kosher retorts. This call was followed by a phone call from Mr. J.T. Brezley, Regional Area Director, OSHA, who further confirmed Mr. Burns' comments. The measurements included in the FDA-3511 for the kosher room were taken by the firm for our benefit since they had the necessary training for confined spaces.

Record Review:

An important accomplishment during this inspection was the review of every processing record for FDA-regulated products from January 1, 2007 to July 20, 2007. FDA Investigators E. Harold Blackwood, and Claudette D. Brooks led this team. Georgia Department of Agriculture sanitarians Allison Strickland, Thomas Rowland, Kathy Worthington, Chad McCord, and Mike Butts assisted.

During the inspection a variety of records were reviewed. These included areas related to incoming raw materials, product preparation, processing records, product hold logs, maintenance records, and shipping and distribution records.

The [redacted] Daily Retort Processing Records (retort operator's log) for the red meat line [redacted] retorts [redacted] were reviewed for the time period January 1, 2007 to July 20, 2007. Included with this record is the corresponding continuous temperature/pressure chart for each retort. All kosher room processing records were reviewed for the time period of January 1 to July 20, 2007 for retorts [redacted]. Only FDA-regulated products are processed in these vertical steam retorts. The kosher room review included the retort operator's logs, the puller's record, temperature/pressure continuous chart, and part of the kitchen record (this record showed dry fill testing). In the front section of the building the firm operates [redacted] vertical still steam retorts that are used for both FDA and USDA products. These processing records were reviewed for the 25 days between January 1, 2007 and July 20, 2007 that FDA-regulated product was processed in these retorts. Also included in the review of the processing records for these vertical retorts were three additional days for each month January 1, 2007 and July 20, 2007. These additional 21 days the firm only processed USDA-regulated products. The Product Hold Log and Finished Product Hold Log were reviewed from January 1, 2007 to July 20, 2007. Michael Duggan, Castleberry HACCP Coordinator, assisted the record review team, providing explanations when needed, and copies of records. Mr. Duggan's primary responsibility is in reviewing processing records for the firm.

Challenges to [redacted]

By comparing processing records to timestamps on FDA samples 428113 and 420352, we were able to determine the production of the product containing C. Botulinum toxin was on [redacted] and/or [redacted]. No one could definitively verify if the timestamp on the ink-jetting system was set to match the wall clock used by the retort operators and the times recorded on the retort logs. The ink-jetting system

previously was located at the end of the conveyor just prior to the [redacted] retorts. Management moved the ink-jetting system into the kitchen, locating it just beyond the can wash station after seaming.

With our focus on [redacted] we began a series of challenges to these [redacted] retorts to see if they could fail. Our first test began on [redacted] On 7/27/07 a team assembled consisting of Bumble Bee employees; Castleberry employees; FDA investigators James Lewis, Linda Stewart, and Bob Neligan; Dr. John Floyd, USDA; and Ms [redacted] Attorney. This test was video taped by Bumble Bee. A transcript summarizing the test on [redacted] was provided by Bumble Bee, and reviewed by Bob Neligan, FDA, prior to finalizing (exhibit 12; 3 pages). The cooling water valve on this [redacted] was taken off and everyone could see the valve had worn a deep groove in the surrounding rubber gasket. This groove prohibited proper seating of the valve. To simulate a normal day of production, this cooling water valve was opened and closed several times. After each successive use, the valve was observed to increase in the leakage amount. By the last test, the valve produced 1700 mL of water in a 60 second period. Clearly, this valve was leaking a substantial amount of water into the bottom of [redacted] This simulates what could occur during a cook cycle as the work day progressed. If actual cans were in the retort during this challenge this would have increased the amount of water in the bottom of this retort from condensation. [redacted] with a damaged cooling water valve, was shown to have an excess of water in the bottom of the retort during the test cook cycle on 7/27/07.

During this same test on [redacted] it was observed the indicator light on the panel was not functioning during the cooling phase of the cooking process. Kirk Baumann, Maintenance Manager, removed the lens, replaced the bulb, secured the lens back in place, and the cooling indicator light illuminated, indicating the process was in the cooling phase. Leaking valves and burned out alarm lights on the control panel provide a picture of the poor maintenance and inattention this firm was giving the [redacted] retorts.

On Saturday 7/28/07 a similar team of Bumble Bee, Castleberry, FDA, and USDA assembled to begin our series of challenges to [redacted] (exhibit 13; 2 pages). We began by examining the retort for leaks. No significant leaks were observed before start-up. It was observed that the [redacted] bypass drain valve was not functioning. In the event water is leaking into a retort from the [redacted] inlet, this valve is designed to expel the water before it could enter the retort.

We then began to operate [redacted] through its initial steps, including a vent process of pushing the [redacted] out of the drain valve, to examine it during a cook cycle. With the drain valves open on [redacted] the venting of [redacted] created such a backflow of [redacted] and steam through the drain line upstream that the entire room filled with steam. The water, still in [redacted] began to collapse the steam in the vessel causing a loud banging of the pipes. This unexpected result from venting [redacted] forced Castleberry management to cease the challenge on [redacted] No further work was accomplished on [redacted] that day. It did show that under certain circumstances

the venting of one [redacted] downstream will cause [redacted] and steam to flow upstream and enter another [redacted] when a drain valve is open.

Testing did resume on [redacted] on 7/30 & 31/07 (exhibit 14; 5 pages). Based on the events of Saturday July 28, we requested that the [redacted] tank be overfilled and then vent [redacted] into the overfilled tank. It should be noted that [redacted] was only half-filled with [redacted] for this test. The purpose of the challenge was to see if venting a [redacted] into a full [redacted] tank would cause water to backflow into an adjacent retort. Again, this created a safety hazard with the [redacted] tank bumping and bouncing off the floor. The overflow pea-trap on the [redacted] tank did expel water but not a rate sufficient to prevent water from filling the [redacted] vent pipe on the tank. The design of the vent pipe for the [redacted] tank associated with [redacted] is a [redacted] of pipe approximately [redacted] with a [redacted] going straight up to atmosphere above the roof line. A proper design would be a vertical vent from the top of the [redacted] tank straight to atmosphere. Even under these stressed conditions on the [redacted] tank, Fred Nolte, Bumble Bee, and Bob Neligan, FDA, did not observe any significant amounts of water coming from the opened bottoms of any of the [redacted]. However, it was observed that the overflow drain valve on [redacted] was under so much pressure it opened on its own and remained in a partially opened position for a period of time. This was a result of the pressure being exerted by the overfilled tank. After the system cooled for approximately 15 minutes, the valve returned to the closed position on its own. This overflow drain could be another entry point for water to enter a [redacted] retort if pressure was being exerted upstream from an overfilled [redacted] tank. The retort operators and the maintenance workers both stated they had seen conditions where the [redacted] tank had been overfilled and would rumble and jump off the floor.

On 7/30/07 Bumble Bee management brought in [redacted] a local plumber, to thread a fiber optic camera down the drain manifold to see if any blockages in the drain line caused the steam and [redacted] to enter [redacted] and [redacted] during the venting of [redacted] on 7/28/07 (exhibit 15; one page). This was a most unusual occurrence to vent one [redacted] and have such a back pressure that the [redacted] would travel upstream and enter another [redacted] Bumble Bee personnel, Castleberry personnel, the FDA team, and Dr. John Floyd, USDA all watched as the fiber optic camera found no blockages. The inside of the [redacted] tank, as well as the vent pipe for the tank, were examined with the camera and no blockages were found.

This led the FDA inspection team to examine other conditions of [redacted] that could have created the under-processing of a limited number of cans. It was observed early on in this inspection that under-processing seemed to occur only on a cluster of [redacted] cans or more during the cook cycle. Each [redacted] holds approximately [redacted] cans per cook cycle. FDA sample 428113, with a timestamp of "0223" produced on May 8, 2007, and sample 420352, with a timestamp of "1950" produced on May 7, 2007 were positive for C. Botulinum toxin. Other cans in the samples within 1-2 minutes from the timestamp were negative for the toxin. This narrows the affected cans down to approximately 100 or more cans per retort cook cycle on those days. The seamers used by this firm can operate at a maximum speed of [redacted] cans per minute. Normal operations would decrease that rate down to [redacted] cans per minute. It still remains viable that a limited amount of water could

cover the bottom layer of cans in a [redacted] retort causing small clusters of swollen cans. One design flaw noted with [redacted] was the condensate drain had the condensate bleeder located on the top of a "T" connection. The condensate bleeder could only expel water above the [redacted] condensate drain pipe. A proper design would place the condensate bleeder on the bottom of the drain pipe, assuring all water from inside the retort and in the condensate drain pipe would be expelled. Another design flaw with [redacted] was the condensate drain itself was not in view of the retort operators. If a condensate drain was clogged, no one could easily detect this condition. Investigator Neligan recommended to Fred Nolte that each condensate drain pipe be reconfigured to allow a visible check of proper operation.

One critically important event with [redacted] was the low-pressure reading. A (normal) pressure inside a retort of [redacted] psig correlates to an operating temperature of [redacted]. [redacted] was continually reading a pressure of, on average, 8 psig. This would correlate to an operating temperature of 235°. A list of randomly selected [redacted] processing logs reveals the following (exhibit 16 A- E):

February 26, 2007 [redacted]
Process start @ 12:55; pressure recorded by operator: 7 psig
Process start @ 3:55; pressure recorded by operator: 7 psig

March 19, 2007 [redacted]
Process start @ 9:51; pressure recorded by operator: 5 psig

April 24, 2007 [redacted]
Process start @ 11:11; pressure recorded by operator: 8 psig
Process start @ 4:48; pressure recorded by operator: 9 psig
Process start @ 9:31; pressure recorded by operator: 9 psig
Process start @ 3:34; pressure recorded by operator: 9 psig

May 7, 2007 [redacted]
Process start @ 11:09; pressure recorded by operator: 12 psig
Process start @ 2:46; pressure recorded by operator: 12 psig
Process start @ 6:06; pressure recorded by operator: 10 psig
Process start @ 9:55; pressure recorded by operator: 8 psig
Process start @ 2:19; pressure recorded by operator: 8 psig

May 8, 2007 [redacted]
Process start @ 10:10; pressure recorded by operator: 8 psig
Process start @ 2:03; pressure recorded by operator: 10 psig

Process start @ 5:46; pressure recorded by operator: 9 psig
Process start @ 10:20; pressure recorded by operator: 9 psig
Process start @ 2:39; pressure recorded by operator: 9 psig

On February 16, 2007 [redacted] was taken out of service. Between February 16 & 26, 2007 [redacted] had a new mother board replaced. The mother board controls and maintains proper function of the retort. On February 26, 2007 [redacted] was placed back into service. When the firm's management was questioned, no one could identify the events that led to the mother board being replaced and the records prior to February 16 for this retort do not reveal any obvious discrepancies. Beginning on February 26, 2007 when [redacted] was placed back into service, this retort began showing a measured pressure inside the vessel of, on average, 8 psig. This directly correlates to an operating temperature of 235° F. The Hot Dog Chili Sauce was routinely cooked in the [redacted] retorts at [redacted]F for [redacted] minutes with an initial temperature inside the cans of, on average, [redacted]° F. The initial temperature of the [redacted] inside the vessel was also, on average, [redacted] F.

The recorder chart from February 26 to May 22, 2007 for [redacted] was reading an average of 248° F. However, a one-page work report, issued by [redacted] Technical Specialist, states on May 30, 2007 the bias on the recording temperature device (RTD) for the [redacted] recorder chart was found at 124.4. In [redacted]'s own words in this report he states "I checked the bias and found 124.4. That's far out of line. A high bias is 4." (exhibit 17; one-page report). There are no records to show that management addressed the low pressure readings on [redacted] from February 26, 2007 until Mr. [redacted]'s visit on May 30, 2007. [redacted] continued to be operated during this time span.

It can be shown that [redacted] has an RTD and accompanying chart recorder that were not correctly reading the actual temperature inside the vessel. This same retort consistently shows a pressure of approximately 8 psig which correlates to an operating temperature of 235° F. It is clear there is a problem with [redacted]. The final element of concern is the mercury-in-glass thermometer (MIG). During the timeframe of the low pressure readings in [redacted] MIG #924 was used on retort [redacted] On 8/2/07 management was able to locate MIG #924 and a calibration was performed with Bumble Bee personnel, Castleberry personnel, and the FDA present. This calibration revealed MIG #924 was low by 2° (exhibit 18; one-page). Management stated they suspected this MIG had a broken column of mercury. After the calibration test did not reveal a broken column, a propane torch was brought in to run the mercury column to the maximum upper limit of 270°. If a broken column of mercury was located in the stem of the MIG this final test would reveal the broken column. It was observed that MIG #924 did not have a broken column of mercury and was within a reasonable (2°) range.

On each of the cook cycles noted above, the retort operator recorded on his log that the MIG and the recording chart were exactly the same. This was seen consistently in the records for [redacted]. One exception in the above listed records is the May 7th 6:06pm cook cycle where the retort operator listed the MIG at 248° and the recorder chart at 247° F. While one cannot identify anything wrong from just this information, it was found that a retort operator was not reading the MIG or conducting

condensate bleeder checks on [redacted] during a cook cycle. This was observed on the second day of this inspection. William Conley, QA Manager, and Bob Neligan, FDA, visited the [redacted] line. Seeing that [redacted] had just finished a cook cycle, Conley and Neligan both went to review the operator's retort log. The retort operator had failed to enter the second check of both the MIG and recorder chart temperatures and failed to enter 4 of the 6 required condensate bleeder checks (exhibit 19; 3 page 7/18/07 retort operator's log). Contribute to this, the 3/26/07 retort log from the kosher room vertical still retorts (exhibit 20; 2 pages). The retort operator's log cites a recording chart temperature of 248° on the third cook cycle for retort [redacted]. The third cook cycle occurred at midnight. The first cook cycle for this retort occurred at noon. The recording chart actually shows the 248° during the first cook cycle at 12:30 pm, not 12:30 am (third cook cycle). This recording chart is printed in real-time as the cook cycles progress through the day. This is not a situation of a pre-printed recording chart being misaligned.

The challenges placed on [redacted] and # [redacted] revealed that it is possible to have a situation of water in the bottom of a retort during a cook cycle. [redacted] was operating with a temperature recorder out of bias. Between 2/26/07 and 5/22/07 this retort was showing a pressure in the vessel of, on average, 8 psig which correlates to an operating temperature of 235°. There is evidence of a retort operator not checking the mercury-in-glass or the required condensate bleeder checks on [redacted]. Whether a small cluster of cans had a lower initial temperature than other cans in that cook cycle or, on occasion, water was covering the bottom layer of cans, it can be shown that cans of Hot Dog Chili Sauce did not receive an adequate thermal process. Laboratory results of both the firm's sample and FDA samples found Clostridium Botulinum toxin in small clusters of cans from these retorts.

MANUFACTURING CODES

For FDA-regulated products an example of the lot coding on the cans is as follows:

Top line: "Best by August 10, 2009"
Bottom line: " CA CM2 1234"

Top line explanation: All Castleberry's products are based on that day's production. The "best by" date would be the day of production plus two years. The above example would reflect actual production on August 10, 2007. Please note that a "day's production" does not change when the time stamp extends beyond midnight. A lot code will show a date of production for August 10 and a timestamp of "0223". In actuality, this literally would be 2:23am on the morning of August 11. However, this firm follows a "day's production" for the total length of time associated with the start of production that day.

Bottom line explanation: CA = Castleberry's
CM2 = formula code + production period

1234 = military time stamp

The tray label in casing would have a code of "7222". The first digit is the year followed by the julian date.

For the simulated-meat products manufactured in the firm's kosher room [redacted] and [redacted] brands) a lot code for the cans is as follows:

Top line:	"08107 CS"
Bottom line:	"VB 1234"

Top line explanation:
08 = month of production
10 = day of production
7 = year of production
CS = Castleberry co-packer designation

Bottom line explanation:
VB = formula code
1234 = military time stamp

COMPLAINTS

There have been no complaints filed from consumers with the U.S. Food and Drug Administration concerning this firm since the last FDA inspection. This inspection was directed by the FDA Office of Emergency Operations based on 7/17/07 initial findings of Clostridium Botulinum poisoning in two patients in Texas and two patients in Indiana.

RECALL PROCEDURES

The firm has established recall procedures in place and performs two mock recalls annually. The firm's recall procedures were demonstrated during this inspection with the 7/21/07 recall of [redacted] cases of Hot Dog Chili Sauce under various brands and [redacted] cases of [redacted] pet food. The recall was based on initial information from the Indiana Department of Health and Texas Department of Health that patients in their states had consumed Castleberry's Hot Dog Chili Sauce prior to the onset of symptoms indicative of Botulinum poisoning.

On 7/18/07, Steve Mavity, Senior VP of Technical Services and Quality Assurance, Bumble Bee LLC, announced the firm was voluntarily recalling Hot Dog Chili Sauce, under the Austex, [redacted], and Castleberry's brands, manufactured from April 30, 2007 to May 22, 2007. On 7/21/07 Mr.

Mavity announced that Bumble Bee was voluntarily expanding the recall to include all FDA-regulated and USDA-regulated products manufactured on the [redacted] line for a period of two years. The significance of the two-year period is all cans receive an ink-jetted lot code that includes a 'best by" date. The expiration date this firm has given their products is 24 months. The expanded recall included all products with "best by" dates from July 21, 2007 to July 21, 2009. Please reference the Summary section of this report for the FDA-regulated products under the expanded recall.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1

The system, equipment, and procedures used for thermal processing of foods in hermetically sealed containers were not operated and administered in a manner that ensures commercial sterility is achieved.

Specifically, the firm had cans of Castleberry's Hot Dog Chili Sauce from their May 8, 2007 production analyzed for microbiological contamination by a recognized outside laboratory [redacted]. The sample was received by the lab on July 19, 2007 and six cans with a lot code of "Best By May 08 2009 CA CM4 0223" and a timestamp of "0224" were analyzed for Clostridium Botulinum toxin. Four of the hermetically sealed cans in the firms sample were positive for Clostridium Botulinum toxin. Shipping records reviewed on this inspection show this product was released and shipped in interstate commerce.

Reference: 21 CFR 113.40(j)

Supporting Evidence and Relevance:

Based on the following observations, commercial sterility was not achieved for Hot Dog Chili Sauce:

1) FDA sample 428113 collected on 7/18/07 from the firm's warehouse located at [redacted] Augusta, GA 30901 and FDA samples 420352 and 420353 collected on 7/19/07 from the same warehouse were positive for C. Botulinum toxin per ELISA tests and mouse bio-assay.

2) The challenges performed on [redacted] and [redacted] revealed both retorts could produce a small portion of finished product that would not achieve a thermal process sufficient to destroy Clostridium Botulinum spores. This was a result of poor maintenance of the retorts and an overall failure of management to correct ongoing deficiencies in the facility.

FDA Documentary samples 432090 and 432091, dated 8/10/07, document the interstate shipment of the May 7, 2007 and May 8, 2007 production lots associated with the physical samples.

Discussion with Management:

There was no discussion from management or the firm's attorney on this item.

OBSERVATION 2

Each retort did not have an accurate temperature-recording device.

Records show the temperature recorder for [redacted] was not accurately recording the operating temperature during thermal processes from February 26, 2007 to May 22, 2007. Specifically, a [redacted] work report issued by [redacted] technician, states on May 30, 2007 the bias on the temperature recorder was at 124.4. This observation is coupled with processing records from February 26, 2007 to May 22, 2007 showing a pressure reading of 7 psi to 9 psi during the cook cycle in [redacted]. A pressure reading of 8 psi correlates to an operating temperature inside the retort of approximately 235 degrees.

Reference: 21 CFR 113.40(a)(2)

Supporting Evidence and Relevance:

Mr. [redacted]s report (exhibit 17) states the bias on the recorder chart was found at 124.4. His report includes "that's far out of line. A high bias is 4". His report goes on to state "I was asked about the maintenance on the retorts and I told them that two years ago the [redacted] were maintained very well, but they are maintained poorly now". Exhibit 19, the retort operators log for 7/18/07, shows the retort operator did not check or record the second mercury-in-glass thermometer reading, recording chart reading, and four of the six required condensate bleeder checks for [redacted] on the first cook cycle.

Discussion with Management:

There was no discussion from management or the firm's attorney on this item.

OBSERVATION 3

Failure to supply a suitable water valve used for water cooling to prevent leakage of water into the retort during processing.

Specifically, this inspection found the water cooling inlet on [redacted] was leaking at a rate sufficient to cover cans in the bottom of the retort during a thermal process. Additionally, the cushion water bypass drain valve on [redacted] was not functioning. This valve is designed to prevent water from entering the retort during a thermal process. It was also noted that the overflow drain valve on [redacted] would randomly become caught in an open position during the cook phase of operation.

Reference: 21 CFR 113.40(a)(11)

Supporting Evidence and Relevance:

All of the malfunctioning valves described in this observation were observed by Bumble Bee, Castleberry, and FDA personnel.

Discussion with Management:

Investigator Neligan explained the leaking cooling water inlet valve is specific to [redacted] Mr. Waits explained to Mr. Van Ells the subject testing was performed 7/27/07. Investigator Neligan continued by stating the bypass drain valve is associated with the [redacted] inlet on [redacted] and is designed to prevent [redacted] from entering the retort. As the [redacted] inlet valve closes, this bypass drain valve, located in front of the inlet valve, should automatically open.

OBSERVATION 4

The condensate bleeder was not checked with sufficient frequency to ensure removal of condensate or equipped with an automatic alarm system for the continuous monitoring of condensate bleeder functioning.

Specifically, the high condensate alarm o[redacted] was observed to be intermittently non-functioning. On 7/19/07, a stream of water was observed flowing from the condensate bleeder for approximately 5 minutes and the condensate alarm never turned on. In addition, the retort operators stated the high condensate alarm on [redacted] was often perceived as a false alarm. The reason cited was a mineral build-up on the sensor from hard water used in processing.

Reference: 21 CFR 113.40(c)(5)

Supporting Evidence and Relevance:
Removal of condensate from a[redacted]retort is critical in assuring cans on the bottom layer during processing are not covered with water. Having condensate alarm lights that intermittently operate is not an acceptable practice. Further, the significance of the alarm is lost when operators state that the retorts are giving false alarms.

Discussion with Management:

It was clarified to management that the reason cited as a mineral build-up causing the false alarms was information reported from the retort operators.

OBSERVATION 5

Required information was not entered on designated forms at the time the observation was made by the retort or processing system operator or designated person.

Specifically, on 7/18/07 it was observed that a retort operator had completed a thermal process cycle on [redacted] and failed to record the second mercury-in glass and temperature recorder reading. This same [redacted] cycle showed the retort operator failed to record 4 of the 6 required condensate bleeder checks.

Reference: 21 CFR 113.100(a)

Supporting Evidence and Relevance:

This 7/18/07 retort operators log is provided as exhibit 19 and shows the first cook cycle for [redacted] does not have the required information.

Discussion with Management:

Management was informed that this shows a retort operator is not reading the mercury-in-glass thermometer during a cook cycle. Mr. Waits, General Manager, inquired if this was due to a lack of training or to negligence. We informed management that this is an example of a lack of supervision and overall failure of proper management.

OBSERVATION 6

Failure to maintain fixtures in repair sufficient to prevent food from becoming adulterated.

Specifically, routine maintenance is needed on the [redacted] line. This was evidenced by a control panel light bulb burned out on [redacted] valves on [redacted] and [redacted] not working, and the high water fill sensor in the [redacted] tank for these [redacted] not functioning properly. Also, it was observed that the steam spreaders in the bottom of vertical still retorts [redacted] in the kosher room were broken and the spreader in the front vertical [redacted] was broken.

Reference: 21 CFR 110.35(a)

Supporting Evidence and Relevance:

[redacted] Technical Specialist, states in his May 30 report (exhibit 17) that " two years ago the [redacted] were maintained very well, but they are maintained poorly now".

Discussion with Management:

We informed management that leaking and inoperative valves, inoperative sensors, control panel lights burned out, and broken steam spreaders are an example of the overall breakdown in management.

OBSERVATION 7

Failure to properly adjust the temperature-recording device. The temperature recorded on the temperature-recording device chart was higher than the mercury-in-glass thermometer during processing.

Specifically, this was observed on 1/3/07, [redacted], chart reading 271 and MIG reading 254; 1/12/07, [redacted], chart again reading 10 degrees higher than the MIG; 1/19/07, [redacted], chart at 251 and MIG reading 248; 6/4/07, [redacted] chart recorder at 246 and MIG at 236; 6/18/07, [redacted], the chart recorder was 3 degrees higher than the MIG; and lastly, 6/29/07, [redacted] recording chart reading 250 and MIG at 247.

Reference: 21 CFR 113.40(a)(2)

Supporting Evidence and Relevance:

This was observed by the FDA record review team. All processing records from January 1, 2007 to July 21, 2007 were reviewed for all FDA-regulated products manufactured by this firm.

Discussion with Management:
There were no comments from management regarding this observation.

REFUSALS

Repeatedly, from 7/18/07 to 7/20/07, the FDA team requested the following records for review: retort maintenance, retort repairs, internal investigations into problems during the spring of 2007, all [redacted] corporation correspondence, and distribution records. On the evening of 7/20/07 the U.S. Food and Drug Administration issued an FDA-482c to the firm which stated, in part, that the firm

would have 24 hours to provide the FDA team all of the records requested. It was stated that failure to comply with this request would constitute a prohibited act in accordance with the F,D,& C Act.

GENERAL DISCUSSION WITH MANAGEMENT

At the close of the inspection, the inspection team held a discussion and an exit interview with Messrs. James T. Waits and James Van Ells and Ms. [redacted], Attorney. An FDA-483, Inspectional Observations, was issued to Mr. Waits and each item was read aloud and discussed with those members of firm's management. Investigator Neligan provided an opportunity for everyone to read the list of deficiencies before beginning the dialogue. He explained the format of the FDA-483 items. The items listed below correspond to those objectionable findings listed on the FDA-483. Management's responses were as follows:

1. No questions/comments from management. All were in agreement with the observation and indicated they understood the issue.

2. Investigator Neligan elaborated on the pressure (Psig) as related to the operating temperatures. No questions/comments from management.

3. Investigator Neligan explained the leaking cooling water inlet valve is specific to [redacted]. Mr. Waits explained to Mr. Van Ells the subject testing was performed on 7/27/07. Investigator Neligan continued by stating the bypass drain valve is associated with the [redacted] inlet on [redacted] and is designed to prevent [redacted] from entering the retort. As the [redacted] valve closes, this bypass drain valve, located in front of the inlet valve, should automatically open.

4. Mr. Waits asked about the statement in Observation #4 on the FDA-483 indicating mineral build-up on an alarm sensor was a result of hard water. He asked how we knew there is "hard water" used in processing. Investigator Neligan stated that is the information he had received from the retort operators. He further stated that we could check the water if necessary. Investigator Neligan stated the focus is on the fact that the alarm is routinely going off. Clarification was requested by management on exactly who cited mineral build-up on the sensor as the reason it would either fail to function or would go off incorrectly. Investigator Neligan stated the retort operators provided that information.

5. Investigator Neligan stated the evidence points to a retort operator not doing his job. Mr. Waits asked whether Investigator Neligan thought the individual was not properly trained or simply did not care about the work. Investigator Neligan responded that malfunction extends from the retort operators through to the retort supervisors. If there are episodes when the work is not done properly, it is an apparent reflection of failure on the entire group. Mr. Van Ells stated accountability starts with management.

6. Investigator Neligan stated routine maintenance is needed on [redacted]. He further stated there is benefit in providing validation information on the retorts to the Agency. Ms[redacted] stated the information will be in the response.

7. Management had no comments to Observation #7.

Investigator Blackwood provided a summary of findings during the records review. He recommended the firm adopt a better recordkeeping system as it relates to the retort operators recording the time of day. He suggested the firm use either military time or record 'am' or 'pm' in annotation within the production records.

Investigator Neligan further expounded on the firm's overall neglect of the equipment and the apparent disconnect between the different departments in the company. He stated there was no commitment from the employees in making the products and there was not adequate management oversight. This failure in management was ultimately the reason for the Clostridium Botulinum toxin in the cans.

Mr. Waits stated he has told management they must work together. He spoke of a cultural change necessary within this facility. He stated there will not be any "stand-alone silos".

Investigator Neligan stated management's challenge is to bring the plant into compliance by reestablishing cohesiveness between the departments and pride within the employees. Mr. Van Ells stated they are working on a list of things that need improvement. He stated he plans to begin with proper employee training.

Mr. Waits stated that through the ownership change, Castleberry's lost its identity and so did the employees. He stated he wants to restore pride to their work and what they do. By that same token, he wants employees to realize that Bumble Bee is a resource for Castleberry.

Ms. [redacted] stated they will be working to compile information and it will be provided to the Agency in a few days.

SAMPLES COLLECTED

Sample 428113, consisting of 29/10 oz. cans of Castleberry's Hot Dog Chili Sauce Original, with a best by date of May 8, 2009. This sample was collected at the firm's [redacted], Augusta, GA warehouse on July 18, 2007. This sample had 17 cans exhibiting swells, all with a timestamp of "0223". The remaining 12 cans, of timestamps in close proximity of "0223", did not exhibit any swelling and were used as controls. Laboratory results found 16 of the 17 swollen cans were positive for Clostridium Botulinum toxin.

Sample 420351 consisted of 96/10 oz. cans of Castleberry's Hot Dog Chili Sauce Original with a best by date of May 23, 2009. This sample was collected at the firm's [redacted], Augusta, GA warehouse on July 19, 2007. The cans collected were from a partial lot of the May 23, 2007 production run that had been placed on QC Hold for further review. The other portion of the lot had already been shipped to Distribution Centers across the country. A field exam of the portion in the warehouse was conducted with no swollen cans found. Sample was negative for C. Botulinum toxin.

Sample 420352 consisted of 96/10 oz cans of Castleberry's Hot Dog Chili Sauce Original with the best by date of May 08, 2009. This sample was collected at the firm's [redacted] Augusta, GA warehouse on July 19, 2007. This lot was placed on QC Hold and was being culled for swollen cans by the firm when the inspection was started. The culling operation stopped when the Georgia Department of Agriculture placed a Stop-Hold on the warehouse on 7/18/07. The field exam of this lot found six swollen cans. These six cans were part of the 96 cans collected for this sample. The time codes of the six swollen cans were 0223, 0223, 0223, 0224, 1351, and 1735. Laboratory results found four of the six swollen cans positive for Clostridium Botulinum toxin.

Sample 420353 consisted of 96/10 oz cans of Castleberry's Austex Hot Dog Chili Sauce Original with a best by date of May 07, 2009. This sample was collected at the firm's [redacted] Augusta, GA warehouse on July 19, 2007. This lot was on QC Hold and had been culled by the firm for swollen cans on June 2 – 3, 2007. The field exam of this lot found one swollen can which was made part of the 96 cans collected for the sample. The time code of the one swollen can was 1950. Laboratory results found this swollen can was positive for Clostridium Botulinum toxin.

Sample DOC 432090 documents the interstate shipment of Hot Dog Chili Sauce manufactured on May 8, 2007 from Castleberry's Food Company in Augusta, GA. This documentary sample, dated 8/10/07, includes an affidavit that was read and signed by Mr. James T. Waits, General Manager, Castleberry's Food Company.

Sample DOC 432091 documents the interstate shipment of Hot Dog Chili Sauce manufactured on May 7, 2007 from Castleberry's Food Company in Augusta, GA. This documentary sample, dated 8/10/07, also includes an affidavit that was read and signed by Mr. James T. Waits, General Manager.

VOLUNTARY CORRECTIONS

The firm ceased all operations in the plant on 7/19/07. Voluntary corrections were submitted to the FDA by the Attorney's of [redacted] representing Castleberry's Food Company. Those voluntary corrections are under review by the U.S. Food and Drug Administration.

EXHIBITS COLLECTED

Exhibit 1A-N): Labeling for the recalled products manufactured by Castleberry's Food Company of Augusta, GA. There are 14 total product labels with four identical copies of each label provided.

Exhibit 2): The 42-page report, dated 6/14/07, issued by [redacted], Director of HACCP Programs and Regulatory Affairs, [redacted] to this firm concerning the causes of swollen cans manufactured at Castleberry's during April and May, 2007.

Exhibit 3): 3-page memorandum, dated 6/5/07, issued from [redacted], stating the analysis and conclusion of swollen cans submitted to their [redacted] Technical Center.

Exhibit 4): 2-page letter, dated 6/19/07, from [redacted] Area Manager, [redacted] stating recommendations for improving the cooling canal systems.

Exhibit 5): 30-page collection of laboratory results from samples submitted by Castleberry's to [redacted] labs in [redacted] These samples span the time period of the April/May problems at Castleberry's.

Exhibit 6A-B): Affidavits read and signed by James T. Waits, General Manager, for DOC samples 432090 and 432091.

Exhibit 7): 10-page organizational chart for Castleberry's Food Co. in Augusta, GA.

Exhibit 8): 5-page list of Bumble Bee distribution centers located throughout the U.S.

Exhibit 9): Single page list of personnel from Bumble Bee, Castleberry, and others that directly participated in this inspection.

Exhibit 10): 2-page floor diagram of the Castleberry plant showing the area of the front vertical still retorts, the [redacted], and the kosher room.

Exhibit 11): Single page (double-sided) listing of the [redacted] products manufactured at this facility.

Exhibit 12): 3-page transcript of events during the testing of [redacted] on 7/27/07.

Exhibit 13): 2-page transcript of events during the testing of [redacted] on 7/28/07.

Exhibit 14): 5-page transcript of events during the testing of [redacted] on 7/31/07.

Exhibit 15): Single page transcript of events during the fiber optic testing of the [redacted] drain lines.

Exhibit 16A-E): 89-pages total of [redacted] processing records representing one day per month from February 2007 to May 2007. This includes the processing records for May 7 and May 8, 2007.

Exhibit 17): Single page report from [redacted] Technical Specialist, stating the repairs made to the chart recorder for [redacted] Report dated May 2007.

Exhibit 18): Single page transcript of events during the testing of mercury-in-glass thermometer #924.

Exhibit 19): 3-page [redacted] processing record for 7/18/07 which shows a failure to include the MIG and recording chart temperature checks on [redacted] ycle one. This also shows a failure to check the condensate bleeders on [redacted] (four of six checks missing).

Exhibit 20): 2-page processing record from the vertical still retorts in the kosher room.

ATTACHMENTS

FDA-482, Notice of Inspection; issued by T. Linda Stewart, CSO, on 7/17/07

FDA-482a, Demand for Records, issued by T. Linda Stewart, CSO, on 7/17/07

FDA-482b, Request for Information, issued by T. Linda Stewart, CSO, on 7/17/07

FDA-482, Notice of Inspection, issued by Robert P. Neligan, CSO, on 7/18/07

FDA-482, Notice of Inspection, issued by T. Linda Stewart & Robert P. Neligan, CSO's, on 7/18/07 for the Castleberry [redacted] Warehouse.

FDA-482, Notice of Inspection, issued by T. Linda Stewart & Robert P. Neligan, CSO's, on 7/18/07 for the Castleberry's [redacted] Street Warehouse.

FDA-482, Notice of Inspection, issued by E. Harold Blackwood, Derek C. Price, Christopher C. Wilcox, and Aaron Wozniak, CSO's, on 7/19/07, for the Castleberry's [redacted] Warehouse.

FDA-482, Notice of Inspection, issued by Michael S. Mignogna, Food Technologist and Processing Authority, CFSAN, on 7/19/07.

FDA-482c, Notice of Inspection-Request for Records, with accompanying issued by Robert P. Neligan & T. Linda Stewart, CSO's, on 7/20/07.

Order Requiring Emergency Permit, issued by Robert P. Neligan & T. Linda Stewart, CSO's on 7/21/07.

FDA-482, Notice of Inspection, issued by James P. Lewis, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-482a, Demand for Records, issued by James P. Lewis, Robert P. Neligan, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-482b, Request for Information, issued by James P. Lewis, Robert P. Neligan, Claudette D. Brooks, and E. Harold Blackwood, CSO's, on 7/25/07.

FDA-483, Inspectional Observations, issued to Mr. James T. Waits, General Manager, by Robert P. Neligan, T. Linda Stewart, Claudette D. Brooks, James P. Lewis, E. Harold Blackwood, and Michael S. Mignogna, Investigators on 8/10/07.

FDA-484, Receipt for Samples, issued by T. Linda Stewart, CSO, on 8/10/07.

FDA-484, Receipt for Samples, issued by T. Linda Stewart, CSO, on 8/10/07.

FDA-3511A, Front vertical still retorts

FDA-3511A, Kosher room vertical still retorts

FDA-3511A [redacted] retorts

Robert P. Neligan, Investigator

Claudette D. Brooks, Investigator

James P. Lewis, Investigator

Theresa L. Stewart, Investigator

Ernest H. Blackwood, Investigator

Michael S. Mignogna, Investigator