Welcome Food Co, Ltd. Jinan Welcome Food Co, Ltd is the parent company for Jinan Uniwell Pet Food Co, Ltd.

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

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

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HISTORY

Jinan Uniwell Pet Food Co, Ltd (Jinan Uniwell) was established as a newly built facility in 2007. Mr. Shengru Liu, Chairman of the Board is the primary owner of Jinan Uniwell. According to Mr. Liu, the owners of Jinan Uniwell are the following three companies (in order of primary ownership):

- Jinan Welcome Food Co. Ltd (parent company and primary owner of which Mr. Liu is the President)

(b) (4)

According to Mr. Liu, Jiangsu (b) (4)

Co are not related and Mr. Liu has no ownership or financial interests in these companies.

Mr. Liu maintains his office at Jinan Welcome Food Co, Ltd which is also the physical location for the Jinan Uniwell facility. Any correspondence should be submitted to Mr. Liu at the firm's physical address.

Jinan Welcome Food Co, Ltd is also the parent company for the following firms which are located in Shandong Province, PRC:

- Jinan Uniwell Pet Food Co, Ltd (manufacturer of jerky treats)

(b) (4)

Mr. Liu stated that only Jinan Uniwell exports products to the U.S. In addition, Mr. Liu stated that

(b) (4)

(b) (4) A check of FDA's FACTS MARCS Firm Management Services (FMS) did not find any of the above identified firms are identified with FDA's FEI numbers.

A check of the FURLS database found that Jinan Welcome Food Co Ltd rather than Jinan Uniwell had registered with FDA in accordance with the Bioterrorism Act of 2002. Mr. Liu stated that the food facility registration was completed under the name of Jinan Welcome rather than Jinan Uniwell since Jinan Welcome is the parent firm. I informed Mr. Liu that since Jinan Uniwell is the actual manufacturer of pet food (jerky treats), the food facility registration should identify Jinan Uniwell as the true manufacturer. Mr. Liu stated that his firm would make this amendment to the food facility registration. It was confirmed following the inspection that Jinan Uniwell is now identified on the food facility registration as a pet food manufacturer.

According to Mr. Liu, the firm manufactures jerky treats upon customer orders. Mr. Liu stated the firm generally manufactures year around although production is slightly less in the summer months.

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Mr. Liu stated the firm generally manufactures six to seven days per week whenever orders are received. Manufacturing generally occurs on one shift which operates from 8:00 AM to 5:00 PM each day.

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

The firm employs (b) (4) Some of these employees live in dormitories on site.

The firm holds a business license to operate from the Jinan 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. Liu, the firm exports in excess of (b) (4)

(b) (4) Mr. Liu stated that the firm rarely sells any of their products domestically. Mr. Liu stated that the firm began exporting products to the U.S. in 2007. All products are shipped through (b) (4)
(b) (4)

JURISDICTION

According to Mr. Liu, Jinan Uniwell manufactures the following types of jerky products:

- Chicken jerky (b) (4)
- Duck jerky (b) (4)
- Pork jerky (b) (4)

Mr. Liu stated that the firm manufactures no combination jerky treat products. Mr. Liu stated that the firm's (b) (4)
(b) (4)

All of the firm's products are packaged under the (b) (4)
(b) (4) Examples of the labels for (b) (4) are identified as Exhibits #4-7. Examples of the labels for (b) (4) are identified as Exhibits #8-10.

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

According to Mr. Liu, Jinan Uniwell began the export of the (b) (4) of jerky treats to the U.S. in November 2008. Mr. Liu stated that the firm began to export the (b) (4) brand of jerky treats to the U.S. in July 2010 after the Purina Co purchased the (b) (4). Mr. Liu stated that he is aware that other Chinese pet food manufacturers are also contracted to produce the (b) (4) although he doesn't know all of the firms in China which are contracted to do so.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Shengru Liu, chairman of the board, is the most responsible individual for Jinan Uniwell. Mr. Liu is also the president and most responsible individual for Jinan Welcome Food Co, Ltd which is the parent company for Jinan Uniwell. Mr. Liu maintains his office at Jinan Welcome Food Co which is also the same address for Jinan Uniwell. Mr. Liu would ultimately make any decisions affecting Jinan Uniwell. Identified as Exhibit #11/11a is an organizational chart with translation which identifies the firm's corporate reporting structure.

Reporting directly to Mr. Liu is Mr. Daxing Li, general manger. Mr. Li has day to day oversight of the firm's manufacturing operations. All senior department managers report directly to Mr. Li.

Ms. Lie Wang is the firm's QC manager. Ms. Wang is responsible for oversight of the firm's HACCP program and the laboratory and testing operations.

An opening meeting was held with Mr. Shengru Liu, chairman of the board, 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 #12. Identified as Exhibit #13 is the business card which was received from Mr. Liu at this opening meeting along with copies of business cards which were previously received from the AQSIQ and CIQ officials present.

A closing meeting was held with Mr. Shengru-Liu, chairman of the board, his staff and representatives from AQSIQ and CIQ at the conclusion of the inspection. A sign-in sheet for the persons who were present at this meeting with translation is identified as Exhibit #14.

Information for this report was provided by Mr. Shengru Liu; Mr. Daxing Li, general manager; Ms. Lie Wang, QC manager; and other managers and staff from the firm. We were accompanied during the inspection by Mr. Li; Ms. Wang; 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 Jinan CIQ.

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FIRM'S TRAINING PROGRAM

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

MANUFACTURING/DESIGN OPERATIONS

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

The Jinan Uniwell Pet Food Co facility is located on the Jinan Welcome Food Co campus. (b) (4)
(b) (4)

According to Mr. Liu, the (b) (4) has a person on site to oversee production operations whenever the firm is manufacturing jerky which is intended to be exported to the U.S. We requested to meet with this individual during the inspection but were told he was not available.

The firm was manufacturing chicken jerky under the (b) (4) brand in workshop #1 during the inspection. Workshops #2 and 3 were not in operation during the inspection. According to the firm, workshop #2 was last used to produce jerky on 3-29-12. Workshop #3 was last used to produce jerky on 3-30-12.

Raw meat products are stored in one freezer which is located on the Jinan Welcome Food Co campus but is operated by a sister company. A visit was made to this facility during the inspection.

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:

(b) (4)

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Ingredient Suppliers:

(b) (4)




(b) (4)



Identified as Exhibit #15/15a is a list of firm's suppliers of chicken breast meat for the years 2010/2011/2012 with translation. Identified as Exhibit #16/16a is a list of firm's suppliers of duck breast meat for the years 2010/2011/2012 with translation. Identified as Exhibit #17/17a is a list of firm's suppliers of pork meat for the years 2010/2011/2012 with translation.

Auxiliary Ingredients:

The firm uses very few auxiliary ingredients in the manufacture of the jerky treat products. According to Mr. Liu, some ingredients are selected by the firm for use in the jerky products and are approved by the (b) (4)  According to firm management, auxiliary ingredients are ordered as needed to complete a production order

(b) (4)



(b) (4)



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(b) (4)



A review was made of the firm's receiving records from 2009 to date. These records were compared against Chinese customs tax forms (fapiao) for 2011 and 2012 as well as randomly selected production records during the past year. As best determined, the firm has only used (b) (4) during at least the past several years as Mr. Liu stated. Glycerin usage also appeared to approximate the quantities observed during this inspection.

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



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(b) (4)

Processing of Chicken Jerky:

The firm was processing chicken jerky in workshop #1 during the inspection. Photographs were taken to document the firm's chicken jerky operations for the receipt and storage of raw materials, product mixing, processing, jerky drying and packaging. These photographs are identified as Exhibit #19.

(b) (4)

According to Mr. Li, once a customer order to produce jerky is received, the firm contacts their suppliers to determine whether that raw material is available in the quantity needed. Mr. Li also stated that at times the firm may also purchase the meat when the price is low and then stock up on the meat in anticipation of receiving an order to produce jerky at a future date. Mr. Li stated that the firm generally receives meat two to three days before needed for production; however, the meat can remain in the freezer for up to three months at some times. All meat deliveries are made during daylight hours.

When a meat delivery is received, the temperature of the meat is checked to verify it is frozen to lower than -15°C (5°F). Temperature checks are documented for each shipment received according to Mr. Li. According to Mr. Li, to date the firm has never had to reject a shipment of meat which was found to be above -15°C.

Meat is generally packed by the suppliers in 2-kg to 10 kg plastic bags within plastic weave bags. According to Mr. Li, the firm generally receives the frozen meat in 5 kg and 10 kg bags; however,

In addition to checking the temperature of the meat, the firm also verifies the supplier's animal health certificate and the supplier's testing records. Samples of the meat are collected and are submitted to the firm's QC laboratory for microbiological testing.

(b) (4)

Identified as Exhibit #19, Photo #3 is a picture of bags of frozen meat being stored in freezer 101 on 4-6-12. An examination of the meat being stored in this freezer found one lot of duck meat was received on 3-1-12. Lots of chicken breast meat in this freezer were observed to have been received two to three weeks before the inspection.

(b) (4)



(b) (4)



Each thawing rack is identified with a tag which identifies the following information for tracing and manufacturing purposes:

- Name of the meat (i.e. chicken breast)
- Raw material tracing number (supplier's ID number and receiving date)
- Rack #
- Start date and time of thawing
- Quantity and size (amount on rack)
- Finished product lot #
- Name of person completing record

(b) (4)



Each tote is identified with a tag which contains the following information:

- Name of the raw material (i.e. chicken breast)
- Raw material tracing number (supplier's ID number and receiving date)
- Finish date and time of thawing
- Prepare time (sorting at inspection table)

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- Tote #
- Finished product load # (order or lot #)
- Name of person completing the record

Ingredient Weighing:

The firm has a separate weighing room which is located next to the semi-processing area where ingredients are weighed. As previously stated the firm uses very few ingredients in the manufacture of their jerky products. (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

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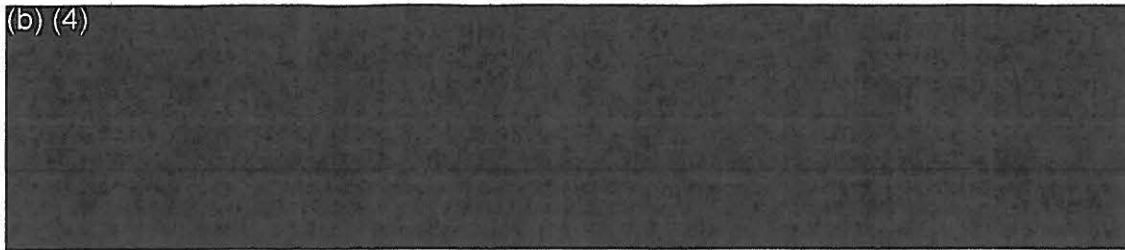
Jinan, China

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(b) (4)



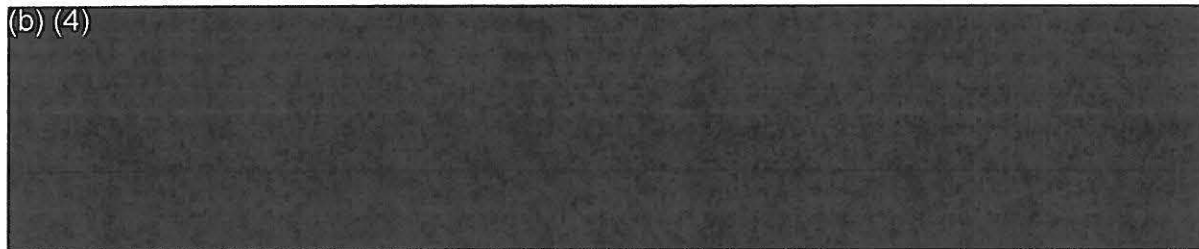
Each cart contains a tag which contains the following information:

- Raw material name (i.e. chicken breast)
- Raw material tracing #
- Ingredient tracing # (glycerin lot #)
- Date and time of thawing
- Mixing lot #
- Finished product lot #
- Name of person completing the record

(b) (4)



(b) (4)



(b) (4)



Each drying rack is identified with a tag which contains the following information:

- Raw material name (i.e. chicken breast)
- Raw material tracing #
- Ingredient tracing #
- Date and time of thawing
- Mixing lot #

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- Time of placing chicken breasts on screens
- Table #/Rack #
- Time entering drying chamber
- Start of heating time (sterilization)
- Drying oven #
- Finished product lot #
- Name of person completing record

(b) (4)



(b) (4)



(b) (4)



(b) (4)



The firm documents the drying of the jerky in each oven using a Drying Tunnel (oven) Temperature Monitor Record. There is one record for each oven. Identified as Exhibit #22/22a is an example of this record with translation. The following information is documented hourly on this record:

- Product lot #
- Raw material tracing #

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- Ingredient tracing #
- Rack #
- Time racks enter channel (oven)
- Temperature and operation of oven
 1. testing date and time
 2. temperature
 3. fan working (yes or no)
 4. exhaust fan working (yes or no)

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



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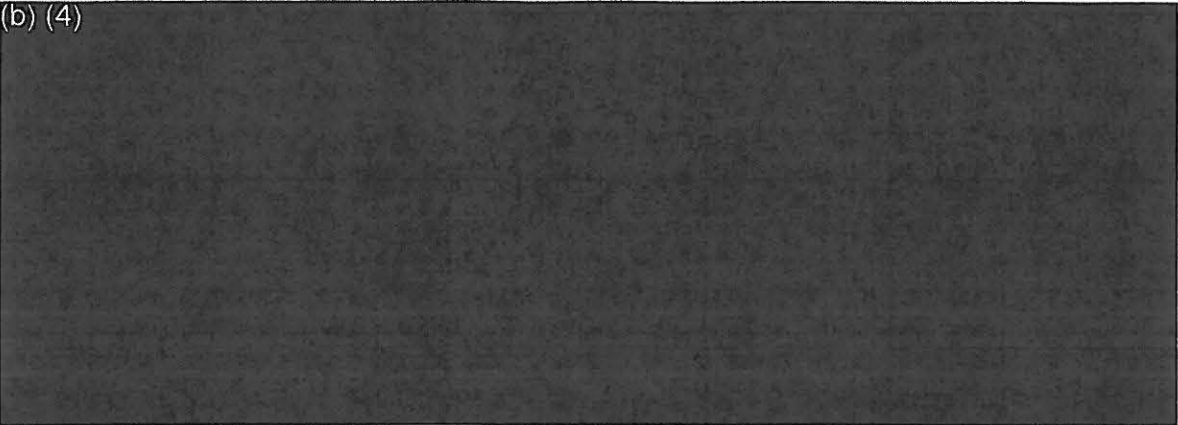
(b) (4)

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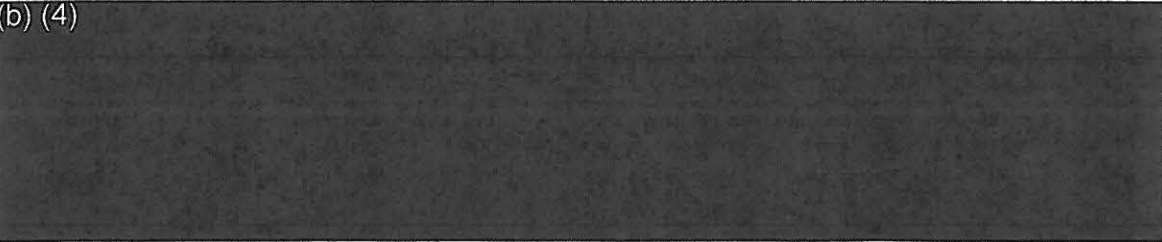
(b) (4)

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(b) (4)

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(b) (4)

(b) (4)

(b) (4)

Each pallet containing tubs of jerky packages is identified with a tag. This tag contains the following information:

- Name of product
- Raw material tracing #
- Date and time of metal detection
- Packaging date
- Number of bags on the pallet
- Time and date of deoxidizer time (when desiccants added to bags)
- Finished product lot #
- Name of person completing record

Following the 24 hour hold in the casing area, the bags are placed into cartons. The cartons of product are then moved to a storage area where they will remain until they are sent to a firm for irradiation. Generally the product lots are sent to the irradiator firm within several days of packaging and casing.

Irradiation:

All jerky products which are produced by this firm undergo irradiation before the product is exported to the U.S. Products are shipped to the irradiator firm's from Jinan Uniwell by means of third party logistics trucks.

The firm has used three different firms to irradiate the jerky products over the past several years. These firms are:

(b) (4)



Mr. Liu stated that JOC Great Wall Corp is responsible for determining which firm will perform irradiation of the jerky as well as overseeing the overall management of the irradiation operation. Mr. Liu stated that recently, irradiation has primarily been performed by (b) (4). (b) (4) has a quality control employee on site to oversee the irradiation of the jerky products at this firm. If irradiation will be performed at either (b) (4) (b) (4) the quality control employee will visit those plants during the irradiation of products. According to Mr. Liu, the (b) (4) also has employees on site at the irradiators to observe the operations when the firm's jerky products are irradiated.

According to Mr. Liu, the (b) (4) is responsible for setting dosage parameters for the jerky products. Although Mr. Liu did not know what those limits were, the firm was able to provide copies of radiation certificates for approximately the past year.

A review of the radiation certificates found that the three irradiators use (b) (4). (b) (4) The radiation certificates for (b) (4) (b) (4) identified a minimum specified dose of (b) (4) with no maximum specified dose specified.

A random review was made of a total of (b) certificates of irradiation for the firm's three irradiator companies between 7-6-11 and 3-27-12 during the inspection. This review found the minimum

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absorbed dose used to irradiate the firm's products was (b) (4) and the maximum absorbed dose was under (b) (4)

According to Mr. Li, the irradiator firms are responsible for placing the irradiated products in their final shipping cases. JOC is responsible for completing the shipping paperwork although they do not take physical possession of the products. All products are shipped to the U.S. through the port of Shanghai.

Product Testing:

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

Physical/Chemistry Laboratory:

(b) (4) are employed in this laboratory.

(b) (4)

(b) (4)

(b) (4)

(b) (4)


(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

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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. Prior to entering the workshop, persons are required to wash their hands with soap and water followed by hand sanitizing using chlorine dioxide solution for 20 seconds in a hand dip station. According to the firm, the sanitizer is changed in the hand dip station (b) (4). The solution in the hand dip station is reportedly maintained at (b) (4). The strength of the (b) (4) solution when tested by me on 4-5-12 was found to be (b) (4).

Prior to entering the workshop, persons are required to step through a sanitizing boot dip containing peroxyacetic acid which is maintained at (b) (4). We were informed that the boot dip solution is (b) (4).

Upon entering the processing area, an employee sprays employees and visitors hands with (b) (4). Hands are sprayed with (b) (4) in the processing area.

Employees handling the exposed product in the workshops are required to wear gloves.

Equipment Cleaning:

The firm has procedures in place for the cleaning of the workshop, equipment and utensils which are used in the manufacture of jerky products. Production employees working in the semi-clean and clean processing areas of the workshop are responsible for the cleaning. Quality control persons verify that cleaning has been performed adequately.

The firm follows the following procedures for equipment cleaning:

(b) (4)



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(b) (4)



(b) (4)



MANUFACTURING CODES

The firm's product coding system has changed in the past month at the request of the (b) (4) An example of the firm's former coding system is:

(example) 2095T0250101WG1

2 = year of production (2012)

095 = Julian date of manufacture

(b) (4)

01 = workshop # (workshop 1 = 1, workshop 2 = 2, etc)

01 = production line

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WG1 = product identification (WG1 = chicken jerky)

In the past month, (b) (4) has initiated a new coding system for the firm's products. An example of the new coding system is as follows:

(example) W1CA6409

W1 = Jinan Uniwell plant ID

CA6409 = Order #

All of the firm's products are identified with a Best By Date. The (b) (4) brand of jerky treats has an 18 month Best By Date. (b) (4) brand of jerky treats has a 24 month Best By Date. According to Mr. Liu, the Best By Dates have been determined by the (b) (4)

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. Customers are requested to retrieve the suspect product if possible for evaluation and testing. The firm's QC department is responsible for any investigations performed. The investigation consists of a review of manufacturing records, testing records, packaging records and distribution records for the suspect product. Reserve samples are also examined and tested to confirm any complaints received.

If a quality issue is found with the suspect product, the general manager is informed and organizes a team to determine a solution to correct the problem. The result of any investigation is forwarded to the firm's customer. If the complaint involves a safety issue, the firm initiates a recall of the product. Any investigation of a complaint is documented.

According to the firm, they have received two complaints in the past two years. These were:

- Complaint dated 1-20-11 (b) (4) of a chicken bone found in chicken jerky, lot # (b) (4) by a consumer. According to the complaint investigation, the firm contacted the raw meat suppliers of this complaint. The firm also enacted processing steps to insure employees did a better job of finding and removing chicken bones before the product was dried and packaged.
- Complaint dated 12-13-11 involving chicken jerky lot # (b) (4) QC staff on site at the firm's irradiator noticed the lot of product was placed into duck jerky cartons rather than chicken jerky cartons. According to the complaint investigation, the firm enacted measures to double check that the product was placed into the correct shipping cartons before the product left the firm.

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According to the firm, they have received no complaints relating to illness or dead of dogs relating to chicken jerky. According to a CVM database query dated 3-9-12, CVM has received (b) (4) complaints involving this firm's products.

A check of FDA's FACTS database found a total of (b) (4) complaints involving this firm's products. All related to the CJT issue. The first complaint in this database was received on 1-3-12. The last complaint was received on 5-1-12. (b) (4) of the complaints involved the (b) (4) brand of chicken jerky treats. (b) (4) complaint involved the (b) (4) brand of pork jerky.

RECALL PROCEDURES

The firm has a written recall procedure. The firm has identified a recall group which consists of management staff from Jinan Uniwell, JOC Great Wall Corp and the Jinan CIQ. Management staff from Jinan Uniwell consists of the general manager (Mr. Daxing Li), the deputy manager (Mr. Jun Li), the purchasing manager and the product development manager.

The Jinan Uniwell staff is responsible for manufacturing and reporting any recalls to the Jinan CIQ. JOC Great Wall is responsible for export operations. (b) (4) is responsible for sales.

The firm's recall procedure operates as follows:

Any reports of product complaints would be reported by the firm's marketing and sales department to the QC department. In turn the QC department would notify the management staff and the firm's laboratory to evaluate product safety. If the investigation and testing finds no safety concerns with the product, the issue would be handled as a complaint. If the investigation and testing finds a safety issue, the situation would be handled as a recall. The information would be reported to the general manager and a recall would be implemented by notifying JOC and the firm's recall group members. The Jinan CIQ and (b) (4) officials would be notified.

Jinan Uniwell would stop manufacturing and trace all raw materials, auxiliary ingredients and packaging materials to determine what other product lots were affected. The recall group would notify the media and consumers regarding the recall. JOC would be notified to identify and segregate any affected products which had not yet been shipped to the U.S. (b) (4) would conduct the recall of any products which were shipped to the U.S. Jinan Uniwell would keep the Jinan CIQ aware of the recall status until the recall was concluded.

The recalled products would be segregated and placed in a return products area using red rope to identify that the product was not to be shipped. All information relating to product lots involved would be documented. The Jinan CIQ would be requested to alert experts to evaluate product risk and develop corrective measures. If CIQ determines the products are safe after their evaluation, the product can be sold. If CIQ determine there is a safety issue, the product will be destroyed.

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According to the firm, they have not been involved in any recalls to date.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Although no FDA-483, Inspectional Observations form, was issued at the conclusion of the inspection, three issues were discussed with Mr. Shengru Liu, chairman of the board at the conclusion of the inspection. These were:

- 1) Broken metal supports were observed on metal screens used to lay out chicken breast meat for the drying process.
- 2) The firm's food facility registration should be updated to identify Jinan Uniwell Pet Food Co, Ltd as the true manufacturer of pet treats rather than Jinan Welcome Food Co (the parent company).
- 3) Shipping records should identify the food facility registration number for Jinan Uniwell Pet Food Co Ltd as the true manufacturer of jerky treat products rather than using the registration number of a Chinese shipper/broker on the shipping records.

Mr. Liu stated that all issues would be corrected immediately. It was observed following the inspection that the firm's food facility registration now identifies Jinan Uniwell Pet Food Co, Ltd as the true manufacturer of jerky pet treats.

An examination of FDA's Online Reporting Analysis Decision Support System (ORADSS) data base on 5-6-12 shows no lines of entry into the U.S. for Jinan Uniwell Pet Food Co Ltd to date. The firm's Chinese broker/shipper (b) (4) - identified as the manufacturer); however, continues to show lines of entry into the U.S. for jerky treat products as late as 5-4-12. As best determined (b) (4)

REFUSALS

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

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

During this inspection informal meetings were held with Dr. Dou relating to AQSIQ's refusal to allow sampling unless AQSIQ conditions were met and concerns addressed. Dr. Dou stated that

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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. Shengru Liu, chairman of the board; his staff; Dr. Dou, the AQSIQ representative; and representatives from the Shandong CIQ and Jinan CIQ. A list of the participants at this meeting is identified as Exhibit #14.

Mr. Liu was informed that the only GMP-type issue found involved broken metal rod supports on the metal screens which were used to hold the meat during drying operations. Mr. Liu stated that these screens would be repaired immediately.

Mr. Liu was informed that the firm food facility registration should be amended to identify Jinan Uniwell Pt Food Co, Ltd as the true manufacturer of pet food rather than the parent firm, Jinan Welcome Food Co, Ltd. Mr. Liu stated that the food facility registration would be corrected. It was observed that the firm's food facility registration was amended to reflect this change after the inspection.

Mr. Liu was informed that the firm should notify their shipper, JOC Great Wall Corp, that the shipping records should identify Jinan Uniwell as the true manufacturer of the jerky treat products which are exported to the U.S. A query of FDA's Online Reporting Analysis Decision Support System (ORADSS) data base on 5-6-12 shows no lines of entry into the U.S. for product shipped by Jinan Uniwell Pet Food Co Ltd to date. The firm's Chinese broker/shipper (JOC Great Wall Corp) was identified as the manufacturer on lines of entry into the U.S. for jerky treat products as late as 5-4-12. As best determined (b) (4) is not a manufacturer of jerky pet treats.

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

One issue discussed with Mr. Shengru Liu, chairman of the board, during the inspection relating to the firm's need to update their food facility registration to identify Jinan Uniwell Pet Food Co, Ltd as

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the true manufacturer of pet food. At the time of the inspection, the firm's food facility registration identified Jinan Welcome Food Co Ltd as the manufacturer of pet food. Jinan Welcome Food Co Ltd is the parent company of Jinan Uniwell and does not manufacture any pet food.

Mr. Shengru Liu stated that the firm would update their food facility registration to identify Jinan Uniwell Pet Food Co Ltd as the true manufacturer of pet food in the future. An examination of the firm's food facility registration following the inspection found the firm's food facility registration has been updated as promised by Mr. Liu.

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 (62 pages)
- 4) (b) (4) [REDACTED] Jerky Tenders label (1 page)
- 5) (b) (4) [REDACTED] Jerky Tenders label (1 page)
- 6) (b) (4) [REDACTED] Pork Jerky label (1 page)
- 7a) (b) (4) [REDACTED] Herb Roasted Chicken Bites label (1 page)
- 7b) (b) (4) [REDACTED] Honey Basted Chicken Bites label (1 page)
- 7c) (b) (4) [REDACTED] Chicken & Cheese Chicken Bites label (1 page)
- 8) (b) (4) [REDACTED] Chicken Tenders label (1 page)
- 9) (b) (4) [REDACTED] Duck Tenders label (1 page)
- 10) (b) (4) [REDACTED] Pork Jerky label (1 page)
- 11/11a) Organizational chart with translation (1 page)
- 12) List of attendees at opening meeting of inspection (1 page)
- 13) Business cards collected from attendees of inspection (1 page)
- 14) List of attendees at closing meeting of inspection (1 page)
- 15/15a) List of suppliers of chicken breast meat for 2010/2012 with translation (6 pages)
- 16/16a) List of suppliers of duck breast meat for 2010/2012 with translation (6 pages)
- 17/17a) List of suppliers of pork for 2010/2012 with translation (6 pages)
- 18/18a) List of suppliers of auxiliary ingredients for 2010/2012 with translation (4 pages)
- 19) Photographs (21 pages)
- 20) (b) (4) [REDACTED] (2 pages)
- 21) Blank copy of Processing input Record (1 page)
- 22/22a) Blank copy of (b) (4) [REDACTED] Monitoring Record with translation (2 pages)
- 23) Blank copy of Moisture Content Test Record (1 page)
- 24/24a) Blank copy of Sterilization Tunnel Temperature Monitoring record with translation (2 pages)

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- 25/25a) Environmental microbial limits and procedures form (2 pages)
 - 26/26a) Summary of firm's raw material surveillance program with translation (2 pages)
 - 27) Comprehensive Test Center of CAIQ test report dated 4-5-12 for (b) (4) (1 page)
 - 28) Comprehensive Test Center of CAIQ test report dated 4-5-12 for (b) (4) (1 page)
 - 29) Comprehensive Test Center of CAIQ test report dated 4-5-12 for chicken jerky lot (b) (4) (1 page)
 - 30) Comprehensive Test Center of CAIQ test report dated 4-5-12 for chicken jerky lot (b) (4) (1 page)
 - 31/31a) List of external audits performed at firm since 2010 (2 pages)

ATTACHMENTS

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


Dennis L. Douppnik, investigator


Lixia Wang, Medical Research Scientist