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## SUMMARY

This directed surveillance inspection of a ground white pepper manufacturer and spice repacker was conducted in conjunction with the California Food Emergency Response Team (CalFERT) investigation into a multi-state *Salmonella* serotype Rissen outbreak associated with consumption of white pepper. This report details both the FDA regulatory inspection and CalFERT investigation, which significantly overlapped in their areas of focus. For this investigation, the joint federal/state emergency response team of CalFERT was composed of members from the FDA San Francisco District Office (SAN-DO) and the California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit. Investigators from the FDB Food Safety Inspection Unit also participated.

This inspection of U.F. Union International Food Co., Inc. (Union International) in Union City, CA was performed under Field Accomplishments and Compliance Tracking System (FACTS) assignment number 1045309. The inspection was conducted in accordance with Compliance Program 7303.803, the Domestic Food Safety Inspection Program, as part of the SAN-DO Fiscal Year 2009 Work Plan. A traceback and environmental investigation were conducted at the Union International facility, coupled with examination of the firm's pepper handling procedures and current good manufacturing practices. As of June 4, 2009, the outbreak encompassed a total of 87 pulsed-field gel electrophoresis (PFGE) matched cases of *Salmonella* Rissen documented across five states: 65 in California, 10 in Nevada, 8 in Oregon, 3 in Washington, and 1 in Idaho. The death of one patient may have been associated with the outbreak (refer to Epidemiology). The earliest confirmed case of illness occurred in (b) (6) with a *Salmonella* Rissen specimen collection date of September 16, 2008 (exposure and illness onset dates unknown). Two samples of pepper collected from a Portland, Oregon restaurant where a case patient had dined initially led CalFERT to Union International. Lian How Brand ground white pepper and ground black pepper were each collected from partially used 5 pound jugs in the restaurant's kitchen. *Salmonella* Rissen with a PFGE pattern indistinguishable from the outbreak strain was isolated from each of the jugs, which were labeled, "Packaged by Union International Food Co. Union City, CA." There were 42 documented illnesses at the time CalFERT initiated investigation at the Union International facility on March 27, 2009. That day, Union International ceased production and distribution of all products packaged on site, according to the firm's management. The firm initiated its first voluntary recall March 28, 2009, encompassing all forms of pepper and all dried spices packaged on site. Also on March 28, FDB investigators placed a state embargo over in-process spices, finished product spices, and raw material pepper. The firm's recall was expanded April 15, 2009 to include Asian-style sauces and oil blends manufactured at the facility.

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As investigations progressed across the affected states and counties, *Salmonella* Rissen matching the outbreak strain was isolated from additional packages of ground white pepper bearing Union International brand names, including one intact (unopened) sample from the Portland, Oregon restaurant; one intact sample from a retail store in Kent, Washington, and one previously opened sample from a casino resort in Reno, Nevada, with a suspected associated illness cluster. All samples from intact containers that resulted in matches to the outbreak strain were of ground white pepper packaged by Union International. The Portland sample of ground black pepper which matched the outbreak strain was drawn from a previously opened container and may have been a result of cross-contamination.

Union International manufactured ground white pepper and repackaged a variety of spices. No lot codes were marked on the firm's products. The firm purchased whole white pepper in bulk, ground the white peppercorns in a machine on site, and hand packaged the ground white pepper into restaurant and consumer sized packages. A variety of spices, including black pepper, paprika, garlic powder and curry powder, among others, were purchased in bulk and repackaged by hand into restaurant and consumer sized packages. Union International also manufactured Asian style sauces and oil blends. Sauces included items such as chili sauce and black bean garlic sauce. Oils included pure sesame oil and sesame/soybean oil blends. While the sauces and oils were a consideration for the firm's recall due to their manufacture on site, no *Salmonella* was isolated from sauces or oils and these products were not the focus of the current inspection. Union International directly imported a portion of its raw materials, primarily ingredients for sauces and some of the bulk spices for repackaging. All forms of pepper were purchased (b) (4), although the pepper originated overseas. Union International's customer base consisted of distributors and primarily (b) (4) restaurants and grocery stores. The firm distributed products mostly throughout Northern California and to states in the Pacific Northwest.

During the initial phase of investigation, CalFERT collected 391 samples for *Salmonella* analysis from the Union International facility in order to determine if contamination was present and to assess its scope in products and the environment. Samples were collected under both FDA and FDB protocols. Of 116 environmental swab samples collected, 46 were found positive for *Salmonella* (40%), as were 14 of 18 in-process white pepper samples collected (78%), and 2 finished product ground white pepper composite samples collected (100%). Positive samples were selected from each of these categories for PFGE analysis. All selected samples were found to be indistinguishable from the outbreak strain of *Salmonella* Rissen, including 19 environmental swab samples, 3 in-process samples, and 2 finished product samples. Additionally, *Salmonella* was identified in 1 of 104 samples (1%) collected from a lot of raw material whole white pepper and matched by PFGE analysis to the outbreak strain. The whole white pepper originated from Vietnam and was purchased by Union International on August 18, 2008 from the importer (b) (4). Laboratory findings were negative for *Salmonella* in 151 other samples collected from the Union International facility, which included finished product ground black pepper and other spices, finished product sauces and oil blends, and raw material ground black pepper and other spices.

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Credentials were shown and the form FDA 482, Notice of Inspection, (FDA 482) was first issued on March 27, 2009 to Mr. Daniel Y. Chen, Vice President and Manager, at the onset of this inspection. The FDA 482 was issued again on a number of subsequent dates, as indicated under Administrative Data. The previous routine FDA inspection concluded March 17, 2008 and was classified Voluntary Action Indicated (VAI) for good manufacturing practice issues that were discussed with the firm, although no form FDA 483, Inspectional Observations, (FDA 483) was issued. Dust and food debris were observed on food and non-food contact surfaces inside the facility, including machine blades, walls, and overhead fixtures. Management promised to correct the observations and create a cleaning checklist within 45 days. No cleaning checklist had been created by the onset of the current inspection.

At the close of the current inspection, the FDA 483 was issued to Mr. Chen on July 24, 2009 with the following six summarized inspectional observations.

1. Failure to manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination:
  - Private laboratory analysis results provided by the hired consultant revealed environmental samples collected from inside the facility were found positive for *Salmonella*.
  - Ground white pepper was stored in open barrels beneath an unscreened roof vent.
2. Failure to maintain white pepper grinding equipment in an acceptable condition through appropriate cleaning and sanitizing: An accumulation of dust was observed on multiple food contact surfaces.
3. The (b) (4) funnels (observed with dried residues) used for (b) (4) of spices and the unlined (b) (4) barrels used to store ground white pepper were not made of materials that allowed for proper cleaning and maintenance.
4. Failure to clean and sanitize (b) (4) scoops used for repackaging spices in a manner that protected against contamination of food: Food residues and a thin film of dust were observed on the scoops.
5. Failure to clean non-food contact surfaces in the white pepper grinding room and the adjacent hallway as frequently as necessary to protect against contamination: Accumulations of white pepper dust and brown stains were observed on multiple surfaces in the immediate vicinity of food contact surfaces.
6. Failure to maintain pipes used to convey oil (food product) in a manner that protected against contamination: Oil was observed collected in pans below pipes and in a plastic bag tied around a pipe in the sauce and oil bottling room.

Present for the closeout discussion were Mr. Chen and Mr. (b) (4) (the firm's hired consultant). Mr. (b) (4) explained that each of the observations listed on the FDA 483 had already been corrected, primarily through an extensive cleaning, sanitizing, and remodeling effort in the facility. He provided a set of documents detailing the firm's new sanitation, production, lot coding, and product testing procedures. He explained that

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Mr. Chen does not plan to perform any grinding of white pepper in the facility in the immediate future, nor until such time that an effective system to contain dust and potential cross-contamination can be implemented. Mr. Chen affirmed each response provided by Mr. (b) (4). The firm's corrections in response to FDA 483 observations were verified to the extent possible, in that equipment and processing rooms appeared clean with no sign of dust or stains at the inspection closeout. After the cleaning and remodeling effort at the Union International facility was considered to be complete by the firm's management, CalFERT collected 100 environmental swab samples on August 4, 2009 for cleaning verification purposes. All samples were negative for *Salmonella*.

Prior to the close of the current FDA inspection, FDB filed a Stipulated Preliminary Injunction against Union International Food Co., Inc. with the Alameda County District Attorney in Alameda County Superior Court on May 21, 2009. As of September 10, 2009, the firm had not yet resumed processing and communications were ongoing with FDB in an effort to satisfy the criteria listed in the preliminary injunction. (b) (7)(A)

FDB led the oversight of the firm's voluntary destruction of products, in addition to review of the firm's reconditioning proposal for spices using irradiation, although FDA weighed in on both matters. Mr. Chen was advised that FDA could also pursue regulatory action against the firm if objectionable conditions were not corrected.

This inspection is classified Official Action Indicated (OAI). Twenty-nine FDA samples were collected during the inspection. *Salmonella* Rissen was identified in two FDA finished product samples: INV 490700 and INV 490701, and 14 FDA environmental swab sub-samples: INV 402154 sub 1, INV 490696 subs 1-6, INV 490702 sub 4, INV 503180 subs 1-5, and INV 503185 sub 1. Documentary Samples 387908 and 387909 were collected to document interstate commerce. Refer to Samples Collected for a full account of FDA and FDB samples.

While no outright refusals were encountered, Mr. Chen provided misinformation and initially refused access to the previously undisclosed adjacent warehouse upon its discovery on April 21, 2009. For this inspection, the core FDA team was comprised of Investigators Erica R. Pomeroy (team lead), Jeanne A. Young, William V. Millar, Min Shan Mabel Liu, and Emergency Response Coordinator (ERC), formerly Investigator, James C. Yee. Other FDA participants listed under Administrative Data assisted the core team with the extensive sampling effort. We (one or more members of the inspection team) were often present at the firm on different days and in varying combinations of team members due to the diverse array of tasks called for by this CalFERT investigation and regulatory inspection. Team member contributions to this report and sources of background information are detailed under Administrative Data. Original photographs taken by members of the inspection team were saved on an officially sealed compact disk, Exhibit 1. Original photographs of Union International products taken by Luis A. Solorzano, Director of Investigations Branch, at the district office (for recall purposes) were saved on an officially sealed compact disk, Exhibit 2.

## **BACKGROUND INFORMATION**

### **Epidemiology**

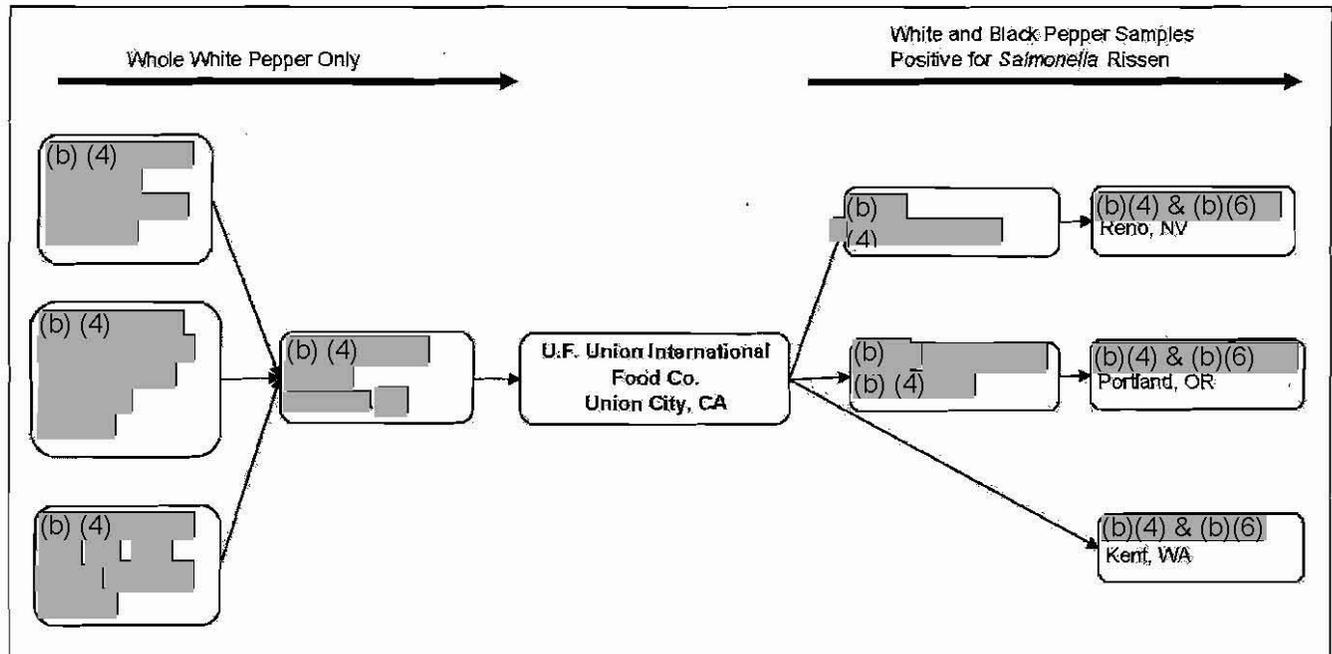
The multi-state outbreak of *Salmonella* serotype Rissen associated with consumption of white pepper was assigned cluster number 0903NVTEE-1 by the Centers for Disease Control and Prevention. The California Department of Public Health, Infectious Diseases Branch, Disease Investigations Section led the epidemiological investigation for California and provided epidemiological information for this report (CDPH email: Attachment A, Pages 1-2). California was part of the coalition of states that collaborated in tracking illnesses for the outbreak. As of June 4, 2009, there were a total of 87 PFGE-matched cases documented across five states: 65 in California (distributed primarily in the Northern half of the state), 10 in Nevada, 8 in Oregon, 3 in Washington, and 1 in Idaho. *Salmonella* sepsis may have contributed to the death of one person who was a hospital patient at the time of suspected exposure to the outbreak strain. The epidemiological line list (Attachment A, Pages 3-5) details outbreak illness cases. Attachment B graphically represents outbreak data in pages 3-7. Page 2 of Attachment B features a map of case patient distribution in California and other states. A confirmed case was defined as a laboratory-confirmed infection of *Salmonella* serotype Rissen with the outbreak PFGE XbaI-enzyme pattern (TEEX01.0014) in a person with a specimen collection date on or after September 16, 2008. Although the earliest *Salmonella* Rissen infection associated with this outbreak had a specimen collection date in September, there was a nearly three-month gap until the next specimen collection date of December 12 for a case with a clear illness onset of December 9. Cases occurred more steadily from that point forward, with specimen collection dates of December 18 (1 case), January 2 (1 case), January 5 (1 case), January 12 (2 cases) and so on, as depicted in the CDPH Epidemic Curve by Specimen Collection Week, Attachment B, Page 7. The complete range of specimen collection dates was September 16, 2008, to May 22, 2009. Clear illness onset dates were only available for 32 cases; these ranged from December 9, 2008, to April 29, 2009. There were eight hospitalizations due to gastrointestinal illness. A case-control was not conducted for this outbreak because white pepper samples collected from restaurants where cases reported eating were found positive for *Salmonella* Rissen matching the outbreak strain PFGE pattern.

The Office of Emergency Operations (OEO) provided historic information pertaining to the outbreak strain of *Salmonella* Rissen. The strain had surfaced once before in FDA sample collection history, also associated with pepper: A 2006 FDA import sample of black pepper from Vietnam yielded *Salmonella* Rissen with a PFGE pattern indistinguishable from the current outbreak strain. The sample was drawn from import entry number EG6-1231826-1/2/1.

### **Traceback to Union International**

The sample and traceback information found in this section, including the Oregon, Washington, and Nevada-related sub-sections, was provided by FDA offices other than SAN-DO and by states and counties, as detailed under Administrative Data. Samples of pepper packaged by Union International, collected at three restaurant or retail establishments across three states, yielded positive results for *Salmonella* Rissen with a PFGE pattern matching the outbreak strain. The samples were collected from a restaurant in Portland, OR with at least one suspected associated illness, a retail

store in Kent, WA, and a casino resort in Reno, NV with a suspected associated illness cluster. The pepper sampled at the three locations traced directly or indirectly back to Union International in Union City, CA. Figure 1 is a traceback diagram, which is featured with additional detail as Attachment C.



*Figure 1.* Traceback diagram for samples of pepper packaged by Union International that were collected at points of service and found positive for *Salmonella* Rissen matching the outbreak strain. Sources of whole white pepper supplied to Union International from November, 2007 to the onset of the inspection are displayed.

(b)(4) & (b)(6) **Portland, Oregon**

Three samples of Lian How Brand pepper in 5 pound plastic jugs (identical to Photo Exhibit 1, Page 9), collected from (b)(4) & (b)(6) restaurant in Portland, Oregon, were found positive for *Salmonella* Rissen matching the outbreak strain. Two of the samples were ground white pepper collected by FDA Seattle District Office (SEA-DO): one from an intact container (SEA-DO FDA sample 513142) collected April 2, 2009 from (b)(4) & (b)(6), and one drawn from a sample that had been collected from a previously opened container by Multnomah County on March 20, 2009 at (b)(4) & (b)(6) (SEA-DO FDA sample INV 501376). The third sample was ground black pepper from (b)(4) & (b)(6) previously opened container, collected March 20, 2009 by Multnomah County and analyzed in the Oregon state laboratory (Oregon Department of Human Services sample G09-0288, Attachment D). A memorandum (attached to this report) from SEA-DO Investigator Nancy E. Doyle, dated April 20, 2009, details information pertaining to the (b)(4) & (b)(6) traceback. (b)(4) & (b)(6) purchased the Lian How Brand pepper from (b)(4) & (b)(6) purchased the pepper from Union International. Documents collected at Union International (Exhibit 3) and identical ones collected by SEA-DO at (b)(4) & (b)(6) revealed that between January 2008 and April 2009,

(b) (4) purchased black and/or white ground pepper in 5 pound jugs from Union International on just three occasions (both types of pepper purchased on all three):

- January 16, 2008
- March 6, 2008
- November 5, 2008

The sale on November 5 was the last occasion Union International sold pepper to (b) (4) prior to ceasing distribution on March 27, 2009. According to Mr. Chen (b) (4) purchased pepper from other sources subsequent to November 5. Invoices for products sold by (b) (4) & (b) (6) obtained by SEA-DO, reveal a pattern of regular supply for ground white pepper. With the exception of February 2008, March 2008, and February 2009 (no shipments sold), (b) (4) sold ground white pepper to (b) (4) & (b) (6) on one to three occasions per month over 2008 and 2009. Each sale consisted of (b) (4) of ground white pepper. Subsequent to November 5, (b) (4) sold ground white pepper to (b) (4) & (b) (6):

- November 11 and 25, 2008
- December 12, 2008
- January 6 and 9, 2009
- March 3 and 13, 2009

(b) (4) supplied ground black pepper to (b) (4) & (b) (6) less consistently, about every one to three months. Each sale consisted of (b) (4). Subsequent to November 5, (b) (4) sold ground black pepper to (b) (4) & (b) (6):

- December 12, 2008
- March 13, 2008

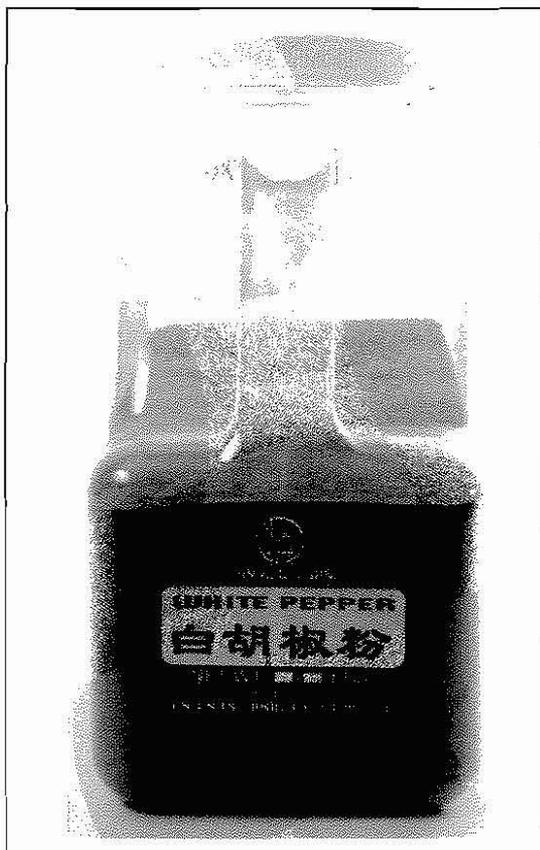
The specimen collection date (per CDPH) for the case patient who reported dining at (b) (4) & (b) (6) was March 3, 2009 (exposure date and illness onset date unknown). Refer to Attachment A, the epidemiological line list for specimen collection data. The samples of previously opened ground white and ground black pepper from (b) (4) & (b) (6) which yielded *Salmonella* Rissen were collected at the restaurant March 20, 2009. The intact sample of ground white pepper yielding *Salmonella* Rissen was collected April 2, 2009 and reportedly purchased by (b) (4) & (b) (6) on the March 13, 2009 invoice from (b) (4).

#### (b) (4) **Kent, Washington**

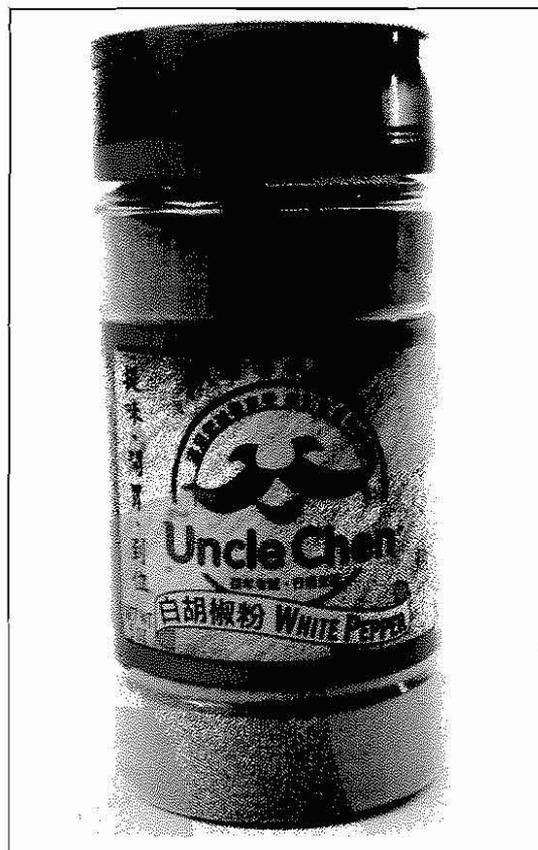
One sample of Uncle Chen brand ground white pepper packaged in intact 5 ounce retail containers (identical to Photo Exhibit 2, Page 9) was collected April 1, 2009 by SEA-DO from (b) (4) in Kent, WA and found positive for *Salmonella* Rissen matching the outbreak strain (SEA-DO FDA sample DI 480437, copy attached to this report). Although Union International did not utilize lot codes, making traceability difficult, a review of sales documents showed that (b) (4) had purchased ground white pepper in 5 ounce Uncle Chen containers

only once between January, 2008 and April, 2009. On November 4, 2008, (b) (4) purchased (b) (4) 5-ounce containers of ground white pepper from Union International. The invoice is included as part of Documentary Sample 387909, collected from Union International (attached to this report). Matching documents collected in Kent are described in SEA-DO Domestic Import Sample 480437.

4/1/09 LAS\*



4/1/09 LAS



\*Photo capture date and photographer's initials

*Photo Exhibit 1.* Five pound plastic jug of Lian How Brand ground white pepper

- Packaging identical to samples collected at (b)(4) & (b) (4) (513142, INV 501376) and (b)(4) & (b)(6) (b)(4) & (b)(6), which yielded the outbreak strain of *Salmonella* Rissen
- Packaging identical to INV 490700, collected at Union International and found positive for *Salmonella* Rissen matching the outbreak strain

*Photo Exhibit 2.* Five ounce plastic container of Uncle Chen ground white pepper

- Packaging identical to the sample collected at (b) (4) (DI 480437), which yielded *Salmonella* Rissen matching the outbreak strain

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(b) (4) & (b)(6) **Reno, Nevada**

One sample of Lian How Brand ground white pepper in a previously opened, 5 pound plastic jug (identical to Photo Exhibit 1) was collected by Washoe County on March 11, 2009 from (b) (4) & (b) (6) in Reno, Nevada and found positive for *Salmonella* Rissen matching the outbreak strain. Washoe County Health District, Environmental Services Division Sample FBI090050(6) was analyzed by the Nevada State Health Laboratory (Attachment E). Photographs of the sample were submitted by Washoe County (Attachment F). A cluster of nine to ten documented *Salmonella* Rissen illness cases had suspected exposures at (b) (4) & (b)(6). Refer to Attachment A for epidemiological information provided by CDPH. Clear illness onset dates for these cases ranged from December 17, 2008 to April 1, 2009. During 2008 and 2009 (b) (4) & (b)(6) purchased Lian How Brand pepper on a regular basis from (b) (4) approximately once every one or two months. (b) (4) purchased Lian How Brand pepper on a regular basis from Union International, approximately once or twice per month. Exhibit 4 features the invoices to (b) (4), collected from Union International.

#### **TRACEBACK FROM UNION INTERNATIONAL**

The traceback information found in this section was collected at Union International, except where noted as provided by the FDA Los Angeles District Office (LOS-DO). Union International purchased bulk white pepper in both whole and pre-ground form. The firm ground much of the whole white pepper received, but sold some repackaged in whole form. All raw material pepper was purchased from two suppliers who were also the importers, according to the firm (b) (4)

(b) (4) Union International maintained no electronic purchase records. Based on documentation the firm gathered through a manual file search, pepper purchases going back through November, 2007 were identified, along with import-related information. LOS-DO verified and supplemented the pepper traceback information through visits to both (b) (4) (b) (4). A memorandum (attached to this report) by LOS-DO Investigator Alexandra Pitkin, dated April 14, 2009, details traceback information collected at (b) (4). The black and white pepper supplied to Union International originated from India, Indonesia, and Vietnam. None of the foreign manufacturers identified appeared related to the foreign manufacturer listed in OASIS (FDA's Operational and Administrative System for Import Support) for the 2006 black pepper sample which yielded *Salmonella* Rissen matching the outbreak strain.

The prevalence of *Salmonella* in the environment of the white pepper grinding room at Union International lent a traceback focus to whole white pepper. Of 40 environmental swabs collected inside the room, 34 (85%) were found positive for *Salmonella*. Food contact surfaces yielding positives for *Salmonella* included the inside of the whole white pepper hopper, the input chute for the grinder, the exit chute for the grinder, and the ground pepper hopper exit chute.

Union International maintained no production records for raw ingredient usage and marked no lot codes on finished products, thus we were unable to definitively track the usage of raw materials in finished products. The firm used whole white pepper more or less on a first in, first out basis for

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quality reasons, although no records of inventory were maintained. Mr. Chen acknowledged that sometimes bags from a previous shipment might have been forgotten in a corner of the warehouse while a new shipment was already being processed. Documents were obtained at Union International (by our inspection team) and at (b) (4) (by LOS-DO) detailing the five most recent shipments of whole white pepper received by Union International. The source of the documents referenced is noted below as “Union” or (b) (4) to indicate whether they were obtained from Union International, (b) (4), or from both entities.

- (b) (4), Purchased January 13, 2009 (Source: Union, (b) (4))
  - Lot (b) (4)
  - Supplier: (b) (4) (Exhibit 5, Page 1)
  - Manufacturer: (b) (4)
  
- (b) (4), Purchased August 18, 2008 (Source: Union, (b) (4))
  - Lot (b) (4)
  - Supplier: (b) (4) (DOC 387908)
  - Manufacturer: (b) (4)
  
- (b) (4), Purchased December 1, 2007 (Source: (b) (4))
  - Lot (b) (4)
  - Supplier: (b) (4) (Attachment G, Page 3)
  - Manufacturer: (b) (4)
  
- (b) (4) Purchased November 30, 2007 (Source: (b) (4))
  - (b) (4)
  - Supplier (b) (4): Attachment H, Page 4 and (b) (4) Attachment I, Page 5
  - Manufacturer: (b) (4)
  
- (b) (4), Purchased November 1, 2007 (Source: Union, (b) (4))
  - Lots (b) (4)
  - Supplier: (b) (4) (Exhibit 6, Page 1)
  - Manufacturer: (b) (4)
  - Note: The shipment originally contained (b) (4) of product, however (b) (4) (some product from each lot) was returned by Union International to (b) (4) due to high moisture content.

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Of the five purchases, only those purchased January 13, 2009 and August 18, 2008 were complete imported lots that were sold exclusively to Union International by (b) (4). The other three purchases were drawn from imported lots of pepper that were partially distributed to Union International and partially to other consignees. Attachment J lists the original import entry numbers for raw material pepper supplied to Union International.

Bags of raw material pepper observed in storage at the Union International facility were matched to purchase invoices by their lot codes. Unused bags remained only from the two most recent purchases. From the January, 2009 purchase, over (b) (4) bags remained. This shipment was not sampled by CalFERT, however three composite samples of whole white pepper (Lot (b) (4) (b) (4)) were collected by (b) (4) and found negative for *Salmonella* using the FDA Bacteriological Analytical Manual (BAM) method. (b) (4) provided the results to FDA (Exhibit 7, Pages 1-7). Refer to Private Laboratory Samples. From the August, 2008 shipment, (b) (4) (b) (4), intact bags remained in storage at the facility from Lot (b) (4) (b) (4). The bags were labeled, (b) (4) (b) (4) "White Pepper." Of 104 samples collected from the (b) (4) (b) (4) bags by CalFERT, one sample was found positive for *Salmonella* Rissen matching the outbreak strain. Lot (b) (4) (b) (4) was purchased August 18, 2008 and received at the Union International facility directly from the Port of Oakland that same day. (b) (4) (b) (4) imported the lot from (b) (4) (b) (4) via FDA import entry NP9-0002100-7. The entry was granted a "May Proceed" from import status by FDA on August 12, 2008. LOS-DO verified that all (b) (4) (b) (4) bags in the entry were sold to Union International. Documentary Sample 387908 (attached to this report) features the documentation collected from Union International associated with this shipment. Among the documents is a (b) (4) (b) (4) certificate of analysis, which states the lot was negative for *Salmonella*.

Mr. Chen recounted an incident in late 2007 which disrupted the normal pepper grinding routine. He explained that whole white pepper from two lots received (b) (4) (b) (4) purchased November 1, 2007) contained a high level of moisture, causing the grinder to clog every one or two days and necessitating frequent cleanings to keep it functioning. Mr. Chen attempted to dry some of the pepper in the sun, but ultimately returned half of the shipment. Refer to Exhibit 6, Page 10 for his letter to (b) (4) (b) (4) describing the situation. According to information obtained by LOS-DO: The moisture content of the whole white pepper from Lot (b) (4) (b) (4) was 13.7 percent (Certificate of Conformity, Attachment K, Pages 2-3). (b) (4) (b) (4) set a maximum limit of 14 percent for all white pepper sold. A May 20, 2009 email from LOS-DO Investigator Pitkin (Attachment L, Pages 1-9) details the (b) (4) (b) (4) Union resolution for the moist pepper incident. Of the (b) (4) (b) (4) of pepper received in November, 2007, Mr. Chen returned (b) (4) (b) (4) bags from Lot (b) (4) (b) (4) and (b) (4) (b) (4) bags from Lot (b) (4) (b) (4). (b) (4) (b) (4)

Mr. Chen explained that he set aside the remaining (b) (4) (b) (4) bags from the moist shipment in the Union International warehouse to let it dry out. In the mean time (per LOS-DO), (b) (4) (b) (4) supplied him with a smaller amount (b) (4) (b) (4) of whole white pepper in November and December of

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2007, followed by a shipment of pre-ground white pepper (b) (4) in early January, 2008. Union International also purchased (b) (4) of pre-ground pepper from (b) (4) in February. The pre-ground white pepper was directly repackaged by Union International. According to Mr. Chen, packaging of the pre-ground pepper continued until it was used up, around approximately mid-2008. At that point, Union International resumed grinding the moist pepper from 2007, which by then had become slightly drier. This account was from Mr. Chen's memory, as no usage records existed. He further recalled that the August 18, 2008 purchase of whole white pepper was (b) (4). He could not remember approximately when he finished grinding the moist pepper from 2007 and began grinding the pepper from August, 2008. A certificate of analysis accompanying the August pepper displays a moisture content of 13.8 percent (DOC 387908), however Mr. Chen noted no problems associated with grinding it. Attachment J features purchase dates, suppliers, and forms of raw material pepper supplied to Union International from November 2007 to the onset of the inspection.

**ADMINISTRATIVE DATA**

Inspected firm: U.F. Union International Food Co., Inc.  
Location: 33035 Transit Avenue  
Union City, CA 94587-2043  
Phone: (510) 471-8299  
FAX: (510) 471-9999  
Mailing address: 33035 Transit Avenue (33055 Transit Avenue also occupied)  
Union City, CA 94587  
Email: unclchen168@yahoo.com  
Website: <http://www.ufunionfood.com>

Dates of inspection: 3/27/2009, 3/28/2009, 3/30/2009, 3/31/2009, 4/1/2009, 4/2/2009,  
4/6/2009, 4/7/2009, 4/13/2009, 4/15/2009, 4/21/2009, 4/28/2009,  
5/8/2009, 5/12/2009, 5/13/2009, 7/8/2009, 7/24/2009

Days in the facility: 17

Participants: Erica R. Pomeroy, Investigator  
Janice Wai, Investigator  
Jeanne A. Young, Investigator  
Bruce D. Broidy, Investigator  
William J. Weis, Investigator  
James C. Yee, Investigator/Emergency Response Coordinator  
Joseph A. Seitz, Investigator  
Benny Y. Gong, Investigator  
Ronald P. Boyce, Investigator  
William V. Millar, Investigator  
Min Shan Mabel Liu, Investigator  
Daniel J. Roberts, Investigator

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Vebina K. Sethi, Investigator (officially: Inspector)

This report was written primarily by Investigator Pomeroy. ERC Yee and Investigator Liu contributed to Manufacturing/Design Operations. Observations listed on the FDA 483 and/or their supporting evidence and relevance were jointly written by ERC Yee and Investigators Young, Millar, Liu, and Pomeroy. ERC Yee contributed to Refusals. Epidemiological background information in this report was provided by the CDPH Infectious Diseases Branch, Disease Investigations Section. Background information for the section entitled, Traceback to Union International, was provided by SEA-DO; OEO; the Oregon Department of Human Services, Public Health Division; and the Washoe County Health District, Environmental Services Division of Nevada. For the section entitled, Traceback From Union International, traceback information on white pepper purchased by Union International was verified and supplemented by LOS-DO.

FDA Credentials were displayed to Mr. Daniel Y. Chen, Vice President and Manager; Mrs. Pei-Ling (Linda) Huang, Chief Financial Officer and Secretary; and to Mr. (b) (4), the firm's consultant. FDA forms issued during the inspection included the FDA 482 (17), FDA 482a (1), FDA 482b (1), FDA 483 (1), FDA 484 (3), and FDA 463a (2). The forms FDA 482 were signed by the inspection participants detailed in Table 1 and issued to Mr. Chen. Initially Mr. Chen stated his title as Manager, however on July 8, 2009, he indicated that he was also the Vice President. We addressed him with both titles on the forms FDA 482 from that point forward. ERC Yee was initially the team lead, however Investigator Pomeroy became the lead upon joining the inspection team on March 30, 2009. Table 1 lists all inspection dates and participants, with the exception of April 2 and May 13, 2009, when issuance of the FDA 482 was unnecessary. Participants on April 2 included ERC Yee and Investigators Millar, Young, Pomeroy, and Seitz. Investigator Pomeroy was the only FDA participant on May 13. The complex nature of this joint federal and state effort resulted in a lengthy inspection with more than one week passing between several visits to the firm. The inspection length and the time gaps between FDA firm visits were a result of time spent dedicated to ongoing CalFERT outbreak investigation activities, including oversight of the recall, destruction, and reconditioning processes, along with communications with the firm related to these processes. The state regulatory action that was pursued during the inspection took priority over other items and was a significant factor as well. The FDA 483 was issued to Mr. Chen. Note that the inspection dates of May 8 and 13 were unintentionally omitted from those listed on the FDA 483, as was the name of Investigator Vebina K. Sethi, who participated on the date of April 1, 2009 (Investigator Sethi is officially an Inspector, however she served in an investigatory role at Union International and signed as Investigator on the FDA 482, therefore she is referred to as such in this report). Not all inspection participants were available to sign the FDA 483, which was signed by Investigators Pomeroy, Wai, Young, Weis, Seitz, Gong, Millar, Liu, and Roberts and by ERC Yee. The three forms FDA 484, Receipt for Samples were issued to Mr. Chen and signed by ERC Yee and Investigators Millar and Wai. Two forms FDA 463a, Affidavit, were presented by Investigator Pomeroy to Mr. Chen, who did not sign the forms in the usual manner, but voluntarily made notations and signed his name under them. The forms FDA 463a accompany Documentary Samples 387908 and 387909, attached to this report.

Table 1  
*Forms FDA 482 Issued: Dates and Participants*

FDA 482 Date	Participants
Friday, March 27, 2009	James C. Yee, Investigator/Emergency Response Coordinator <sup>a</sup> William V. Millar, Investigator
Saturday, March 28, 2009	James C. Yee, Investigator/Emergency Response Coordinator William V. Millar, Investigator Jeanne A. Young, Investigator
Monday, March 30, 2009	James C. Yee, Investigator/Emergency Response Coordinator William V. Millar, Investigator Jeanne A. Young, Investigator Erica R. Pomeroy, Investigator
Tuesday, March 31, 2009	James C. Yee, Investigator/Emergency Response Coordinator William V. Millar, Investigator Jeanne A. Young, Investigator Erica R. Pomeroy, Investigator Joseph A. Seitz, Investigator Daniel J. Roberts, Investigator Janice Wai, Investigator
Wednesday, April 01, 2009 <sup>1,2</sup> Two forms FDA 482 were issued	William V. Millar, Investigator <sup>1,2</sup> Jeanne A. Young, Investigator <sup>1,2</sup> Erica R. Pomeroy, Investigator <sup>1,2</sup> Joseph A. Seitz, Investigator <sup>1,2</sup> Daniel J. Roberts, Investigator <sup>1,2</sup> Benny Y. Gong, Investigator <sup>1,2</sup> Vebina K. Sethi, Investigator <sup>2</sup> (officially: Inspector) <sup>b</sup>
Monday, April 06, 2009	Erica R. Pomeroy, Investigator Ronald P. Boyce, Investigator
Tuesday, April 07, 2009	Erica R. Pomeroy, Investigator William J. Weis, Investigator Jeanne A. Young, Investigator
Monday, April 13, 2009	James C. Yee, Investigator/Emergency Response Coordinator William V. Millar, Investigator
Wednesday, April 15, 2009 <sup>1,2</sup> Two forms FDA 482 were issued	James C. Yee, Investigator/Emergency Response Coordinator <sup>1,2</sup> Erica R. Pomeroy, Investigator <sup>2</sup> Jeanne A. Young, Investigator <sup>1,2</sup> Bruce D. Broidy, Investigator <sup>1,2</sup>
Tuesday, April 21, 2009	James C. Yee, Investigator/Emergency Response Coordinator Erica R. Pomeroy, Investigator Min Shan Mabel Liu, Investigator
Tuesday, April 28, 2009	Erica R. Pomeroy, Investigator William V. Millar, Investigator
Friday, May 8, 2009	James C. Yee, Investigator/Emergency Response Coordinator Jeanne A. Young, Investigator Min Shan Mabel Liu, Investigator
Tuesday, May 12, 2009	Erica R. Pomeroy, Investigator

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Wednesday, July 08, 2009	Min Shan Mabel Liu, Investigator
Friday, July 24, 2009	James C. Yee, Investigator/Emergency Response Coordinator Erica R. Pomeroy, Investigator Min Shan Mabel Liu, Investigator

<sup>a</sup> James C. Yee held the title of Investigator at the onset of this inspection. His title changed to Emergency Response Coordinator (ERC) prior to the close of this inspection.

<sup>b</sup> Vebina K. Sethi is officially an Inspector, however she served in an investigatory role at Union International.

**HISTORY**

U.F. Union International Food Co., Inc. had been in operation for approximately 20 years at the time of inspection. Initially located in South San Francisco, CA, the firm moved to Hayward, CA, before relocating about five years ago to its current facility in Union City, CA. The firm was incorporated in California in 1988 (Attachment M). The official corporate name, as listed on the California Secretary of State corporations website (<http://kepler.sos.ca.gov>), is "U.F. Union International Food, Inc.," although Mr. Chen identified the firm during the inspection as "U.F. Union International Food Co." The firm's website also features this name. The firm's product labels state the name, "Union International Food Co." In this report, the firm is identified, "U.F. Union International Food Co., Inc." (b) (3)

The approximately (b) (4) foot facility in Union City was comprised of two adjacent warehouses, 33035 and 33055 Transit Avenue, which shared a common wall and a metal roll-up door. The existence of the warehouse at 33055 Transit Avenue was initially not disclosed by the firm. Refer to Additional Information and Refusals. The hours of operation were from (b) (4). The firm owned (b) (4). Gross annual sales of the firm's products for the previous "normal" year (i.e. when not impacted by an outbreak) were between (b) (4). Union International sold all products wholesale to distributors and (b) (4) grocery stores and restaurants. The firm used two brand names, Uncle Chen and Lian How, which appeared on the labels of various spices, sauces, and oils repackaged or manufactured at the facility. Union International co-packed products for several companies, including spice products for (b) (4).

A number of related firms with similar names to Union International were identified, both in the United States and overseas. (b) (6)

(b) (6) Daniel Y. Chen, Vice President and Manager, and his wife Pei-Ling (Linda) Huang, Chief Financial Officer and Secretary, oversaw the daily operations of their (b) (4) business, which at the time of inspection employed (b) (4) employees. Mrs. Huang's father, Yung-Pun Huang, was the President of the firm, but resided out of the country and visited the Union City facility up to three times per year.

**Related Firms**

A related firm (b) (4) & (b)(7)(C)

(b) (4) & (b)(7)(C)

The Uncle Chen brand name was used exclusively by U.F. Union International. Mr. Chen and Mrs. Huang repeatedly asserted that no raw materials or finished product ever changed hands between the two companies. The two were separate entities and did not purchase from, or supply, one another (b) (4) & (b)(7)(C)

Mr. Chen was familiar with the (b) (7)(C) firm, but declined to provide any details about the firm or Union International's relationship to it.

Union International directly imported many of its raw sauce ingredients from the manufacturer,

(b) (4)

. The foreign manufacturer (b) (4) Raw material boxes (b) (4) were observed at Union International (b) (4). When we questioned Mr. Chen on the nature of the relationship between the two entities, his consultant, (b) (4), stated that Union International was an independent corporation (not a subsidiary of the foreign company) and advised Mr. Chen he did not need to provide information about the firm (b) (4) to us. Mr. Chen declined to provide information on the relationship.

Through queries (b) (7)(E)

related entities overseas were identified (b) (7)(E) which supplied raw materials to (b) (7)(C) entities over the past two years. The trade connections are detailed in Figure 2. It is unclear whether firms (1) and (2) are representations of the same entity. Each one has an associated list of import entries for which it was filed as the foreign manufacturer.

(b) (4) & (b)(7)(C)

(b) (4)

Attachments N, O, and P feature (b) (7)(E) reports for U.S. imports over 2008 and 2009 from the

(b) (4) & (b)(7)(C)

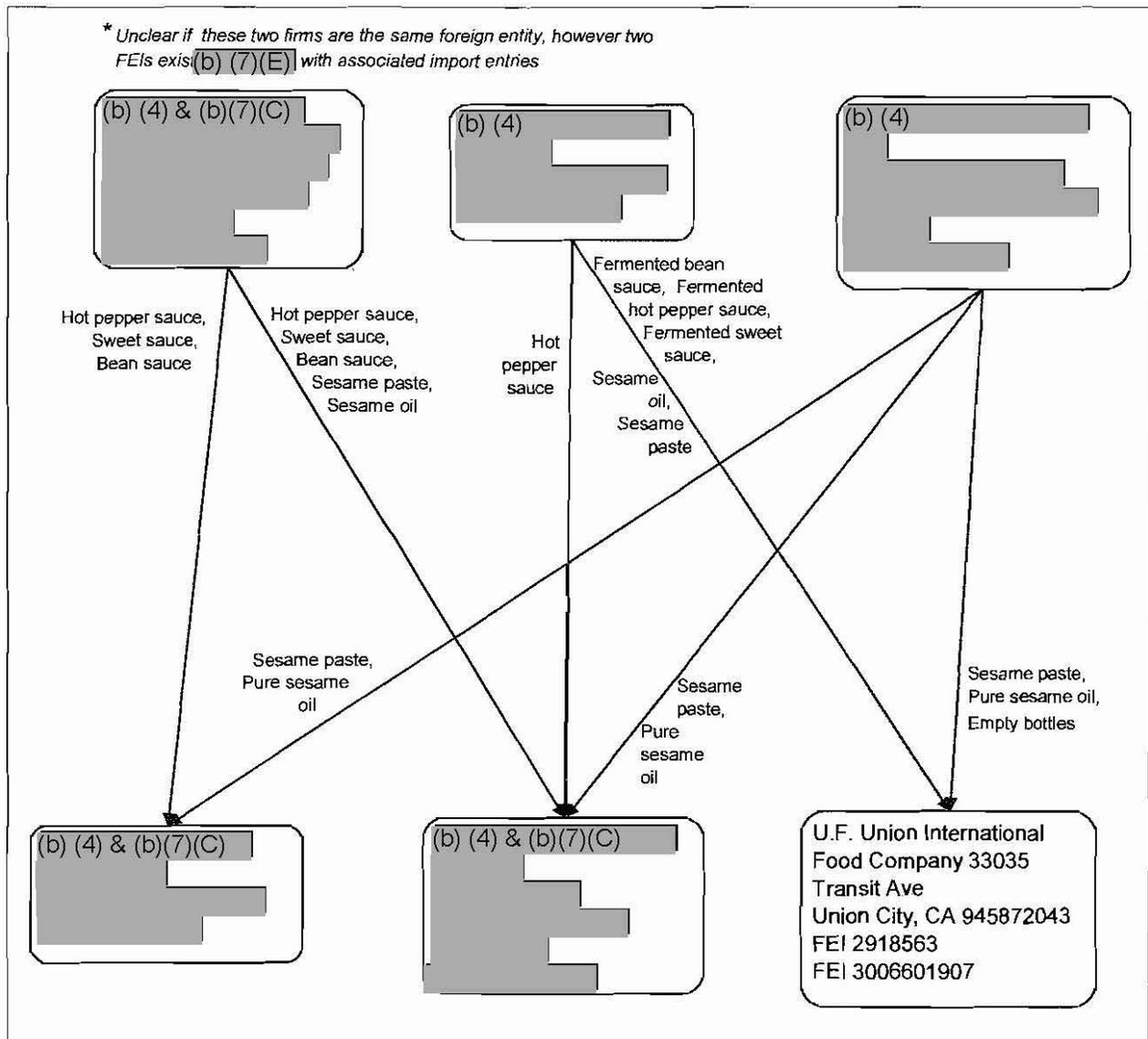


Figure 2. Import patterns for (b) (4) & (b)(7)(C) entities, identified (b) (7)(E) and products they have supplied to (b) (7)(C) entities.

**Inspection History**

1993: The FDA inspection of Union International in 1993 was classified Official Action Indicated (OAI) and found that the firm's labels were worded differently in English and Chinese. Products that were tested and proven to be blends of sesame and soybean oils, as was stated in English on the labels, claimed in Chinese to be pure sesame oil on the labels. The state of California embargoed

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fifteen lots of product in April, 1993. The embargo was lifted in July, 1993 following re-labeling of the products under state supervision.

2003: The FDA inspection in 2003 was classified No Action Indicated (NAI) and identified no objectionable conditions.

2004: Lian How Brand Chili Sauce in 1 gallon plastic jugs (FDA sample 235313) was observed inside a wet box, with abnormal concave indentations in the plastic jars, at (b)(4) & (b)(7)(C) [REDACTED]. This observation prompted a directed compliance inspection at Union International. The directed inspection, initiated in 2004, identified Black Bean Garlic Sauce in 8 ounce plastic jars with bulging seals stored on site at Union International. A number of samples were collected for microbial analysis, as well as for pH and water activity, of sauces and their components. No pathogenic bacteria were identified. The firm voluntarily recalled the black bean garlic sauce from the previous production lot, of October 2004. The inspection was classified OAI, and a Warning Letter was recommended. A CFSAN Health Hazard Evaluation concluded that the potential health hazards associated with the consumption of the product could not be definitively determined. No Warning Letter was issued.

2005: A follow-up inspection in November, 2005 found that most objectionable conditions cited during the 2004 inspection had been corrected, with the exception of some labeling issues. The inspection was classified NAI.

2007: A February, 2007 FDA inspection documented labeling deficiencies and identified three product labels with undeclared soy and/or wheat allergens: Broad Bean Paste, Hot Broad Bean Paste, and Sweet Flour Sauce. The labels listed "flour" instead of wheat flour and "bean" instead of soybean. Union International initiated a voluntary recall of the products. The inspection was classified VAI.

2008: In March, 2008 the FDA inspection was classified VAI for a number of good manufacturing practice issues that were discussed with the firm, although no FDA 483 was issued. The discussion with management noted, "a lack of routine maintenance as evidenced by: White pepper and other dust debris on overhead conduits, wires, walls and manufacturing machines; Packed dry food debris was observed on machine blades, wall and outer cabinet of the mix machine used for wasabi powder and a cracked, soiled wooden stick was observed inside the temporary storage tank of the white pepper manufacturing machine. Mr. Chen promised to correct these observations and create a cleaning checklist within the next 45 days."

2009: A January, 2009 FDB contract inspection for FDA focused on sauces manufactured by the firm, however the firm was advised during the inspection that more frequent cleaning was needed in the pepper grinding room. A Notice of Violations, equivalent to the FDA 483, was not issued.

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**FDA Correspondence**

FDA correspondence may be addressed both to the president and vice president/manager of Union International at the following addresses:

Yung-Pun Huang, President  
U.F. Union International Food, Co.  
Nantong Chau Tau Tsuen Road Town on the 11<sup>th</sup>  
Minhou County, Fuzhou, Fujian China  
Postal Code 350112

Daniel Y. Chen, Vice President and Manager  
U.F. Union International Food, Co.  
33035 Transit Avenue  
Union City, CA 94587-2043

**INTERSTATE COMMERCE**

Union International directly imported approximately (b) (4) percent of raw ingredients, according to Mr. Chen. Refer to Attachments Q and R for a list from the ORADSS database of imported shipments received by Union International over the previous two years, in which the firm was either the importer of record or the consignee. Pepper was not among the firm's direct imports, which included bulk sauce and oil ingredients such as Lian How Brand A Broad Sauce, Lian How Brand 100% Pure Sesame Paste, Lian How Brand Hot Pepper Sauce, Lian How Brand Bean Sauce, and Lian How Brand Fermented Flour, all supplied by (b) (4). Import patterns for (b) (4) entities are diagramed in Figure 2 (Page 18). Additionally the firm imported jalapeno chili peppers from (b) (4) and cayenne mash from (b) (4). Much of the remaining (b) (4) percent of raw ingredients utilized by Union International originated out of the country as well, but were purchased from suppliers within California. All black and white pepper in both whole and ground form were purchased in this manner. Attachment J details the pepper shipments received by Union International between November of 2007 and the onset of the current inspection, together with their countries of origin, FDA import entry numbers, and other OASIS data associated with the original importations by the local suppliers. The traceback diagram in Figure 1 (Page 7) depicts the flow of whole white pepper from foreign manufacturers to Union International.

During the inspection, FDB sample 061040709-A53 of whole white pepper drawn from an intact (not yet opened) 50 kilogram raw material bag stored at Union International was found positive for *Salmonella* Rissen with a PFGE pattern matching the outbreak strain. The bag was labeled, (b) (4)

The bag was purchased by Union International August 18, 2008, in a shipment of (b) (4) bags from the importer, (b) (4) FDA Documentary Sample 387908 (attached to this report) was collected during the inspection to document this shipment. The

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(b) (4) firm imported the lot of (b) (4) via FDA import entry number NP9-0002100-7. The memorandum (attached to this report) by LOS-DO Investigator Alexandra Pitkin, dated April 14, 2009, details traceback information collected at (b) (4). The sea waybill associated with importation of Lot (b) (4) through the Port of Oakland is exhibited in the memorandum. This sea waybill was referenced in, but not included among, the documents obtained at Union International. (b) (5)

FDA Investigational Samples 490700 and 490701 of finished product ground white pepper (intact jugs collected at Union International) yielded *Salmonella* Rissen with a PFGE pattern matching the outbreak strain. While no interstate records could be definitively associated with these samples due to a lack of any raw material usage records or lot codes, the bacteria found in them was PFGE-matched to the bacteria found in the raw material whole white pepper FDB sample 061040709-A53, for which Documentary Sample 387908 was collected to document interstate commerce.

Union International distributed products primarily to (b) (4). Approximately (b) (4) of the spices, sauces, and oils produced by the firm were sold to companies (b) (4), with some sales to (b) (4). Infrequent sales (one instance per state) to (b) (4) were documented in 2008 and 2009. Exhibit 8 features a list of all possible customers for Union International and their locations.

SEA-DO Domestic Import Sample 480437 of ground white pepper, drawn from intact 5 ounce Uncle Chen retail containers, was collected April 1, 2009 from a store in Kent, WA. The sample was found positive for *Salmonella* Rissen with a PFGE pattern matching the outbreak strain. Although the pepper had no lot code to inform a traceback, Union International had sold ground white pepper to (b) (4) only once during 2008 and 2009, on November 4, 2008. A three-part chain of FDA samples documents the interstate sale and transportation of this shipment:

- 1) SAN-DO Documentary Sample 387909, collected at Union International, documents the direct sale of product to (b) (4) in Kent, WA and the transport of product to the local distribution center.
- 2) SAN-DO Documentary Sample 483176, collected at (b) (4) documents the transportation of product from (b) (4) in Kent, WA.
- 3) SEA-DO Domestic Import Sample 480437 of product collected from (b) (4) documents the ordering and purchase of the product directly from Union International.

A memorandum by SAN-DO Investigator Min Shan Mabel Liu, dated May 27, 2009 details transportation information obtained during a visit to (b) (4). The two

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documentary samples, a copy of SEA-DO's collection report, and Investigator Liu's memorandum are attached to this report.

**JURISDICTION**

The labels for two finished product forms of ground white pepper manufactured by Union International are depicted in Photo Exhibits 1 and 2 (Page 9). *Salmonella* was identified in the products displayed in both exhibits. In addition to the spices, sauces, and oils manufactured on site, Union International distributed a variety of food products as received in their original packages. Tea, nuts, beans, sesame seeds, and dried mushrooms fell into this category. These prepackaged products were not subject to the recalls undertaken by the firm during the inspection. Union International provided a product catalogue (Exhibit 9, Part A), featuring most products marketed by the firm, which accounts for some, but not all of the package sizes that were available. The firm's recalled product lists (Exhibit 9, Parts B and C) account for the remaining product types and sizes. The firm's website is <http://www.ufunionfood.com> (Exhibit 10, Pages 1-4). The website states that Union International is a subsidiary of the foreign firm, Union Food (Exhibit 10, Page 1). However, Mr. Chen was questioned specifically on this matter and his consultant, Mr. (b) (4), explained in his presence that Union International was an independent corporation, not a subsidiary. The website also lists Ho-Ben Huang as the father-in-law of Mr. Chen and lists Mr. Chen as the President. According to Mr. Chen, these were errors in translation. Mr. Chen reaffirmed his father-in-law is Mr. Yung Pun Huang, who served in the role as president.

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

Mr. Daniel Y. Chen was the Vice President and Manager of U. F. Union International Food Co., Inc., a position which he had held for the previous 20 years, since the firm's inception. According to Mr. Chen, the role of President was occupied by Mr. Yung-Pun Huang, who resided in China and visited the Union City facility between one and three times per year. Pei-Ling Huang (Linda), Chief Financial Officer and Secretary at the firm, is Mr. Huang's daughter and is married to Mr. Chen. A document provided by Mr. Chen entitled, "Annual Meeting of Shareholders of U.F. Union International Food, Inc. By Written Consent," dated November 30, 2008, lists Yung-Pun Huang, Daniel Y. Chen, and Pei-Ling Huang as the shareholders and directors of the corporation (Exhibit 11, Pages 2-3). Pei Ling Huang is listed as the Agent for Service of Process in the firm's 1988 record of incorporation with the California Secretary of State (Attachment M). Information obtained during the inspection was provided by Mr. Chen, Mrs. Huang, and Mr. (b) (4) (the firm's consultant). One or more of these individuals accompanied our inspection team during visits to the firm.

The official titles assigned to Mr. Chen and Mrs. Huang approximated their duties, although in the small company environment their respective duties were diverse, overlapping and flexible. Mr. Chen appeared to be the most responsible person present at the firm on a regular basis, due to his leading role in FDA interactions, as well as in signing correspondence to FDA, such as Exhibit 12, a letter declaring the firm's representation. However, we also observed that in many respects, Mr.

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Chen and Mrs. Huang shared authority and decision-making responsibilities. Mr. Chen stated that they shared joint authority.

Mr. Huang, President, was consulted for major decisions by Mr. Chen and Mrs. Huang. During the current inspection, the initial decision to voluntarily recall spices was made at the local level, but Mr. Huang was consulted before expanding the recall beyond spices to sauces and oils manufactured by the firm. Mr. Chen explained that during the current inspection, the corrections implemented to date (improvements to the facility and the white pepper grinding room, formation of HACCP plans) and the hiring of consultants and lawyers was all directed from the local level, by himself and Mrs. Huang. The sauce formulations used by the firm were traditional recipes obtained from Mr. Huang.

Mr. Chen described his daily duties as including marketing, customer relations, some raw ingredient purchasing, and oversight of production. Mrs. Huang handled accounting, document management, warehousing and inventory, management of the sales database, and oversight of production (with Mr. Chen). The two were present at the Union International facility nearly every day. (b) warehouse/production employees performed the white pepper grinding and packaging, dried spice repackaging, sauce manufacturing, facility sanitation, and inventory control. The employees worked under the direction of both Mr. Chen and Mrs. Huang. According to Mrs. Huang, she and her husband set the production schedule for each day based on inventory levels and specific customer orders. There was no weekly production schedule. Mr. Chen and Mrs. Huang made joint decisions regarding the hiring and firing of employees.

During the inspection, Mr. Chen was the primary contact answering inspectional questions. He was knowledgeable about the purchasing of ingredients and their suppliers, as well as sales patterns. He interacted with customers on a regular basis and was able to describe the pepper purchasing habits of the (b) (4) distributor (b) (4) which he explained had not purchased pepper from Union International since November, (b) (4). He described in detail the white pepper grinding machine sanitation process and the difficulties encountered when the grinder air filter clogged more frequently during the wet months. Mr. Chen deferred to Mrs. Huang when asked for specific documents, such as invoices, or for sales quantities and dates. Mrs. Huang sorted through file drawers to locate documents requested and operated the firm's sales database by entering queries to generate data. Mrs. Huang was familiar with the details of the labeling issue pertaining to undeclared allergens that was the focus of the 2007 FDA inspection. She described the problems with the original label and how they were resolved, when Mr. Chen was not familiar with the specific details. Both Mr. Chen and Mrs. Huang were observed driving fork lifts in the warehouse.

When our inspection team first learned of the previously undisclosed adjacent warehouse located at 33055 Transit Avenue, Mr. Chen initially refused access, but after speaking with his lawyer, he permitted inspection. Refer to Refusals and Additional Information.

The firm employed Mr. (b) (4)

employees at Union International.

### **Consultants and Legal Representation**

During the current inspection, Union International employed Mr. (b) (4)

(b) (4)

Mr. (b) (4) as the primary contact for regulatory agencies and the coordinator of other consultants and groups working with the firm (Exhibit 12). Mr. (b) (4)

provided legal representation for the firm. Mr. (b) (4)

, provided consulting services to the firm. (b) (4) prepared prerequisite programs, documents and plans leading to the establishment of a HACCP program at the firm, with a focus on their acceptability under the terms of the FDB Stipulated Preliminary Injunction. (b) (4)

, provided technical and scientific expertise relative to food safety and processing issues, especially with respect to the (b) (4) pH

control submissions for the sauce formulations. (b) (4)

provided technical and engineering support for the remodeling and redesign of the processing rooms, air handling and sanitary production facilities at Union International.

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

All training of employees in production and sanitation procedures was conducted on the job by Mr. Chen or Mrs. Huang. No formal training program existed.

### **MANUFACTURING/DESIGN OPERATIONS**

The review of manufacturing operations for this directed inspection focused on the firm's handling of white pepper, with an overview of other spices. The firm's production of sauces and oil blends was not a focus of this inspection, although a number of steps were taken to gauge whether the firm's sauce and oil products posed a health risk to consumers as a result of cross-contamination. Environmental swab samples were collected in the sauce mixing room (refer to Samples Collected). *Salmonella* Rissen was identified in swabs from the room and subsequently Union International expanded the voluntary recall to include all sauces and oils manufactured on site. A wide variety of the sauces and oils were sampled by CalFERT for *Salmonella* analysis. All samples were negative for *Salmonella*. The four primary styles of sauces manufactured by the firm were also sampled for pH and water activity analysis. Analyzed by the FDA SAN-DO laboratory, the pH for the four sauces ranged from 3.58 to 4.29, while water activity ranged from 0.820 to 0.914. The University of California Laboratory for Research in Food Preservation (process authority for FDB) reviewed the

various UIFC sauce products and determined the products were not required to be filed under the state pH control program.

White pepper grinding and spice packaging/repackaging at Union International took place in the approximately (b) (4) square foot warehouse located at 33035 Transit Avenue. The facility was comprised of offices, a warehouse, and a production area featuring three adjacent production rooms branching off a main hallway. Room 1 was the sauce and oil bottling room, Room 2 was the white pepper grinding room, and Room 3 was the sauce mixing room. Spice packaging took place primarily centered around a table in the main hallway outside the sauce and oil bottling room. Attachment S, a diagram of the facility, displays the relative locations of the warehouse and processing areas. At the onset of the current inspection, the firm was manufacturing a soybean oil and sesame oil blend on the oil bottling fill line in Room 1. The firm was not engaged in spice packaging and no white pepper had been ground that day. According to Mr. Chen, all production ceased the initial day of inspection. We observed no production taking place at 33035 Transit Avenue subsequent to the initial day of inspection, however, we did not gain access to the adjacent warehouse and sauce processing area (Room 4) at 33055 Transit Avenue until April 21, 2009. Refer to Refusals for details pertaining to 33055 Transit Avenue.

Table 2

*Union International Pepper Package Sizes and Branding*

Package Type	Case and Package Size	Brand	Pepper Type
Wholesale	10 lb box .	Lian How	Ground black pepper Ground white pepper Whole black pepper Whole white pepper
	10 x 5 lb plastic bag	Lian How	Ground black pepper Whole black pepper Whole white pepper
		Uncle Chen/Lian How	Ground white pepper
	6 x 5 lb plastic jug	Lian How	Ground black pepper Ground white pepper Whole black pepper Whole white pepper
Retail	24 x 5 oz plastic container	Uncle Chen	Ground black pepper Ground white pepper Whole black pepper Whole white pepper

Union International purchased white and black pepper in both whole and ground forms. Only whole white pepper was ground on site. The firm packaged the four types of pepper: whole black, whole white, ground black, and ground white into a variety of wholesale and retail packages, listed in Table 2. The wholesale packages were Lian How Brand products, with the specific exception of ground white pepper in 5 pound bags. This product bore the Uncle Chen brand name on the bag, but was packaged ten bags to a box labeled with the Lian How brand. The retail package utilized for all four

types of pepper was a five ounce plastic container with the Uncle Chen brand name. No lot codes were used on finished products. No formal inventory system existed for finished products and no records of inventory were maintained.

Black and white pepper purchases between November of 2007 and the onset of the current inspection on March 27, 2009 were identified based on information collected at Union International and (b) (6) by LOS-DO. Union International purchased (b) (4) of black pepper over thirteen shipments and (b) (4) of white pepper over seven shipments in a sixteen month span. This amounted to about (b) (4) of black pepper per month on average and about (b) (4) of white pepper per month. Approximately (b) (4) percent of the black pepper was purchased in whole form, while (b) (4) percent was purchased in ground form. The firm repackaged and sold the black pepper in the form it was purchased. About (b) (4) percent of the white pepper was purchased whole and either sold in whole form, or ground by Union International prior to packaging and selling (most was ground). White pepper was the only spice ground by Union International. The grinder assembly in the white pepper grinding room of the facility was dedicated to whole white pepper. The remaining (b) (4) percent of white pepper was purchased in pre-ground form, repackaged, and sold as such. Attachment J details the pepper shipments received by Union International between November of 2007 and the onset of the current inspection.

### **White Pepper Handling**

Whole and ground white pepper were used more or less on a first in, first out basis by Union International. The firm maintained no production records for raw ingredient usage and no records of raw ingredient inventory. Mr. Chen described the white pepper grinding and packaging operation. Whole white pepper was ground by the firm into one particle size. There was no schedule for white pepper grinding; it depended entirely on the inventory of packaged ground white pepper available for sales. Bags of whole white pepper were dumped in the hopper for grinding, some was ground, and some was left sitting in the hopper until the next time it was needed for grinding. There was always some whole pepper in the hopper except when it was completely emptied every (b) (4) for cleaning.

The white pepper grinder assembly is pictured in Photo Exhibits 3 and 4 (Pages 27 and 28). Bulk (b) (4) bags of whole white pepper were poured into the whole pepper hopper (#1). The pepper (b) (4) flowed through the process as follows: (b) (4) After grinding, the white pepper required (b) (4) the ground pepper hopper. It was then transferred to (b) (4) barrels for storage until packaging. Ground white pepper was observed stored in unlined (b) (4) barrels with names of other spices printed on the outside, such as "tenderizer." The barrels were the original bulk packaging containers for other types of spices, re-used for ground white pepper storage. The ground white pepper could be stored in (b) (4) barrels (at times covered or uncovered) in the white pepper grinding room or hallway for up to (b) (4) s prior packaging. In the white pepper grinding room, *Salmonella* was identified in swab samples collected from food and non-food contact surfaces of the grinder

assembly and its platforms, from the walls and electrical equipment, and from the floor. Refer to Samples Collected for a full account of sample results.

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(b) (4)



*Photo Exhibit 3.* White pepper grinding system.

Ground white pepper was packaged (b) (4) into finished product containers over a (b) (4) (b) (4) table approximately (b) (4) from the grinding room, in the adjacent hallway. (b) (4) Ground white pepper was drawn from a drum using one of at least (b) (4) scoops and loaded using one of (b) (4) funnels into the 5 pound plastic jugs or 5 pound clear plastic bags over a table-top scale. The clear plastic bags were sealed shut using a heat sealer situated on top of this (b) (4) table. Spices other than white pepper were (b) (4) packaged in the same manner, using the same funnels and scoops. During the inspection *Salmonella* was identified in swab samples from two areas of the floor under the table, from one of the funnels, and from the table-top scale used for packaging. Refer to Photo Exhibits 5, 6, and 10 (Pages 29, 29, and 40, respectively).

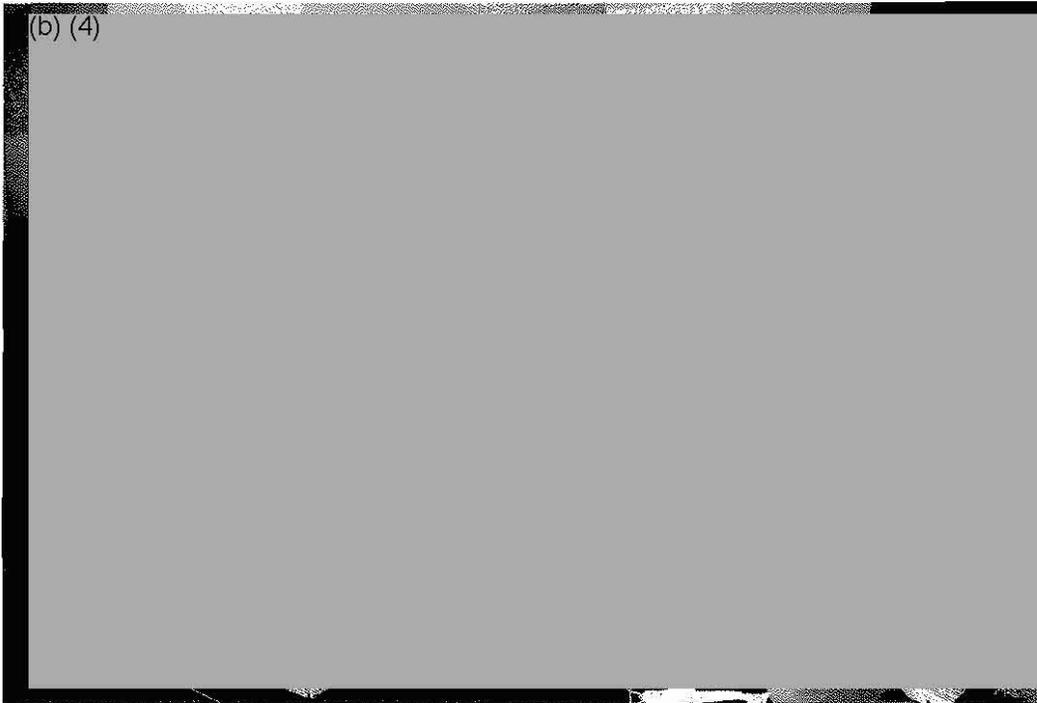
3/28/09 WVM



*Photo Exhibit 4.* White pepper grinding system: grinder close-up.

The 5 pound bags and jugs of ground white pepper were packaged on a regular basis. Typically the grinding, packaging, and sale of white pepper would take place within (b) (4), however finished products sometimes remained in the warehouse adjacent to the processing areas for up to (b) (4) before they were sold. This same turnover rate applied to repackaged 5 pound bags and jugs of whole white, whole black and ground black pepper. The 5 ounce retail sized containers of Uncle Chen pepper were packaged on a less frequent basis because (b) (4). The empty 5 ounce containers were placed into a tray of slots that fit (b) (4) containers, after which pepper was spread and swished over the tops of the containers. Mr. Chen described it as a messy process. A large batch of retail sized pepper containers was packaged (b) (4).

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*Photo Exhibit 5.* Spice packing/repacking table.

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*Photo Exhibit 6.* Packing/repacking area. Mr. Chen demonstrated the spice packaging set-up for a five gallon plastic jug.

### **White Pepper Grinding Room Sanitation**

The white pepper grinder assembly and its surrounding areas were not cleaned and sanitized on a regular basis. Sanitation was conducted on the white pepper grinding system only when it became necessary to keep it functioning every (b) (4). Attached to the grinder was a (b) (4) type air filter that captured dust. Over time the grinder air filter would become clogged and require a cleaning for the grinder to continue operating. Clogging occurred more frequently during (b) (4) the grinder sanitation process was conducted approximately every (b) (4).

For the sanitation process, the following items were cleaned only with (b) (4) the whole pepper hopper (#1), elevator conveyers #1 and #2, and the ground pepper hopper (#2). (b) (4) did not come into contact with these items. The (b) (4) grinder filter, the grinder exit chute pipe, and the sieves were cleaned using a (b) (4). (b) (4) drum was filled with soapy water and brought into the white pepper grinding room. After an initial (b) (4) cleaning, the smaller components were submerged in this drum and the larger sieves were held over the drum and sponged down, letting the dirty water fall into the drum. These wet-cleaned components were then taken to the (b) (4) wash area in the sauce mixing room, where they were rinsed and then sanitized in the large receptacle equipped with a hose and drain. During the inspection, *Salmonella* was identified in a swab sample collected from this wash area drain. While the sieves were out of place, the cone above the sieves in the pepper grinding system was first cleaned with (b) (4) and then rinsed with (b) (4) in its place, with a barrel placed underneath it to catch the rinse.

### **MANUFACTURING CODES**

No manufacturing codes, production dates, or "best by" dates were marked on products manufactured or repackaged by Union International.

### **COMPLAINTS**

Union International maintained no complaint file. Mr. Chen did not remember receiving any complaints of illness prior to his firm's recall. He received one complaint of illness subsequent to the initiation of recall, but he believed that it was not associated with a Union International brand product. No complaints associated with Union International were documented in FACTS subsequent to the previous FDA inspection in March 2008.

### **RECALL PROCEDURES**

During the inspection, Union International initiated a voluntary recall of all dried spice products packaged by the firm on March 28, 2009. The recall and press releases for spices were modified by the firm and re-issued a number of times for previously unaccounted for package sizes or spice types. The firm expanded the voluntary recall to include sauces and oil blends manufactured on site on April 15, 2009. Exhibit 9, Parts B and C, list all products recalled by the firm. No written recall

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procedures existed. Employees of the firm made phone calls to notify customers and letters were also sent out. As recalled products were returned to the Union International facility, they were placed under embargo by FDB. The recall was assigned a Classification of "1" by FDA. Recall numbers F-887-9 through F-943-9 were assigned for 57 total products subject to recall. SAN-DO sent a letter to the firm on June 11, 2009, informing Mr. Chen that the recall appeared to be ineffective at all levels (attached to this report). Exhibit 13, Pages 6 - 8 feature the firm's response to FDA, while Exhibit 13, Pages 3 - 5 include other recall-related feedback from the firm. Refer to Recall Enterprise System (RES) event number 51672 for all details pertaining to the recall.

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

The CalFERT team (FDA and FDB members) jointly witnessed many of the objectionable conditions during this inspection and collaborated in documenting the observations. FDB issued two Notices of Violation (NOVs) to Union International on March 27 and April 21, 2009 (Attachments T and U). The NOVs and the FDA 483 issued July 24, 2009 featured similar observations. Representing Union International, Mr. (b) (4) submitted a written response to the observations listed on the NOVs to FDB, with a copy to FDA (Exhibit 13, Pages 15-17). In Exhibit 13, Mr. (b) (4) original response is attached to a letter from Mr. (b) (4), legal representation for Union International, in response to recall-related communications from FDA.

The FDA 483 was issued to Mr. Chen on July 24, 2009. Present for the FDA 483 closeout discussion from the firm were the Mr. (b) (4) Consultant for Union International, and Mr. Chen, Manager and Vice President of Union International. Present from FDA were Investigators Pomeroy and Liu, and ERC Yee. There were no FDB investigators present. The firm's responses to observations were primarily provided by Mr. (b) (4), as the firm's representative, in the presence of Mr. Chen, who affirmed that the corrections and improvements described by Mr. (b) (4) were accurate. Mr. (b) (4) described a wide range of sanitation activities that were conducted and improvements to the facility that were implemented already by the time of closeout. To the extent possible, we (Investigators Pomeroy and Liu and ERC Yee) observed these items corrected. A facility walk-through showed that equipment and processing rooms appeared clean. Mr. (b) (4) frequently alluded to a set of documents that included Standard Operating Procedures (SOPs) and Hazard Analysis Critical Control Point (HACCP) plans, which he had submitted to FDB and FDA in order to demonstrate correction of the conditions observed at the firm. The documents were part of the firm's effort toward complying with the terms specified in the Stipulated Preliminary Injunction filed by FDB in the Alameda County Superior Court on May 21, 2009 (Attachment V). Refer to Exhibit 14, Parts A-Z for copies of these documents, which Mr. (b) (4) provided on July 24, 2009.

**Observations listed on form FDA 483**

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**OBSERVATION 1**

Failure to manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically,

- We received private laboratory test results dated 4/5/09, provided by your firm's hired consultant/private laboratory, which detail environmental samples found positive for *Salmonella* that were collected by the consultant in your facility.

The following private laboratory sample numbers for environmental scrapings and debris samples collected on 3/28/09 in the white pepper grinding room were found positive for *Salmonella* (quoted directly from laboratory report):

- "#11 - dust and debris from smaller roof vent (spinner)"
- "#12 - dust and debris from smaller roof vent (spinner)"
- "#13 - conveyer outlet to grinder, plastic cover & miscellaneous debris"
- "#14 - debris and powder from top of funnel feeding sieve set"
- "#15 - scrapings from same area as sample #14 above"
- "#16 - powder and debris from top of grinder assembly"
- "#17 - fine grind white pepper from sieve set outlet feeding hopper conveyer"

Samples 13-17 were collected from components of the white pepper grinding system, while the roof vent associated with samples 11 and 12 was located at the ceiling of the grinding room.

The following private laboratory sample numbers for environmental swab samples collected on 3/28/09 in the white pepper grinding room were found positive for *Salmonella* (quoted directly from laboratory report):

- "#C - grinder support stand shelf"
- "#E - plastic strip door on hallway side of entry to grinder room"
- "#F - extension cord found in grinding room"

Sample C was collected from the white pepper grinding system. Samples E and F were collected in the vicinity of the grinding system.

- On 3/27/09 we observed (b) (4) barrels containing in-process ground white pepper stored without covers, approximately (b) (4) directly beneath an unscreened, approximately (b) (4) in diameter roof turbine vent that was open to the outside environment in your firm's white pepper grinding room. A portion of duct tape was hanging from the ceiling adjacent to the vent, also directly over the barrels. It hung from an array of tape strips positioned over ceiling insulation surrounding the vent, some of which extended up into the vent. We further observed no covering over the whole white pepper hopper, which contained in-process white pepper and was located approximately (b) (4) to the side of the barrels beneath the roof turbine vent in the white pepper grinding room.

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Reference: 21 CFR 110.80(b)(2)

**Supporting Evidence and Relevance:**

- Exhibit 15, Pages 1-7 (b) (4) Findings dated April 5, 2009 for samples collected at Union International March 27 and 28, 2009.
- Attachment W: CalFERT Samples Table. Samples collected by CalFERT for *Salmonella* analysis between March 27 and April 7, 2009 in the warehouse and processing areas located at 33035 Transit Avenue.
- Attachment X: CalFERT PFGE Matched Samples. Samples from Attachment W found positive and PFGE matched to the outbreak strain of *Salmonella* Rissen.
- Photo Exhibits 7, 8
- FDA environmental swab samples found positive for *Salmonella* Rissen relating to Observation 1: INV 402154 sub 1, INV490696 subs 1-6, INV 490702 sub 4, INV 503180 subs 1-5, and INV 503185 sub 1 (collection reports attached to this report).

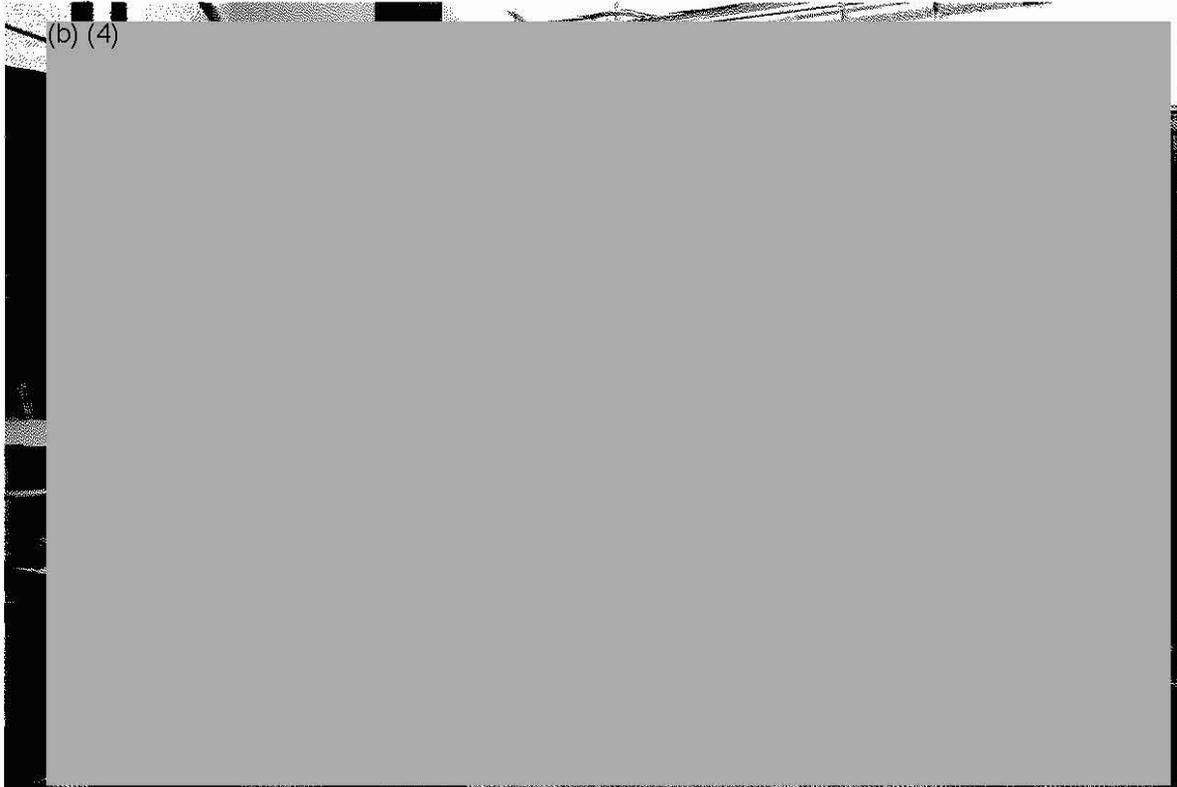
On April 5, 2009, I (Investigator Pomeroy) received a copy of private laboratory test results from Mr (b) (4) Union International's hired consultant. (b) (4) performed the sample collection and analysis for the results dated April 5, 2009 detailed under Observation 1.

Prior to the current inspection, Union International had never conducted product or environmental testing for pathogens. The previous two shipments of whole white pepper purchased by Union International (January 2009 and November 2008) were (b) (4) white pepper. While (b) (4) is a form of heat treatment, no supplier guarantee that the products were free of pathogens accompanied the shipments. According to Investigator Pitkin's Memo, whole pepper supplied by (b) (4) to Union International was not subjected to (b) (4)

(b) (4) No formal sanitation program or schedule for cleaning existed at Union International prior to this inspection. Good manufacturing practice concerns had been discussed with Mr. Chen during the previous inspection, such as dust and food debris that were observed on food and non-food contact surfaces in the white pepper grinding room. Mr. Chen had committed to creating a cleaning checklist within 45 days, however no checklist had been created by the onset of the current inspection. Mr. Chen was also advised during the January, 2009 state contract inspection to conduct more frequent cleaning in the white pepper grinding room. Sanitation procedures are an important preventative control factor for limiting cross-contamination in the event that contamination enters the process via raw materials.

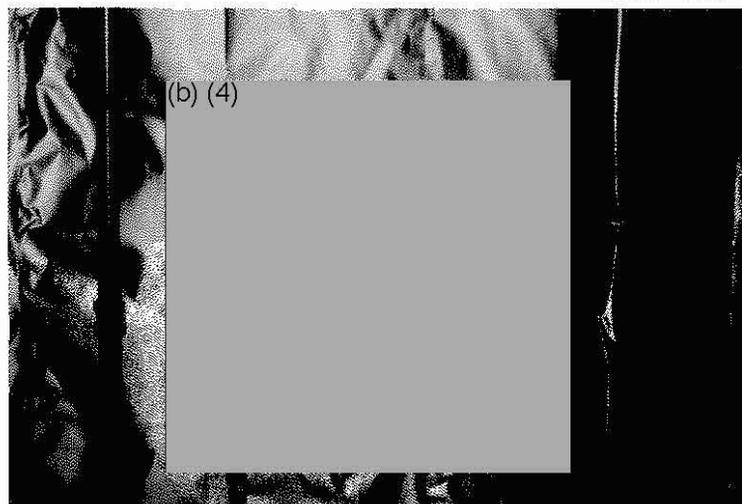
We (ERC Yee and Investigator Millar) observed (b) (4) barrels without covers, stored beneath the unscreened roof vent on March 27, 2009 as described under Observation 1 (Photo Exhibits 7 and 8).

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*Photo Exhibit 7.* White pepper grinding room. Uncovered (b) (4) barrels of ground white pepper were stored directly underneath the open roof turbine vent.

3/30/09 WVM



*Photo Exhibit 8.* White pepper grinding room. The roof turbine vent described under Observation 1 was open to the outside environment, lacked a screen, and had duct tape hanging from it.

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**Supporting Samples:**

In addition to the private laboratory sample results listed under Observation 1, 46 of 116 CalFERT environmental swab samples collected in the facility (40%) were positive for *Salmonella*. Of these, 19 were PFGE analyzed and all 19 were matched to the outbreak strain of *Salmonella* Rissen. In the white pepper grinding room, CalFERT collected 18 in-process white pepper samples from the grinder assembly and from the (b) (4) barrels in which the pepper was stored after being ground until the time of packaging. Of these, 14 (78%) were positive for *Salmonella*. PFGE analysis was conducted for 3 of the 14 samples and all 3 matched the outbreak strain. Refer to Samples Collected and to Attachments W and X (CalFERT samples collected and CalFERT PFGE matches).

**Discussion with Management:****Clean-up and Facility Improvements**

With respect to environmental *Salmonella* contamination found in the facility, Mr. (b) (4) pointed to extensive cleaning and sanitation that was conducted and to facility improvements and engineering controls that were implemented. Refer to Mr. (b) (4) June 11, 2009 letter to FDB and FDA (Exhibit 16). To the extent possible, we (Investigators Pomeroy, Yee, and Liu) observed the corrections. We conducted a facility walk-through and observed that equipment and processing rooms appeared clean, with no sign of dust or stains. Mr. Chen does not intend to perform any white pepper grinding in the facility in the future, nor until such time that an effective system can be implemented to contain dust and any potential cross-contamination. All white pepper grinding equipment was removed from Room 2, the white pepper grinding room, and (b) (4)

(b) (4)

Clean-up of the facility included two instances of professional cleaning and sanitizing of Rooms 1, 2, and 3 by (b) (4). The remodeling and facility improvements were performed with technical and engineering guidance from (b) (4). The ceilings in the rooms were refinished (sanitized and insulation replaced), the vents were fitted with cages and pans, and (b) (4) were installed on the walls. The floors were coated with epoxy resin. A (b) (4) filtered air supply system was installed by a professional service, to ensure Room 2 (now the spice packaging room, formerly the white pepper grinding room) has negative pressure and Rooms 1 and 3 have positive pressure, reducing the risk of contamination from dust in Room 2 to the other rooms and the warehouse. All production and packing equipment from Rooms 1, 2, and 3 was disassembled, cleaned, and sanitized repeatedly by Union International staff. Cleaning verification samples were collected by (b) (4) and analyzed for *Salmonella*, followed by repeated cleaning, sanitizing and retesting until all results were negative. Refer to Private Laboratory Samples for details on (b) (4) samples collected and analysis methodologies. On August 4, 2009, after all facility improvements had been implemented and subsequent to the final analyses of verification samples collected by (b) (4), CalFERT collected 100 environmental swab samples from equipment and production rooms in the facility at 33035 Transit Avenue. All samples were negative for *Salmonella*. As of September 10, 2009, production activities had not yet resumed at Union International.

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**Food Safety Protocols**

Mr. (b) (4) submitted a set of corrective action documents to FDB and FDA in response to the preliminary injunction. He specifically referenced the firm's newly drafted Sanitation Standard Operation Procedures (SSOPs) (Exhibit 14, Part Z), production SOPs (Exhibit 14, Part H), HACCP Plans (Exhibit 14, Parts A-F), and Sample Collection and Testing Protocols (Exhibit 14, Part Y).

The SSOP details Good Manufacturing Practice (GMP) requirements and cleaning procedures for the facility and equipment, including specifics on the type and strength of sanitizer. It features recordkeeping requirements and environmental testing for *Salmonella* every (b) (4) to validate the sanitation. The production SOPs assign responsibilities for sanitation monitoring and recordkeeping during production. They call for a production report record detailing raw material lot numbers utilized in finished product lot codes, which the firm will assign to all products. The HACCP plans describe the process flow for various product types including oils, sauces, and spices and prescribe critical control points pertaining to product safety that will be monitored plus monitoring records that will be maintained. The specific HACCP plans for Repackaging of Dried Spices and Repackaging of White and Black Pepper Products (Exhibit 14, Parts D and E) list a receiving critical control point of verification that each lot received is accompanied by a supplier certificate showing the product to be pathogen free. Verification procedures in the plans include laboratory testing of raw material spices for all pathogens (b) (4) and for *Salmonella* (b) (4). The Sample Collection and Testing Protocols prescribe (b) (4) testing of finished products composed of dry spices for *Salmonella*, *Listeria*, and *E.coli* O157:H7

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**OBSERVATION 2.**

Failure to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing.

Specifically, on 3/27/09 and 3/28/09 we observed an accumulation of white pepper dust on the following food contact surfaces inside your firm's white pepper grinding room:

- 1) The inside surfaces of the whole pepper and ground pepper hoppers
- 2) The intakes for the (b) (4) which transported whole and ground white pepper
- 3) The (b) (4) that funneled ground white pepper into the (b) (4) barrels

Reference: 21 CFR 110.80(b)(1)

Supporting Evidence and Relevance:

- Attachment W: CalFERT Samples Table. Samples collected by CalFERT for *Salmonella* analysis between March 27 and April 7, 2009 in the warehouse and processing areas located at 33035 Transit Avenue.
- Attachment X: CalFERT PFGE Matched Samples. Samples from Attachment W found positive and PFGE matched to the outbreak strain of *Salmonella* Rissen.
- Photo Exhibit 9
- Table 3

3/28/09 WVM (cropped)

(b) (4)



Photo Exhibit 9. White pepper grinder close-up. Whole white pepper (b) (4)

hopper.

We (ERC Yee and Investigator Millar on March 27, 2009; ERC Yee and Investigators Millar and Young on March 28, 2009) observed dust accumulations on food contact surfaces in the white pepper grinding room as described under Observation 2.

I (Investigator Pomeroy) interviewed Mr. Chen regarding the sanitation procedures for the white pepper grinding system. All equipment had been torn down by that time, so he described the process with the aid of a hand written diagram. He explained that the system was cleaned (b) (4) whole pepper was continually added to the system as needed and some amount of whole pepper was generally present in the whole pepper hopper at all times. If an older lot of raw material pepper were used up, product from a new lot could be added into the hopper behind it.

**Supporting Samples:**

FDB environmental swab samples listed in Table 3, collected March 27, 2009, in the White Pepper Grinding Room were found positive for *Salmonella*. Sample 173032709-8 from the whole white pepper seed (b) (4) chute (depicted in Photo Exhibit 9) was further analyzed and PFGE matched to the outbreak strain of *Salmonella* Rissen.

Table 3

*FDB Environmental Swab Samples Positive for Salmonella Related to Observation 2*

Location	Description	Sample ID	Lab
White Pepper Grinding Room	Grinder exit chute	173032709-14	CDPH FDL
	Hopper #2 - chute exit	173032709-20	CDPH FDL
	Seed <sup>a</sup> (b) (4) chute to grinder	173032709-8 <sup>b</sup>	CDPH FDL
		173032709-9	CDPH FDL
	Seed hopper - inside	173032709-1	CDPH FDL
		173032709-2	CDPH FDL
		173032709-3	CDPH FDL
173032709-4		CDPH FDL	

<sup>a</sup>Whole pepper is also referred to as "pepper seed."

<sup>b</sup>FDB Sample 173032709-8 was PFGE analyzed and matched to outbreak strain of *Salmonella* Rissen.

The equipment surfaces yielding swab samples positive for *Salmonella*, listed in Table 3, included specific areas described in Observation 2 with an accumulation of white pepper dust. Four positive samples were collected inside the seed hopper (whole pepper hopper) and two positive samples were collected from the "Hopper #2 - chute exit," the (b) (4) that funneled ground white pepper into (b) (4) barrels at the end of the grinding system. Other food contact surfaces yielding positive swab samples were in proximity to those areas described above with an accumulation of dust. Two positive samples were isolated from the "seed (b) (4) chute to grinder," the (b) (4) which transported whole pepper, and one was isolated from the grinder exit chute (b) (4). Refer to Samples Collected and to Attachments W and X (CalFERT samples collected and CalFERT PFGE matches, respectively).

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### Discussion with Management:

Refer to the Discussion with Management under Observation 1. All white pepper grinding equipment was removed from the facility and stored (b) (4). The firm does not intend to perform any grinding of white pepper in the facility in the future, until such a time that an effective system to contain dust and any possible contamination can be implemented. The newly drafted SSOP (Exhibit 14, Part Z) addresses cleaning and sanitizing during the repacking operation.

### OBSERVATION 3

The design, materials, and workmanship of equipment and utensils does not allow proper cleaning and maintenance.

Specifically,

- On 3/27/09 we observed dried residue on the inside surfaces of (b) (4) funnels that your firm used in the (b) (4) of dried spices (b) (4). The funnels were not made from a material that allowed for proper cleaning and maintenance.
- On 3/27/09 and 3/28/09 we observed (b) (4) unlined (b) (4) barrels being used to store in-process ground white pepper. The (b) (4) barrels were not made from a material that allowed for proper cleaning and maintenance. According to one processing employee we questioned, your firm never cleaned the barrels.

Reference: 21 CFR 110.40(a)

### Supporting Evidence and Relevance:

- Attachment W: CalFERT Samples Table. Samples collected by CalFERT for *Salmonella* analysis between March 27 and April 7, 2009 in the warehouse and processing areas located at 33035 Transit Avenue.
- Attachment X: CalFERT PFGE Matched Samples. Samples from Attachment W found positive and PFGE matched to the outbreak strain of *Salmonella* Rissen.
- Photo Exhibits 6, 10, 11

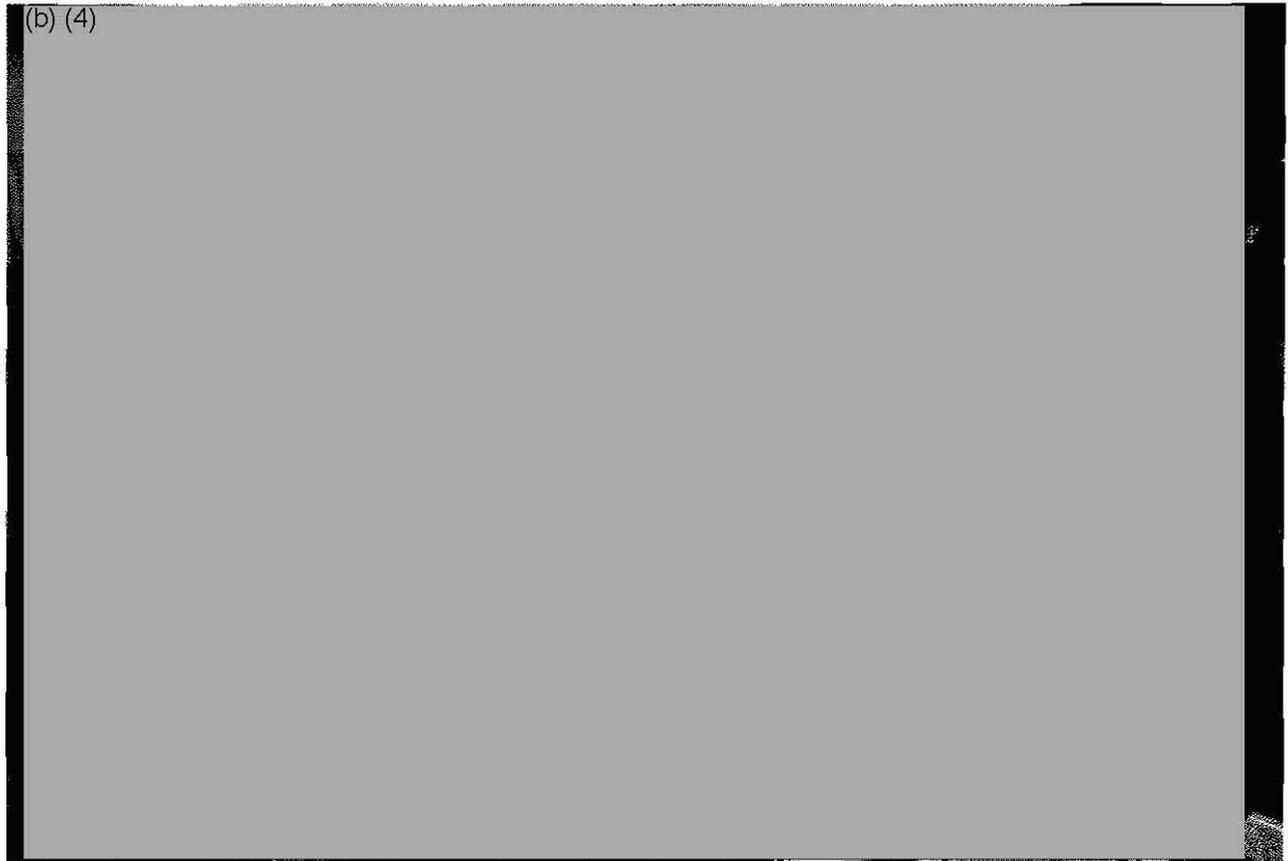
During a walk-through inspection of the White Pepper Grinding Room (Room 2) on March 27, 2009, we (Investigator Millar and ERC Yee) observed what appeared to be ground white pepper being stored in several unlined (b) (4) barrels. These barrels appeared to have an approximate size (b) (4). Mr. Chen confirmed that the item being stored in the unlined (b) (4) barrels was ground white pepper. I (Investigator Millar) asked Mr. Chen what the next manufacturing steps were once the white pepper was collected in the barrels. Mr. Chen stated that the barrel (b) (4). Mr. Chen described the packing process

by stating the operator (b) (4)

(b) (4). Photo Exhibit 6 (Page 29) depicts this packaging arrangement. We (Investigator Millar and ERC Yee) observed residual build-up on the interior surface of the (b) (4) funnels used for the packing process. I (ERC Yee) interviewed one of the processing employees regarding sanitation of the unlined (b) (4) spice storage barrels. He explained that the barrels were not cleaned (not cleaned using a wet process, nor air cleaned).

We (ERC Yee and Investigators Millar and Young) observed ground white pepper stored in unlined (b) (4) barrels on March 28, 2009 as described under Observation 3.

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*Photo Exhibit 10.* Packing/repacking table. (b) (4) funnels were observed with powder residue inside. An accumulation of dust (top circle) was observed on the plastic shields covering the phone and electrical outlets.

**Supporting Samples:**

One environmental swab sample collected from the inside of one of the (b) (4) funnels

visible in Photo Exhibit 10 was found positive for *Salmonella* (FDB sample 173032709-48, collected March 27, 2009, analyzed in the CDPH Food and Drug Laboratory). Three additional samples were found positive for *Salmonella* in the vicinity of the repacking table, also depicted in Photo Exhibit 10:

- FDB sample 173032709-49 (table-top scale)
- FDA sample 490702 sub 4 (floor under (b) (4) repacking table)
- FDA sample 402154 sub 7 (floor under left side of (b) (4) repacking table)

The samples are listed in Table 4, under Observation 5 (Page 44), in context with other samples found positive in the packaging table area.

In-process ground white pepper sampled from inside the unlined (b) (4) barrels (Photo Exhibit 11) yielded 14 positive findings of *Salmonella* (FDB samples 173032709- 29, 30, 32-43 collected March 27, 2009 and analyzed at the CDPH Food and Drug Laboratory). PFGE analysis was conducted for 3 of the 14 and all 3 matched the outbreak strain of *Salmonella* Rissen (FDB samples 173032709-30, 32, 34).

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*Photo Exhibit 11.* (b) (4) repacking area. Unlined (b) (4) barrels were used to store in-process white pepper after grinding.

**Discussion with Management:**

Refer to the Discussion with Management under Observation 1. Mr. (b) (4) explained that (b) (4) funnels will be used for future repacking operations at the firm. All (b) (4) barrels used

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to store product in the future will (b) (4) as reflected in the Production SOP (Exhibit 14, Part H).

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**OBSERVATION 4**

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food.

Specifically, on 3/28/09 we observed thin films of dust on the handles and food residues on the inside surfaces (b) (4) scoops stored in a drawer under the spice repacking table. According to your firm, all spice repacking operations utilize (b) (4) scoops and are carried out at the repacking table situated in the main hallway, approximately (b) (4) from the white pepper grinding room.

Reference: 21 CFR 110.35(a)

Supporting Evidence and Relevance:

- Photo Exhibit 12

We (ERC Yee and Investigators Millar and Young) observed dust and residues on (b) (4) scoops in the repacking area March 28, 2009, as described under Observation 4 (Photo Exhibit 12).

3/28/09 WVM (cropped)



*Photo Exhibit 12.* Packing/repacking table. (b) (4) scoops used for repacking had a thin film of dust on the handle and visible food residue on the inside surface.

Discussion with Management:

Refer to the Discussion with Management under Observation 1.

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**OBSERVATION 5**

Failure to clean non-food-contact surfaces of equipment as frequently as necessary to protect against contamination.

Specifically,

- On 3/27/09 and 3/28/09 we observed an accumulation of white pepper dust on the following non-food contact surfaces inside your firm's white pepper grinding room:
  - 1) The electrical conduits, circuit boxes, and electrical wiring along the west wall of the room
  - 2) Throughout the floor area
  - 3) The metal support pole located at the center of the roomAdditionally, we observed a layer of white pepper dust approximately 1/8 inch thick on the pepper (b) (4), a component of the white pepper grinding system.
  
- On 3/27/09 we observed an accumulation of white pepper dust on the following non-food contact surfaces in the hallway outside your firm's white pepper grinding room:
  - 1) The west wall of the hallway in which the (b) (4) hand repacking table is situated (dust covered the wall)
  - 2) The plastic shields covering the phone and electrical outlets directly over the (b) (4) repacking table
  - 3) The floor scale stored by the (b) (4) repacking table
  - 4) The floor in front of the (b) (4) repacking table
  - 5) Adjacent to the heat sealer on the (b) (4) repacking table, which your firm used to (b) (4) repackaged spices
  
- On 3/27/09 and 3/28/09 in your firm's white pepper grinding room, we observed three dried brown residual stains on the outside of the (b) (4) ground pepper hopper, each approximately (b) (4) in size. The hopper dispensed ground white pepper into (b) (4) barrels for temporary storage prior to packaging. We observed additional dried brown residue on the west wall of the white pepper grinding room, adjacent to the equipment control panel. The panel was situated approximately (b) (4) from the ground pepper hopper.

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Reference: 21 CFR 110.35(d)(3)

Supporting Evidence and Relevance:

- Attachment W: CalFERT Samples Table. Samples collected by CalFERT for *Salmonella* analysis between March 27 and April 7, 2009 in the warehouse and processing areas located at 33035 Transit Avenue.

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- Attachment X: CalFERT PFGE Matched Samples. Samples from Attachment W found positive and PFGE matched to the outbreak strain of *Salmonella* Rissen.
- Photo Exhibits 10, 13, 14, 15, 16
- Table 4
- FDA environmental swab samples found positive for *Salmonella* Rissen relating to Observation 5: INV 490702 sub 4; INV 490696 subs 1,4,5, INV 402154 sub 7, INV 503180 subs 1-5 (collection reports attached).

When we (ERC Yee and Investigator Millar) first arrived at the firm on March 27, 2009, Mr. Chen showed us into the processing areas. In the white pepper grinding room, we observed dust accumulation on equipment and other surfaces, including the walls and floor. A relatively heavy layer of dust approximately 1/8 inch thick covered the (b) (4), as described under Observation 5. We (ERC Yee and Investigators Millar and Young) observed brown stains and residues on non-food contact surfaces in the white pepper grinding room on March 28, 2009, as described under Observation 5.

Table 4

*Environmental Swab Samples Positive for Salmonella Related to Observations 3 and 5*

Location	Description	Sample ID	Sub	Lab
(b) Packing Area	Floor under (b) repacking table	490702	4	SAN-LAB
	Floor under left side of packing table	402154	7	SAN-LAB
	(b) (4) funnel	173032709-48	-	CDPH FDL
	Table-top Scale	173032709-49	-	CDPH FDL
White Pepper Grinding Room	Drain in white pepper room under hopper	490696	1	SAN-LAB
	Electrical conduit	503180	2	SAN-LAB
	Equipment control panel	503180	1	SAN-LAB
	Floor and wall under pallet racks in Rm. #2.	490696	4	SAN-LAB
	Floor drain under grinder	503180	4	SAN-LAB
	Floor sq. Area, NW adjacent curtain	503180	5	SAN-LAB
	Fuse box panel	503180	3	SAN-LAB
Roof support pole in middle of Rm #2.	490696	5	SAN-LAB	

Note. Samples with sub-numbers listed in the chart (FDA samples) were all PFGE matched to the outbreak strain of *Salmonella* Rissen.

<sup>a</sup>Funnels were alternately described as (b) (4) by the collectors

**Supporting Samples:**

Table 4 lists FDA and FDB environmental swab samples found positive for *Salmonella* related to Observation 5, collected March 27 and 28, 2009 in the hand packing area and white pepper grinding room. All FDA sub-samples presented in the chart were PFGE analyzed and found to match the

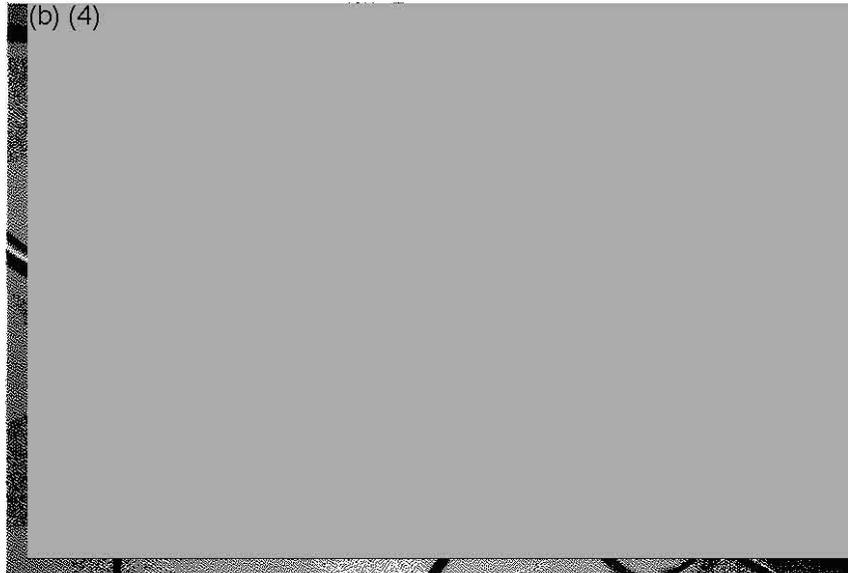
outbreak strain of *Salmonella* Rissen. Specific swab sampling sites are depicted in Photo Exhibits 13, 14 and 15. Refer also to Photo Exhibit 10 (under Observation 3, Page 40) depicting the phone and electrical outlet. The heat sealer is pictured in Photo Exhibit 16, although no *Salmonella* was found on it. The areas yielding swab samples positive for *Salmonella* in Table 4 included specific non-food contact surfaces described in Observation 5, on which an accumulation of white pepper dust was observed (such as floor areas, electrical equipment, and the support pole). The (b) [redacted] packing area listed in the table was located in the hallway outside the white pepper grinding room.

3/28/09 WVM



*Photo Exhibit 13.* White pepper grinding room. A build-up of powder on the (b) (4) [redacted] (circled left) and throughout the floor (circled bottom right), and a brown residual stain on the (b) (4) [redacted] ground pepper hopper (circled top right) were observed.

3/28/09 WVM



*Photo Exhibit 14.* White pepper grinding room. An electrical conduit along the west wall of the room was observed covered with white pepper dust.

3/28/09 WVM



*Photo Exhibit 15.* White pepper grinding room. A control panel and wiring were observed covered with white pepper dust. Dried brown residues were visible on the west wall adjacent to the equipment control panel (circled).

3/27/09 WVM

(b) (4)



*Photo Exhibit 16.* Packing/repacking table. An accumulation of brown dust was observed on the (b) (4) repacking table by the heat sealer (hallway outside white pepper grinding room).

**Discussion with Management:**

Refer to the Discussion with Management under Observation 1. Mr. (b) (4) noted that packing and repacking operations will be conducted on tables made entirely of (b) (4) in the future.

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**OBSERVATION 6**

Failure to maintain equipment, containers and utensils used to convey food in a manner that protects against contamination.

Specifically, on 3/27/09 in your firm's sauce and oil bottling room, we observed a collection of food product oil in (b) (4) pans placed beneath areas where (b) (4) pipes joined along the soybean oil pipeline. A plastic bag with a collection of food product oil inside it was tied around a T-connector pipe on the sesame oil pipeline. The soy and sesame pipelines were components of your firm's processing system used to (b) (4)

(b) (4)

Reference: 21 CFR 110.80(b)(7)

Supporting Evidence and Relevance:

- Photo Exhibits 17, 18

We (ERC Yee and Investigator Millar) observed food product oil collected in pans and a bag suspended beneath a pipe on March 27, 2009, as described under Observation 6.

3/30/09 WVM



*Photo Exhibit 17.* Sauce and oil bottling room. A bag containing oil was attached under a pipe.

During a walk-through inspection of the firm's sauce and oil bottling room, Room #1, I (Investigator Millar) observed indications of leaks in the firm's transfer lines for the manufacturing of a soybean/sesame oil blend product. Leakage was indicated by oil residue on the exterior surfaces of the transfer lines where the piping was joined by threaded connectors and below these connectors, the firm had placed containers such as (b) (4) pans and plastic bags to contain the leaks from spreading. See Photo Exhibits 17 and 18 for illustration. I asked Mr. Chen about containers placed beneath the transfer lines and he responded by stating that he has tried to fix the leaks but was unsuccessful. I asked Mr. Chen about the cleaning process for the transfer lines and he stated that the lines were cleaned (b) (4) using (b) (4). The firm used these transfer lines to convey (b) (4)

(b) (4)

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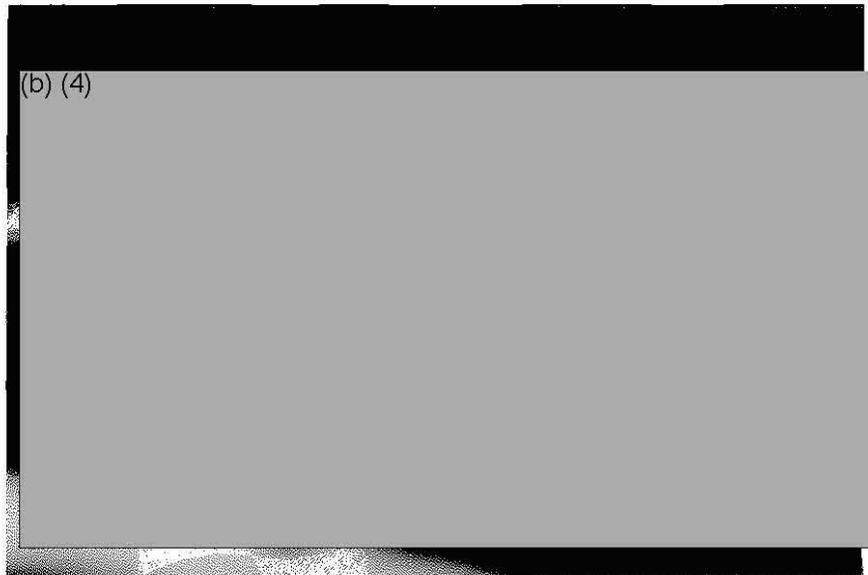
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(b) (4)

(b) (4)

Leaks in the transfer lines indicate the system could be open to environmental exposure, such as to microorganisms in airborne dust. When the motorized pumps are not in operation, the pressure within the piping and the atmospheric pressure would be at equilibrium, allowing air to move freely. It would be difficult to assess if the interior surfaces of the transfer lines became contaminated, as there was limited accessibility.

3/30/09 WVM



*Photo Exhibit 18.* Sauce and oil bottling room. A pan containing oil was observed underneath a pipe.

**Discussion with Management:**

Mr. [REDACTED] stated that all leaky piping had been repaired. All pipes were flushed, cleaned, and sanitized multiple times.

**REFUSALS**

On March 28, 2009, I (ERC Yee) questioned Mr. Chen regarding the extent of Union International's property holdings as we sat in the conference room located at 33035 Transit Avenue. He had escorted me on a process tour through the full warehouse and processing areas occupied by that address. Mr. Chen conveyed to me that his firm had no other properties and utilized no other facilities for storage or processing besides the one we had toured. The misinformation he provided became apparent on April 21, 2009 when we (ERC Yee, Investigators Pomeroy and Liu, and several FDB investigators), learned of a previously undisclosed adjacent warehouse utilized by Union International at 33055 Transit Avenue (Room 4). We (ERC Yee and Investigator Pomeroy)

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observed recognizable Union International products through an outside tinted window on the far side of the adjacent warehouse. When I (Investigator Pomeroy) questioned Mr. Chen about the warehouse and requested access in the presence of FDB Investigator Mike Needham on April 21, Mr. Chen first replied that he rented it to a friend and that he did not have the key with him. Mr. (b) (4) entered the room at that point and asked Mr. Chen if he wanted to refuse inspection. He advised Mr. Chen to call his lawyer. Mr. Chen said nothing more, called his lawyer, then returned a few minutes later and granted us access to the newly discovered warehouse.

On March 28, 2009, I (ERC Yee) was told by Mr. Chen that all spices were repacked on the repacking table in the hallway outside the white pepper grinding room. On April 4, 2009, we (Investigators Pomeroy and Young), questioned Mr. Chen about the packing of smaller distribution volume spices, such as (b) (4). It became clear that some of these spices were packaged elsewhere. Mr. Chen explained to us that his firm utilized the (b) (4) table in the break/lunch room to pack these smaller volume spices. He said sometimes they would pack them in the lunch room and other times they would bring the table out into the warehouse. Mr. (b) (4) was present for some of this discussion. On April 4, 2009, Mr. (b) (4) called me (Investigator Pomeroy) and said he had discussed the issue further with Mr. Chen and his wife and (b) (4) with the help of an interpreter. He informed me that Mr. Chen had lied about using the lunch room table as a repacking table. Mr. (b) (4) explained that Mr. Chen's cultural background made him distrust and fear authority and that he had come up with the cleanest place he could imagine, when asked about a repacking location. Mr. (b) (4) said the firm's actual practice was to repack the smaller volume spices on a drum or other surface in the warehouse.

**GENERAL DISCUSSION WITH MANAGEMENT**

All observations discussed with management are covered under Objectionable Conditions and Management's Response. The form FDA 483 was issued to Mr. Daniel Y. Chen, Vice President and Manager, on July 24, 2009.

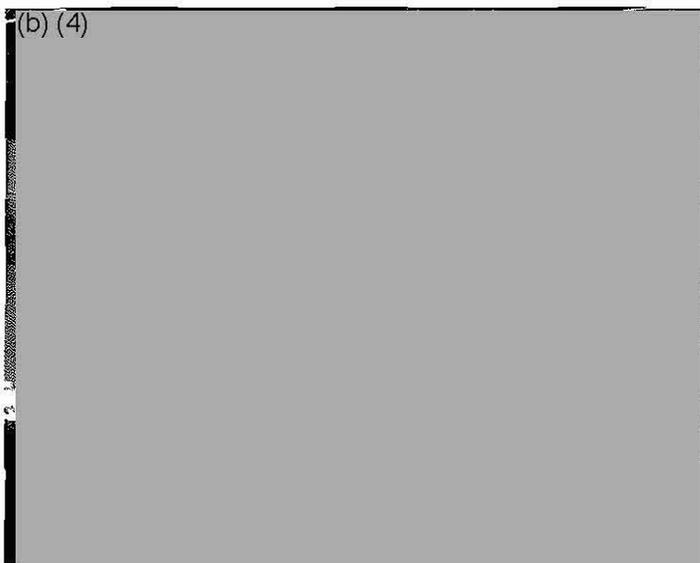
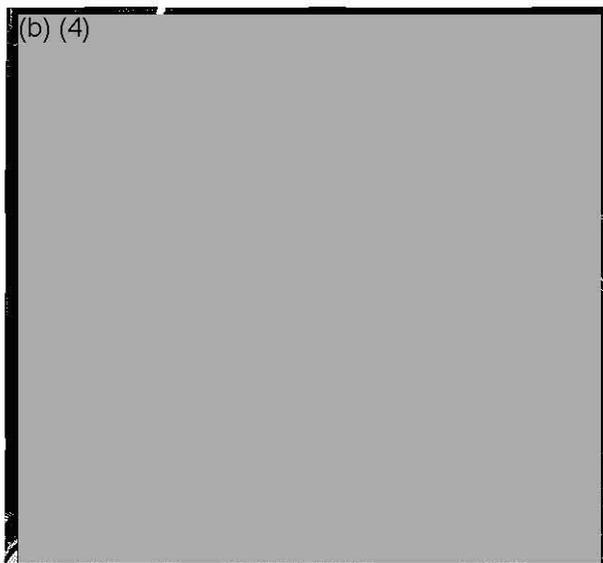
**ADDITIONAL INFORMATION**

On April 21, 2009, we (ERC Yee and Investigators Pomeroy and Liu) became aware of a previously undisclosed warehouse utilized by Union International located at 33055 Transit Avenue, depicted in Photo Exhibits 19 and 20.

The approximately (b) (4) square foot warehouse (referred to by the firm as Room 4) held raw materials for both spices and sauces, in-process fermenting sauces, and dried spice and sauce finished products. When we first gained access to the warehouse, it contained a vast array of materials stacked up against each other, such that assessing a true count was impossible because the majority of products stored there were inaccessible.

4/21/09 ERP (cropped)

4/21/09 ERP



*Photo Exhibit 19.* Warehouse at 33055 Transit Avenue. View facing northwest from near the southeast corner.

*Photo Exhibit 20.* Warehouse at 33055 Transit Avenue. View facing east from the west side roll-up door.

An estimated [redacted] (b) (4) [redacted] barrels of fermenting sauces were among the products observed stacked across the floor, as well as stacked (b) (4) levels high on a platform that spread across about (b) (4) of the warehouse. (b) (4) tanks containing chili sauce in the warehouse were an estimated two thirds and one half full. Pallets of raw materials observed included whole white pepper from the January, 2009 purchase. Approximately (b) (4) pallets of finished product spices, sauces, and oils were stored in the warehouse. One roll-up door was observed that connected the newly discovered warehouse to the adjacent warehouse at 33035 Transit Avenue. FDB investigators placed a blanket embargo over all products in the new warehouse on April 21, 2009. Union International claimed the door between the two warehouses was never opened and the new warehouse was used only for sauce manufacturing and product storage, not spice production. (b) (4) collected a total of 86 environmental swab samples and 3 raw material whole white pepper samples from Room 4. All samples were negative for *Salmonella*. Refer to Private Laboratory Samples. As of September 10, 2009, discussions between Union International and FDB to determine a course of action regarding products in the Room 4 were ongoing.

#### **SAMPLES COLLECTED**

For this inspection and CalFERT investigation, we (CalFERT members, including FDA inspection team members) collected samples jointly by utilizing both FDA and FDB sample collection protocols. The term, "protocols" refers here to the general collection practices of the two regulatory

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agencies, which differ in sub-sample designation and grouping. Samples were analyzed in either federal or state laboratories, including the CDPH Food and Drug Laboratory (FDL), the FDA San Francisco District Laboratory (SAN-Lab), the FDA Pacific Regional Laboratory Southwest (PRL-SW), and the FDA Southeast Regional Laboratory (SRL). All samples referenced were collected by CalFERT at Union International's 33035 Transit Avenue facility.

The CalFERT Investigation Samples section details samples collected jointly by the two regulatory agencies during the first phase of the investigation, prior to any clean-up efforts undertaken by the firm. This phase of sampling was geared toward identifying if contamination was present in the facility environment or in products packaged on site, and assessing its scope. A second objective was to explore potential raw material sources of the contamination. The FDA Samples section of this report features an itemized list of those CalFERT samples that were collected per FDA protocols and assigned FDA sample numbers. Two FDA documentary samples were collected. The private laboratory hired by Union International, (b) (4) also collected samples during the initial phase of the investigation, prior to any clean-up efforts undertaken by the firm. Following this phase, (b) (4) engaged in a number of post-cleanup verification samplings. Refer to the section entitled, Private Laboratory Samples, for (b) (4) analysis results. Subsequent to all other sample collections, CalFERT undertook a final post-cleanup verification sampling effort at the Union International facility (33035 Transit Avenue warehouse). This sampling effort is described under CalFERT Facility Clean-up Verification Samples.

### CalFERT Investigation Samples

From March 27 to April 7, 2009, we (CalFERT) collected a total of 391 samples for *Salmonella* analysis at the Union International facility, under both FDA and FDB sample collection protocols. Discrepancies in sample counting techniques between FDA and FDB should be taken into account, although efforts were made to reconcile the sample tallies to reflect the most accurate representation of sample collection data. The 391 samples were collected as follows.

- 78 FDB environmental swab samples: One sample was counted per area swabbed. Samples were analyzed individually by the FDB lab.
- 38 FDA environmental swab sub-samples: One sub-sample was counted per area swabbed. Sub-samples were analyzed individually by the FDA lab, although 38 swab sub-samples (each from a unique location) were distributed among 10 FDA sample numbers.
- 258 FDB product samples: Each sample counted was individual, i.e. composed of just one sub-sample. Samples were analyzed individually by the FDB lab.
- 17 FDA product samples: Each sample counted was composed of multiple sub-samples. Sub-samples under each sample number were composited for analysis by the FDA lab.

Refer to FDA Samples for a list of specific sub-sample quantities for each sample. Attachment W is a table depicting the 391 CalFERT samples (and sub-samples) collected for *Salmonella* analysis from March 27 to April 7, 2009 at the Union International facility. Attachment X features samples from Attachment W found positive for *Salmonella* and PFGE matched to the outbreak strain of

*Salmonella* Rissen. Attachment Y is an email from FDL with tables featuring sample analysis data submitted by SAN-Lab (Pages 2-5) and by FDL (Pages 6-13) for CalFERT samples collected. The data from these tables, together with analysis results (for FDA samples only) from other participating FDA laboratories, were incorporated to create Attachment W, the complete CalFERT samples table.

In addition to those samples collected for *Salmonella* analysis, we (CalFERT) collected 96 FDB style samples for pH and water activity analysis, covering four varieties of finished product sauces, on April 15, 2009 at the Union International facility.

### ***Environmental Swab Samples***

One hundred sixteen environmental swab-samples were collected in the processing areas, warehouse, and restrooms of the Union International facility. Of these, 46 (40%) were positive for *Salmonella*. Three adjacent rooms branching off a main hallway formed the processing area. Refer to Attachment S for a facility diagram with FDA positives indicated.

- White pepper grinding room: 40 swab samples were collected from food and non-food contact surfaces. Of these, 34 samples (85%) were positive for *Salmonella*. PFGE analysis was conducted for 19 of the 34 swab samples and all 19 matched the outbreak strain of *Salmonella* Rissen.
- Sauce mixing room: 25 swab samples were collected. Of these, 8 samples (32%) were positive for *Salmonella*. PFGE analysis was conducted for three of the eight swab samples and all three matched the outbreak strain of *Salmonella* Rissen.
- (b) (4) packing/repacking area: 16 swab samples were collected. Of these, 4 samples (25%) were positive for *Salmonella*. Two of the four were PFGE analyzed and the two were matched to the outbreak strain of *Salmonella* Rissen.
- Sauce and oil bottling room: 20 swab samples were collected. All 20 were negative for *Salmonella*.
- Warehouse area and restrooms: 15 swab samples were collected. All 15 were negative for *Salmonella*.

### ***Finished Product Samples***

Eighty-nine finished product samples were collected for *Salmonella* analysis from among products that were manufactured or repackaged by Union International and stored in the warehouse on site.

- White pepper samples: Two finished product ground white pepper samples were collected per FDA protocols (ten subs per sample). Of the two, both samples (100%) were positive for *Salmonella* Rissen with a PFGE pattern matching the outbreak strain. The products were a 5 pound plastic jug of Lian How Brand ground white pepper and a 5 pound plastic bag of Uncle Chen brand ground white pepper.
- Black pepper sample: One finished product ground black pepper sample was collected per FDA protocols (ten subs per sample) and found negative for *Salmonella*.

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- Other spices: (all negative for *Salmonella*) 42 finished product samples of spices other than pepper were collected per FDB protocols (one sub per sample). Six samples each were collected of garlic powder, Lian How Brand garlic chopped, Lian How Brand granule garlic, Lian How Brand minced garlic powder, Lian How Brand onion powder, paprika (bagged), and Lian How Brand paprika. All samples of spices other than pepper were negative for *Salmonella*.
- Sauces and oil blends: (all negative for *Salmonella*) 44 finished product samples of the Asian-style sauces and oil blends manufactured by Union International were collected per FDB protocols (one sub per sample) for *Salmonella* analysis. In this case, one sub-sample consisted of between one and six jars or bottles of the product for composite analysis, depending on container size. All sauces and oils sampled were negative for *Salmonella*.

Ninety-six samples were collected per FDB protocols for pH and water activity (Aw) analysis. Twenty-four samples each were collected of Lian How Brand Hot Broad Bean Sauce (FDB samples 061041509 A1-A24), Uncle Chen Extra Hot Chili Garlic Sauce (FDB samples 061041509 B1-B24), Uncle Chen Fresh Ground Chili Paste, (FDB samples 061041509 C1-C24), and Black Bean Garlic Sauce (FDB samples 061041509 D1-D24). The 96 samples were analyzed in SAN-Lab, where each group of 24 was assigned to an FDA sample number in FACTS (535044, 535078, 535080, and 535083, respectively). The analysis results were as follows:

- Lian How Brand Hot Broad Bean Sauce
  - pH subs 1-12 range 3.79-3.84
  - Aw subs 1-3 range 0.892-0.894
- Uncle Chen Extra Hot Chili Garlic Sauce
  - pH subs 1-12 range 3.64-3.71
  - Aw subs 1-3 range 0.912-0.914
- Uncle Chen Fresh Ground Chili Paste
  - pH Subs 1-12 range 3.58-3.64
  - Aw Subs 1-3 range 0.893-0.900
- Black Bean Garlic Sauce
  - pH Subs 1-12 range 4.17-4.29
  - Aw subs 1-3 range 0.820-0.822

***In-Process Product Samples***

Eighteen in-process white pepper samples were collected per FDB protocols (one sub per sample) in the white pepper grinding room. Of these, 14 (78%) were positive for *Salmonella*. Used here, the term "in-process" refers to pepper sampled from the grinder assembly (pre- or post-grinding) and ground white pepper sampled from the multiple (b) (4) barrels in which it was stored after being ground until the time of packaging

- Ground white pepper: 16 in-process ground white pepper samples were collected from the (b) (4) barrels. Of these, 14 samples (88%) were positive for *Salmonella*. PFGE analysis was conducted for 3 of the 14 samples and all 3 matched the outbreak strain of *Salmonella* Rissen.
- Whole white pepper: Two in-process whole white pepper samples were collected from the grinding machine whole pepper hopper. The two were negative for *Salmonella*.

### ***Raw Material Product Samples***

One hundred sixty-eight samples were collected from various intact (unopened) bags of raw materials stored on site at Union International. Raw material forms of pepper observed on site were limited to whole white pepper and ground black pepper. No ground white pepper or whole black pepper were observed in raw material form at the facility.

- Whole white pepper: 104 raw material whole white pepper samples were collected per FDB protocols (one sub per sample) from 11 intact bags of (b) (4). One sample (approximately 1%) from one bag in the lot was positive for *Salmonella* Rissen. The sample was PFGE analyzed and matched to the outbreak strain.
- Ground black pepper: (all negative for *Salmonella*) 52 raw material ground black pepper samples were collected, representing 2 different raw material lots stored on site at the facility. Of these samples, 50 were collected per FDB protocols (one sub per sample) and 2 were collected per FDA protocols (one sample of four subs and one of five subs). All raw material ground black pepper samples were negative for *Salmonella*.
- Other raw material spices: (all negative for *Salmonella*) 12 samples of a variety spices in raw material form were collected per FDA protocols. Samples were collected of curry powder (8 subs), mustard flour (30 subs) and of ground paprika, chopped garlic, chopped onion, dehydrated granulated garlic, dehydrated powdered garlic, dried horseradish powder, horseradish powder, minced garlic, onion powder, and ground chilies (15 subs each). All raw material samples of spices other than pepper were negative for *Salmonella*.

### **FDA Samples**

The CalFERT samples described above that were collected per FDA protocols for *Salmonella* analysis are listed in Table 5. The 27 FDA samples were collected jointly by FDA and FDB CalFERT members, but were assigned FDA sample numbers and collection reports were entered into FACTS by the lead FDA collectors. Although broad FDA protocols were used for collection of these samples (in contrast with state protocols), some modifications to specific FDA procedures for sub-sample quantities were made during this outbreak investigation/inspection. Refer to Table 5 for sub-sample quantities collected in each case. All samples listed in the table were investigational in nature. FDA samples found positive for *Salmonella* were PFGE analyzed and all were matched to the outbreak strain of *Salmonella* Rissen. Attachment S is a facility diagram with locations of FDA environmental samples found positive for *Salmonella* indicated. Two FDA documentary samples, DOC 387908 and DOC 387909, were collected, making a total of 29 FDA samples.

Table 5  
*CalFERT Samples Collected Per FDA Protocols*

Sample ID	Sample Type	Sub	Description	Lab	Confirmation
402154	Swab	1	Door strips at doorway of Rm #2	SAN-LAB	Negative
		2	Heat sealer	SAN-LAB	Negative
		3	Heat sealer stand	SAN-LAB	Negative
		4	Power cords	SAN-LAB	Negative
		5	Floor under right side of packing table	SAN-LAB	Negative
		6	Floor under middle section of packing table	SAN-LAB	Negative
		7	Floor under left side of packing table	SAN-LAB	Salmonella
490694	Raw Ingredient	1-4	(b) (4)	SAN-LAB	Negative
			(b) (4)		
490695	Raw Ingredient	1-5	(b) (4)	SAN-LAB	Negative
490696	Swab	1	Drain in white pepper rm under hopper	SAN-LAB	Salmonella
		2	(South) wall by grinding machine	SAN-LAB	Salmonella
		3	Outlets in rm #2.	SAN-LAB	Salmonella
		4	Floor and wall under pallet racks in rm. #2.	SAN-LAB	Salmonella
		5	Roof support pole in middle of rm #2.	SAN-LAB	Salmonella
		6	Large shovel in rm. #2.	SAN-LAB	Salmonella
490699	Finished Product	1-10	Lian How ground black pepper - 5 lb container	SAN-LAB	Negative
490700	Finished Product	1-10	Lian How ground white pepper - 5 lb container	SAN-LAB	Salmonella
490701	Finished Product	1-10	Uncle Chen Ground White Pepper - 5 lbs heat sealed bags	SAN-LAB	Salmonella
490702	Swab	1	(b) (4) repacking table	SAN-LAB	Negative
		2	Large floor scale by (b) repacking table	SAN-LAB	Negative
		3	Wall next to (b) repacking table	SAN-LAB	Negative
		4	Floor under (b) repacking table	SAN-LAB	Salmonella
503180	Swab	1	Equipment control panel	SAN-LAB	Salmonella
		2	Electrical conduit	SAN-LAB	Salmonella
		3	Fuse box panel	SAN-LAB	Salmonella
		4	Floor drain under grinder	SAN-LAB	Salmonella
		5	Floor sq. Area, nw adjacent curtain	SAN-LAB	Salmonella
503181	Swab	1	Large scoop #1	SAN-LAB	Negative
		2	Large scoop #2	SAN-LAB	Negative
		3	Medium scoop #1	SAN-LAB	Negative

		4	Medium scoop #2	SAN-LAB	Negative
		5	Small scoop #1	SAN-LAB	Negative
		6	Medium scoop #3	SAN-LAB	Negative
503182	Swab	1	Toilet, under seat, inside rim	SAN-LAB	Negative
		2	Sink, faucet area, spout, drain	SAN-LAB	Negative
503183	Swab	1	Toilet, under seat, inside rim	SAN-LAB	Negative
		2	Sink, faucet area, spout, drain	SAN-LAB	Negative
503184	Swab	1	Rubber gloves by sink	SAN-LAB	Negative
		2	Smock on filling line	SAN-LAB	Negative
		3	Smock on equip near corner	SAN-LAB	Negative
		4	Curtain joining rm#1 & rm#2	SAN-LAB	Negative
503185	Swab	1	Chili sauce wash area -Cleaning Vessel, Int. Botm & Drain	SAN-LAB	<i>Salmonella</i>
503186	Swab	1	Brooms	SAN-LAB	Negative
503187	Raw Ingredient	1-15	Ground chilies - cayenne	SRL	Negative
520363	Raw Ingredient	1-30	Mustard flour	PRL-SW	Negative
520364	Raw Ingredient	1-8	Curry powder	SRL	Negative
530355	Raw Ingredient	1-15	Dehydrated powdered garlic	SRL	Negative
530356	Raw Ingredient	1-15	Chopped garlic	SRL	Negative
530357	Raw Ingredient	1-15	Onion powder - sensient	SRL	Negative
530358	Raw Ingredient	1-15	Chopped onion	SRL	Negative
530359	Raw Ingredient	1-15	Minced garlic	SAN-LAB	Negative
530360	Raw Ingredient	1-15	American paprika (ground)	SAN-LAB	Negative
530361	Raw Ingredient	1-15	Dehydrated granulated garlic	SAN-LAB	Negative
530362	Raw Ingredient	1-15	Horseradish powder	SAN-LAB	Negative
530363	Raw Ingredient	1-15	Dried horseradish powder	SAN-LAB	Negative

**Private Laboratory Samples**

(b) (4) provided private laboratory services to Union International during this inspection.

(b) (4) collected samples and analyzed them for the firm using (b) (4)

[REDACTED]

At Union International’s 33035 Transit Avenue warehouse, (b) (4) conducted one initial phase of sampling prior to any facility clean-up efforts, followed by three phases of post-cleaning verification

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sampling, as summarized in Figure 3. Samples collected during Phases 1, 2 and 3 yielded positives for *Salmonella* from the analysis techniques employed (Mr. (b) (4) noted that the (b) (4) in Phase 3 may have resulted in a number of false positives). Phase 4 yielded negative results.

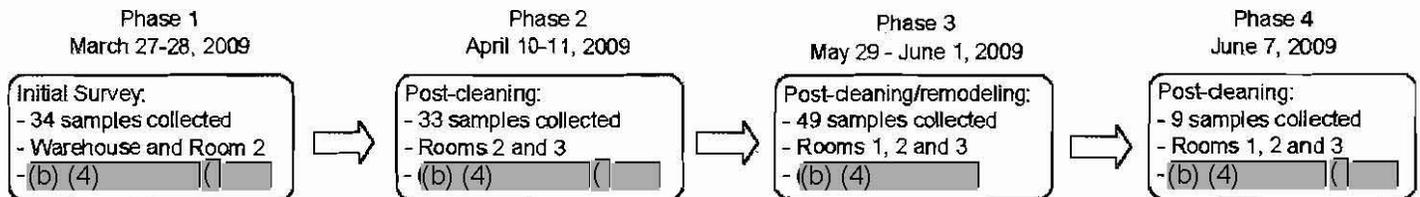


Figure 3. Samples collected by (b) (4) in the warehouse and processing areas located at 33035 Transit Avenue.

In Phase 1, (b) (4) collected 34 environmental and product samples in the facility processing areas on March 27 and 28, 2009, prior to any clean-up efforts undertaken by the firm. (b) (4) utilized the (b) (4) for the samples and provided FDA with a report of the analyses (Exhibit 15). The white pepper grinding room yielded the following sample results:

- Debris/scraping samples: 6 of 6 (100%) were positive for *Salmonella*
- In-process white pepper samples: 4 of 8 (50%) were positive for *Salmonella* (all positives were ground)
- Environmental swab samples: 3 of 8 (38%) were positive for *Salmonella*

(b) (4) collected three finished product samples of ground white pepper, two of which (67%) were positive for *Salmonella*: a 5 pound plastic jug of Lian How ground white pepper and a 10 pound box with a plastic liner of Lian How ground white pepper. Additionally, nine raw material ground black pepper samples (representing two lots) collected from bags stored in the warehouse area were negative for *Salmonella*.

Over the course of the Union International facility clean-up process, (b) (4) conducted a series of post-cleaning verification environmental swab collections in the processing areas at 33035 Transit Avenue. The sauce and oil bottling room (Room 1), the white pepper grinding room (Room 2) and the sauce mixing room (Room 3) were all targeted.

In Phase 2, (b) (4) collected 33 environmental swab samples after the first facility cleaning by a professional service. The (b) (4) were utilized and (b) (4) provided FDA with a report of the results.

- April 10, 2009: Post-cleaning in the white pepper grinding room: 12 of 21 swabs (57%) were positive for *Salmonella* (Exhibit 17)
- April 11, 2009: Post-cleaning in the sauce mixing room: 5 of 12 swabs (42%) were positive for *Salmonella* (Exhibit 18)

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In Phase 3, (b) (4) collected 49 environmental swab samples after a second professional cleaning and a remodeling of the facility. (b) (4) utilized (b) (4) and provided FDA with a report of the analyses.

- May 29, 2009: Post-remodeling and cleaning:
  - White pepper grinding room: 3 of 12 swabs (25%) were presumptive positive for *Salmonella* (Exhibit 19)
  - Sauce mixing room: 2 of 12 swabs (17%) were presumptive positive for *Salmonella* (Exhibit 20)
  - Sauce and oil bottling room: 12 of 12 swabs were negative for *Salmonella* (Exhibit 21)
- June 1, 2009: Thirteen “Post-positive” cleaning samples were collected in the three rooms (Exhibit 22), focusing on specific areas found presumptive positive on May 29. Of the 13, samples from 5 pieces of equipment (38%) in the white pepper grinding room were found presumptive positive for *Salmonella*. The (b) (4) packing/filling unit was a surface found presumptive positive on May 29.
  - Interior housing of the (b) (4) packing/filling unit
  - Wheels and stand of the (b) (4) packing/filling unit
  - (b) (4) pound capacity scale
  - (b) (4) heat sealer unit
  - Rm 3 - support plate under sink

In Phase 4, (b) (4) collected 9 environmental swab samples after additional in-house cleaning of the facility. (b) (4) utilized (b) (4) (b) (4) for the samples and provided FDA with a report of the analyses (Exhibit 23).

- June 7, 2009: Nine “Post-positive” cleaning samples were collected in the three rooms. Areas covered included specific equipment found presumptive positive on June 1. All nine were confirmed negative for *Salmonella*.

Additional Samples in Room 4: (b) (4) collected a total of 86 environmental swab samples and 3 raw material whole white pepper samples in the previously undisclosed adjacent warehouse located at 33055 Transit Avenue (Room 4). All samples were negative for *Salmonella*. The samples collected were as follows:

- May 8, 2009: 21 environmental swabs were collected from lids of fermenting sauce drums and the pallets that held them. (b) (4) Exhibit 24.
- May 12, 2009: Three whole white pepper composite samples were collected from raw material (b) (4) (purchased by Union International January 13, 2009). Thirteen environmental swabs were collected from the exterior of the pepper sacks. (b) (4) Exhibit 7.
- May 29, 2009: 12 environmental swabs were collected from equipment and various surfaces. (b) (4) Exhibit 25.

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- July 15, 2009: 40 environmental swabs were collected from various surfaces under the supervision of FDB investigators. (b) (4) Exhibit 26.

**CalFERT Facility Clean-up Verification Samples**

On August 4, 2009, a CalFERT follow-up team composed of FDA and FDB investigators returned to Union International to conduct a sampling effort for facility clean-up verification at 33035 Transit Avenue. FDA members on the CalFERT verification team included Investigator Weis (of the original inspection team) and SAN-Lab Microbiologist Henry K. Lau. The verification team collected 100 environmental swab samples from primarily non-food contact surfaces on the floors, walls, and equipment in the sauce and oil bottling room, white pepper grinding room, sauce mixing room and the hallway adjoining the rooms. The samples were analyzed by SAN-Lab and by CDPH FDL (50 samples by each lab). All 100 samples were negative for *Salmonella*. A memorandum (attached to this report) by Investigator Weis, dated August 4, 2009, details the sampling effort.

**VOLUNTARY CORRECTIONS**

Voluntary corrections undertaken by Union International included:

- Ceased production and distribution upon learning the firm may have been associated with an ongoing outbreak
- Initiated voluntary recalls of products (described under Recall Procedures)
- Destroyed potentially contaminated products, including but not limited to all sauces and oils returned under the recall, and packages of returned spices that had been opened (FDB led the monitoring of destruction activities)
- Conducted facility cleaning and sanitation prior to May 21, 2009, when the FDB Stipulated Preliminary Injunction was filed against Union International.

Later corrections undertaken by the firm, such as the development of food safety procedures, were made in an effort to comply with the terms of the preliminary injunction.

**DESTRUCTION AND RECONDITIONING**

Union International voluntarily destroyed potentially contaminated products under a review and oversight process led by FDB. The destruction included but was not limited to all sauces and oils returned under the recall, plus packages of returned spices that had been opened.

Union International petitioned FDB to allow the reconditioning of some potentially contaminated spice products that were under FDB embargo using an irradiation process. FDB led the review process for the firm's reconditioning proposals, although FDA participated. As of September 10, 2009, FDB oversight of the firm's reconditioning of spices was ongoing. At that time, one initial attempt at reconditioning of products by the firm had failed, as evidenced by *Salmonella* found in white pepper subsequent to the irradiation process.

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**EXHIBITS COLLECTED**

- |  | Pages |
|--|-------|
| 1. Officially sealed compact disk containing original photographs taken by members of the inspection team.   | 1     |
| 2. Officially sealed compact disk containing original photographs of Union International products taken by Luis A. Solorzano, Director of Investigations Branch, at the district office (for recall purposes). | 1     |
| 3. Union International Invoices and Sales Order Picking Lists to (b) (4) for January 16, March 6, and November 5, 2008   | 6     |
| 4. Union International Sales Journal documenting sales to (b) (4) for 2008 and 2009.   | 3     |
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**ATTACHMENTS**

- Forms FDA 482 (17)
- Forms FDA 482a (1) and 482b (1)
- Form FDA 483 (1)
- FDA Ineffective Recall Letter to Union International
- Collection Reports
  - INV 402154
  - INV 490696
  - INV 490700
  - INV 490701
  - INV 490702
  - INV 503180
  - INV 503185
  - Copy of SEA-DO DI 480437
- Documentary Samples
  - DOC 387908
  - DOC 387909
- Memoranda
  - April 14, 2009, from LOS-DO Investigator Alexandra Pitkin
  - April 20, 2009, from SEA-DO Investigator Nancy E. Doyle
  - May 27, 2009, from SAN-DO Investigator Min Shan Mabel Liu (with DOC 483176)
  - August 4, 2009, from SAN-DO Investigator William J. Weis

Lettered Attachments	Pages
A. CDPH Email: Epidemiology background information, CDPH Epidemic Line List (June 4, 2009) for <i>Salmonella</i> Serotype Rissen Cluster 0903NVTEE-1	5
B. Epidemiological charts and graphs for <i>Salmonella</i> Rissen Cluster 0903NVTEE-1 (final update June 4, 2009), obtained from CDPH	7
C. Traceback Diagram for white and black pepper samples found positive for <i>Salmonella</i>	1
D. May 5, 2009 email from Hillary Booth, FoodNet Special Studies Coordinator under the Oregon Department of Human Services with attached Oregon State Public Health Laboratory PFGE Analysis Report (forwarded from SEA-DO to SAN-DO)	2
E. Washoe County Health District, Environmental Health Services Division (Nevada) Epidemiological Investigation Report dated March 11, 2009	7
F. Photo Journal from (b)(4) & (b)(7)(C) accompanying Washoe County Health District (Nevada) Epidemiological Investigation Report dated March 11, 2009	3
G. Documents associated with December 1, 2007 whole white pepper purchase from	15

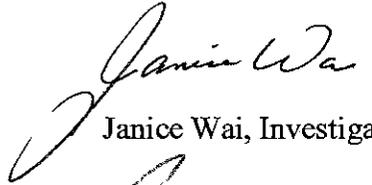
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Y. CDPH FDL email with analysis results tables submitted by both SAN-Lab and FDL (Note: Page 1 is the email, pages 2-5 were printed from one sheet in an Excel file, labeled: "FDA SAN-Lab," and pages 6-13 were printed from a second sheet in the Excel file, labeled "CDPH FDLB")	13



Erica R. Pomeroy, Investigator



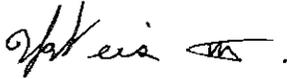
Janice Wai, Investigator



Jeanne A. Young, Investigator



Bruce D. Broidy, Investigator



William J. Weis, Investigator



James C. Yee, Investigator



Joseph A. Seitz, Investigator



Benny Y. Gong, Investigator



Ronald P. Boyce, Investigator



William V. Millar, Investigator



Min Shan Mabel Liu, Investigator



Daniel Roberts, Investigator



Vebina K. Sethi, Investigator