SUMMARY OF FINDINGS

This comprehensive inspection of a bakery product manufacturer was conducted in accordance with CPG 7303.803 "Domestic Food Safety", FACTS Assignment #9454648, and as a follow up to gather information for the OEI and recall databases. The previous inspection of the firm was conducted from 01/25 – 28/2013 and was classified NAI. The current inspection covered the manufacturing, storage and distribution of various bakery products, including hazelnut macaroons used in Dark Chocolate Hazelnut ice cream sandwiches and Oatmeal Sammie ice cream sandwiches.

Jeni's Splendid Ice Creams LLC currently has two manufacturing sites: this location, and the location at 909 Michigan Ave, Columbus, OH (FEI 3008586462). This location on Chesapeake Ave. manufactures bakery products such as cookie, crisp and candy inclusions for use in the production of ice cream, yogurt and sorbet products which are manufactured at the firm's 909 Michigan Ave. facility. The firm also produces ice cream sandwiches, in which the ice cream is received from the 909 Michigan Avenue facility. The finished product is then sent back to the 909 Michigan Avenue facility for distribution. Additionally, the corporate offices of Jeni's Splendid Ice Creams, LLC located at Chesapeake Ave., Suite L (next door to the manufacturing facility). Both the Chesapeake Ave. and Michigan Ave. facilities fall under the same LLC and have the same management and procedures. The firm's history remains unchanged from the previous inspection.

On 08/19/2014, credentials were presented and an FDA 482 Notice of Inspection was issued to Danielle L. Gugliemotto, Shift Leader, who identified herself to be the most responsible person at the firm at the time of my arrival. Within a half hour of my arrival, Mr. John Lowe, CEO, arrived and identified himself to be the most responsible person at the firm. The following individuals have a responsible role in the manufacture and distribution of bakery products and ice cream sandwiches at the firm:

John (NMI) Lowe, CEO – Mr. Lowe identified himself to be the most responsible person at the firm. During the inspection, I witnessed him giving verbal orders to employees. He also instructed all employees to withhold any documentation that I requested during the inspection. During the inspection, Mr. Lowe also requested that I not interview any employees but him; I told him this would not be possible. Mr. Lowe has been with the company for over 5 years in his current position. As CEO, he has the authority to hire and fire personnel, authorize corrections to objectionable conditions, and make purchasing decisions. In addition to being CEO, Mr. Lowe is also part owner of the company, along with Jennifer, Charley, and Tom Bauer. The Bauers have limited roles in the day-to-day operations of the company. Mr. Lowe stated that he has the final say on all matters at the firm. He was present at the start of the inspection and during the closeout meeting.

Stephanie N. McBride, Production Director – Ms. McBride was out of the country during the inspection. She has been with the company for 4 years and has the authority to hire and fire personnel, and to correct objectionable conditions pertaining to production. All managers at both the

Chesapeake Ave. and Michigan Ave. facilities report to her. Ms. McBride reports directly to Mr. Regis Duffy, COO.

Steven N. Boutros, Facilities Manager – Mr. Boutros stated that he is responsible for the maintenance and upkeep of the Jeni's facilities. He also stated that he is responsible for working with contractors such as plumbers, roofers, etc. Mr. Boutros accompanied me throughout most of the inspection and answered questions about the facility and manufacturing operations. He reports directly to Ms. McBride.

Julie A. Gabor, Regulatory Manager – Ms. Gabor stated that she is responsible for the firm's FDA compliance, HACCP, labeling, and quality control. She accompanied me throughout most of the inspection and answered questions about manufacturing operations. Ms. Gabor reports directly to Ms. McBride.

Meredith L. Honaker, Bakery Manager – Ms. Honaker stated that she is responsible for planning the weekly production schedule at the Chesapeake Ave. facility, organizing the employees, and troubleshooting any problems that may arise. All employees in the Chesapeake Ave. facility report to her. She was present periodically throughout the inspection to answer questions. Ms. Honaker reports directly to Ms. McBride.

The firm has been renting this space on Chesapeake Ave for the past 4 years; it is approximately (b) (4) square feet. During my inspection, I observed the production of hazelnut macaroons that are used in the firm's Dark Chocolate Hazelnut ice cream sandwiches. I watched as the ingredients were weighed out, egg whites were whipped in (b) and (b) (4) mixers, and then the dry ingredients were folded into the egg whites. The mixture was then piped out onto sheets and left to sit out on speed racks for (b) (4) then baked. I also observed the assembly of Oatmeal Sammie ice cream sandwiches in the packing room. During this process, vanilla ice cream (produced at the Michigan Ave. facility) is scooped out onto an oatmeal cookie, and another oatmeal cookie is sandwiched on top of the ice cream. The ice cream sandwich is then placed in a plastic bag and heat-sealed shut. The sealed ice cream sandwich is then placed inside the appropriately labeled cardboard carton, and placed in a case containing 14 ice cream sandwiches. The cases are then placed in the freezer for storage. Ms. Gabor informed me that the firm uses a system called "(b) for inventory management. Each product, including ingredients and finished products, are assigned an '(b) (4)' number that (b) can track.

During my inspection I also looked at the storage, shipping and receiving areas. The shipping/receiving area has two large garage doors; I noticed that one of them had a gap between the floor and the garage door, approximately ½ inch wide. I pointed this out to Mr. Boutros, who stated that they would work on correcting it immediately. This was an item of discussion with Mr. Lowe during the closeout meeting. There was no evidence of rodents or other pests in the facility; Mr. Boutros stated that the firm uses (b) (4) for pest control. They come in monthly to check traps and

the exterior bait stations. Mr. Boutros said that the firm checks the traps themselves on a weekly basis.

During the inspection, Ms. Gabor and Mr. Boutros said they would be unable to provide me with any records under the direction of Mr. Lowe. Mr. Lowe requested a close-out meeting with only he and myself present. During this meeting, I again requested the following information:

- List of products manufactured at this facility
- Top 3 suppliers and customers
- % product the firm introduces into interstate commerce
- Recall SOP
- Complaint SOP/list of complaints
- Pest control records
- Training records
- Organizational chart
- Floor plan
- Cleaning SOP

After repeated requests, Mr. Lowe declined to provide me with any of this information, citing section 414 of the FD&C Act. He would also not provide me with any information related to the firm's distribution patterns and locations of retail stores. He instructed me to "look at the website".

Part of this assignment was also directed at gathering information from previous recalls that had not been closed out at the firm; one recall was from 2008 and was conducted as a result of lack of labeling on the firm's ice creams. The second recall was involving the firm's "Influenza Sorbet" from 2013, which involved disease and drug claims. Mr. Lowe vehemently denied that any recall involving the Influenza Sorbet was ever conducted. He declined to provide any information regarding the recall from 2008 and the alleged recall from 2013. The only information he would provide was that the firm no longer manufactured the Influenza Sorbet.

I also requested to conduct a label exam during my meeting with Mr. Lowe. He complied, and provided me with the labeling for the firm's Oatmeal Cream ice cream sandwiches. No issues were noted.

During the closeout meeting with Mr. Lowe, I also informed him of the gap in the garage door in the shipping receiving/area; he stated that this issue would be corrected immediately. I also provided him with a FSMA information sheet and asked him if he had any additional questions; he said no.

No samples were collected during the current inspection. No refusals of records or documents that I was entitled to were encountered. The firm is registered as required. FACTS OEI data was current. All inspectional correspondence can be addressed to Mr. John Lowe, CEO, at the firm's mailing address listed in the Administrative Data section of this report.

ADMINISTRATIVE DATA

Inspected firm:	Jenis Splendid Ice Creams LLC
Location:	1145 Chesapeake Ave Ste E Columbus, OH 43212-2286
Phone:	614-488-3224
FAX:	614-488-3236
Mailing address:	1145 Chesapeake Ave Ste L Columbus, OH 43212-2286
Dates of inspection:	8/19/2014
Days in the facility:	1
Participants:	Allison M. McGloin, Investigator

ATTACHMENTS

1. FDA 482 Notice of Inspection, issued to Danielle L. Gugliemotto, Shift Leader, dated 08/19/2014; 3 pages

Allison M. Mcgloin, Investigator

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SUMMARY (DSM)

This initial inspection of a medium sized ice cream, sorbet, and frozen yogurt manufacture was conducted in accordance with an email request from COL-RP ASCSO (HFR-CE4530) dated 1/24/13 to follow up on potential drug claims for one of the firm's products on the firm's website. It was also conducted in accordance with CP 7303.803 – Domestic Food Safety Program, and FACTS Assignment 1490193 OPID 6578147. This was the initial inspection of the firm. In addition to this assignment to follow up on the labeling issue, this was a comprehensive initial inspection.

This inspection found the firm operates as a manufacturer of ice cream, sorbet, and frozen yogurt products. The firm was in operation and the manufacturing and packaging of Brambleberry Crunch ice cream in pint sized plastic containers with code 3-029-1 was observed.

An FDA 483 (Inspectional Observations) was issued to John (NMI) Lowe, Chief Executive Officer, for condensate/ice buildup in the large walk in freezer used to store finished product and for condensate/ice observed on the finished product shipping containers. One discussion item was issued to the firm for one of the firm's products name Influenza Sorbet and/or Influenza Sorbet Rx having a recognized disease on the label and the firm's website content having a recognized disease on the firm's product specific webpage and social media websites. Management stated the FDA 483 observation was already corrected and the firm changed the name of the product and destroyed the remaining inventory with the influenza name at, the firm's manufacturing location and at the firm's retail scoop shops. The firm changed their website content, however still had a recognized disease on the firm's website and pictures of the Influenza product on the firm's social media websites after the change.

Documentary sample DOC794867 was collected to document the influenza product name and drug claims.

No evidence of rodent or pest activity was observed. No evidence of misuse of food additives or color additives or chemical or pesticides was observed. The firm is registered under the Bioterrorism Act of 2002. On 1/25/13, FDA Industry Guidances for Claims That Can Be Made for Conventional Foods and Dietary Supplements, and Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide, were provided to Mr. Lowe. Firm information was evaluated in FACTS and firm name, establishment type, legal status, contact, percent wholesale and interstate, number of employee, and website information changes were made.

ADMINISTRATIVE DATA (DSM)

Inspected firm:	Jenis Splendid Ice Creams
Location:	909 Michigan Ave Columbus, OH 43215-1108

Phone:	614-488-3224
FAX:	
Mailing address:	1145 Chesapeake Ave Ste L Columbus, OH 43212-2286
Dates of inspection:	1/25/2013, 1/29/2013, 1/30/2013, 2/5/2013
Days in the facility:	4
Participants:	Dell S. Moller, Investigator Kirk A. Dymbrowski, Investigator

On 1/25/13, Credentials were shown an FDA 482 (Notice of Inspection) was issued to John (NMI) Lowe, Chief Executive Officer, who identified himself as the most responsible person at the firm. The FDA 482 for the manufacturing location was issued at 1145 Chesapeake Avenue, Suite L, Columbus, OH 43212 (corporate office). The labeling and website content, and the close out was held at the corporate office. The product was produced and labeled at the manufacturing location (909 Michigan Avenue, Columbus, OH 43215). The most responsible person, with the authority to make changes to labeling and website content, is located at the corporate office. After the FDA 482 was issued, it was determined Mr. Lowe's legal name was John (NMI) Lowe, IV.

The FDA 483 was issued to John (NMI) Lowe, Chief Executive Officer. The FDA 463a was presented to John (NMI) Lowe, Chief Executive Officer, however Mr. Lowe stated he refused to sign the affidavit without first consulting legal counsel.

This was a team inspection consisting of Dell S. Moller Investigator, and Kirk A. Dymbrowski, Investigator. This report was written by both Investigators and the sections of this report written by an the individual Investigator are identified by the initials of the respective Investigator. Investigator Dymbrowski was present on each day of the inspection, however was not present for late morning and afternoon on 1/25/13.

Accompanying us on 1/25/13 was Jason L. Channels, Food Safety Specialist, for the Ohio Department of Agriculture (ODA), under ODA authority, to follow up on the labeling issue and to assist the FDA as needed. Jason Channels, Food Safety Specialist was not present the other days of the inspection.

HISTORY (KAD and DSM)

According to Mr. Boutros, the firm is an LLC corporation. The firm began operations at the North market in Columbus, OH in 1996. In 2010 the firm purchased, and began ice cream production out of the current facility. The building was erected in 1991. The building originally housed Quality

Meats. The firm's bakery operations briefly operated out of this facility before moving back to the 1145 Chesapeake Ave., Columbus, OH location. The firm has conducted 1 recall of product (Influenza Sorbet Rx and/or Influenza Sorbet) resulting in product destruction for labeling during this inspection. See Recalls section of this report for more information. The firm does not have a compliance history.

Official Correspondence should be addressed to: John (NMI) Lowe, Chief Executive Officer, located at 1145 Chesapeake Avenue, Suite L, Columbus, OH 43212.

The firm's hours of operation are: 8:00am to 5:00pm, Monday through Friday. The firm has approximately (b) employees. The firm is currently registered under the Bioterrorism Act of 2002.

INTERSTATE COMMERCE (KAD)

According to Mr. Boutros the firm conducts 0% retail distribution from this location. Mr. Boutros estimated that the firm's interstate distribution from this location is approximately 25%. (b) (4) (b) (4) and (b) are examples of interstate wholesale customers. Some of the firm's wholesale customers include (b) (4) (b) (4) and (b) (4) (a distributor). Wholesale orders are shipped through (b) according to Mr. Boutros. Shipments to distributors, according to Ms. McBride, are picked-up and arranged by the distributors. The firm maintains 3 trucks and 2 vans for local distribution to wholesale customers and the firm's own retail stores, which the firm refers to as "scoop shops". The firm has (b) scoop shops, one in (b) (4) and (b) in (b) according to Mr. Boutros. The firm distributes primarily within central Ohio. The firm, according to Mr. Lowe, utilizes television and radio advertising within the Columbus, OH area only. The firm has a website, www.jenis.com, for promotion and internet sales of products.

The firm receives incoming ingredients from interstate commerce, such as; (b) (4) (b) (4) in California; (b) (4) from (b) (4) Finished product containers from (b) (4) in (b) (4)

We requested representative shipment records for product outside of Ohio and Ms. McBride informed us that this request would need to be in writing.

JURISDICTION (DSM)

The firm is a manufacturer of ice cream, sorbet, and frozen yogurt products and distributes them in interstate commerce outside of Ohio to 1 firm owned retail location and through internet sales.

Attached are website printouts showing representative products for the firm. This website information was printed out at the COL-RP and attached to this report.

The firm does not give any FD&C guarantees. The firm does not have any labeling agreements.

Mr. Lowe stated any documentation would need to be requested in writing.

See Documentary sample DOC794867 for the firm's website printouts provided by the firm showing ingredient and nutritional information for, at least a portion of, the firm's products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (KAD)

John (NMI) Lowe IV, Chief Executive Officer, is the most responsible member of the firm, according to himself and evidenced through his direction of Mr. Boutros and Ms. McBride. As such, he has the authority to hire and fire personnel and authorize corrections to objectionable conditions and make purchases. Mr. Lowe has been with the firm for 4 years, in his current position. Stephanie N. McBride, Director of Operations, reports to Mr. Lowe. Mr. Lowe was present during the inspection on 1/25/13, received the FDA-482, Notice of Inspection and answered questions. Mr. Lowe was not present on site during the inspection of the facility at 909 Michigan Avenue, Columbus, OH. Mr. Lowe was present at the closeout meeting, and received the FDA-483, Inspectional Observations, which took place at 1145 Chesapeake Avenue, Columbus, OH, on 2/5/13.

Steven D. Boutros, Facilities Manager, was the first member of the firm we met on 1/29/13. Mr. Boutros stated that he had been with the firm for 5 years and in his current position for 2 years. Mr. Boutros was present on 1/29 & 30/13, accompanied us throughout the plant and answered questions. Mr. Boutros was not present at the issuance of the FDA-482 or during the closeout meeting. Mr. Boutros is responsible for maintaining the facilities, equipment and production operations at the 909 Michigan Avenue, Columbus, OH location. Mr. Boutros reports to Stephanie N. McBride, Director of Operations.

Stephanie N. McBride, Director of Operations, introduced herself as the most responsible member of the firm for operations, shortly after we entered the facility on 1/29/13. Ms. McBride explained she has been with the firm for 2.5 years, and in her current position for 9 months. Ms. McBride has the authority to hire and fire personnel, and to correct objectionable conditions pertaining to production. Ms. McBride's authority was observed in her direction of personnel. All managers, including the bakery at 1145 Chesapeake Avenue, Columbus, OH, report to Ms. McBride. Ms. McBride reports to Mr. Lowe. Ms. McBride explained that beneath managers there are assistant managers, shift leaders and employees.

FIRM'S TRAINING PROGRAM (DSM)

The firm has a documented training program consisting of CGMP training of new employees, followed by the new employee observing a trained employee performing the task, and then the new employee performing the task under a trainer's observation. Periodic refresher training is given to the employees. No training records were reviewed. Ms. McBride stated all requests for documents would need to be in writing.

MANUFACTURING/DESIGN OPERATIONS (KAD)

Manufacturing takes place in an approximately (b) (4) single story facility, erected in 1991. The firm's premises receive routine pest control services from (b) (4) Production scrap is composted, according to Mr. Boutros. Mr. Boutros explained that the firm's waste removal service is performed by (b) (4) and that potable water is supplied by a City of Columbus municipal source. Mr. Boutros explained that the firm maintains security through a sign-in log, locks, employee challenge of all unrecognized persons and through training of personnel to recognize food and facility security risks.

Ms. McBride explained how raw materials and ingredients are received in the receiving area and checked in. Once a shipment is inspected and checked in, Ms. McBride explained, the items will be removed to (b) (4) According to Mr. Boutros, employees in the receiving area inspect incoming shipments for temperature, damage and item numbers.

Minor ingredients, such as flavorings, are staged and combined into a pre-mix in the prep area, Mr. Boutros explained. The pre-mixes are then held in refrigerated storage overnight to be consumed in production the following day.

We observed the production of Brambleberry Crisp ice cream, packaged in 16oz., semi-opaque, cylindrical, plastic containers, with a snap on plastic lid, coded 3-029-1. The pre-mix had been made the day before, according to Mr. Boutros. We observed the pre-mix being added to the ice cream mix base. The ice cream mix base, from (b) (4) was observed being added to the ice cream machine (which the firm refers to as the batch freezer) with the pre-mix. Once the ice cream is formed in the batch freezer it is dispensed into a 3 gallon bucket.

We observed employees scooping the ice cream into the pre-labeled pint containers by hand. The employees worked (b) (4) into the pint between (b) (4) The employees also (b) (4) n the pint container, by hand. The (b) (4) s produced at the firm's bakery, located at 1145 Chesapeake, Columbus, OH (FEI: 3006737348). After the ice

cream, sauce, and topping have been filled into the pint container, the container is labeled and placed into a cardboard box, each box will contain 8 pint-sized containers. The boxes are pre-labeled with a white, stick-on, label. The product is then placed in the walk-in freezer to harden. Mr. Boutros explained that ice cream typically hardens in 6 to 8 hours.

After hardening the pints are placed into a separate freezer, which the firm refers to as the Big Freezer. The Big Freezer is where finished product is staged awaiting shipment to customers or the firm's own retail locations. A large buildup of ice and frost was observed on the ceiling in the Big freezer (EXHIBIT 1 Photograph 1, Observation Item #1), frost and ice were noted on some cases of finished product (EXHIBIT 1 photograph 2). Ms. McBride stated that maintenance had been performed on the freezer the previous week, and provided a maintenance invoice for review. We observed a maintenance person working on the freezer on the second day of the inspection. The problem was corrected prior to the conclusion of the inspection.

Finished product is shipped out, according to Mr. Boutros, via the firm's own delivery vehicles; two vans and three trucks. Wholesale orders are shipped through (b) (4) according to Mr. Boutros. Shipments to distributors, according to Ms. McBride, are picked-up and arranged by the distributors.

Ms. McBride stated that the firm does not conduct any microbiological or chemical testing on incoming ingredients. The firm receives quality statements and COAs from suppliers, according to Ms. McBride. The firm, according to Ms. McBride, has conducted microbiological testing on finished product for total coliform count.

Batch records, SSOPS, shipping invoices, lab test analyses sheets and other records associated with production were not made available for review. Ms. McBride stated that John NMI Lowe IV, CEO, had directed management not to make records available for review without a written request from the FDA.

MANUFACTURING CODES (DSM)

According to Ms. McBride, the firm utilizes a numerical code for its products. It consists of the year and the Julian date for the day of production and the batch run for that day. An example is below

3-029-1

The "3" represents 2013, the "029" represents the 29th day of the year, and the "1" represents the first batch of the day. This code example represents the first batch produced on 1/29/13.

COMPLAINTS (DSM)

Mr. Lowe explained the firm's complaint handling procedures to us. If a complaint were received, information would be obtained and he would be notified. He would discuss this with his team and determine proper actions to take. We asked Mr. Lowe if there was a written procedure and Mr. Lowe stated he did not know. We also asked Ms. McBride concerning complaints and Ms. McBride stated the firm has a complaint form to capture information about the complaint and it is discussed with members of her team and also with Mr. Lowe. We asked to see a complaint procedure, including this form, and Ms. McBride stated we would need to request that in writing.

We asked Mr. Lowe if the firm had any complaints of missing nutritional labeling or other label complaints and Mr. Lowe stated no. We informed Mr. Lowe of a complaint received by the FDA of missing nutritional panel labeling and Mr. Lowe and Ms. McBride did not have any other response. I (DSM) explained that we observed the manufacturing process and that the labels were hand applied and this appeared to be a one-time occurrence and Ms. McBride appeared to nod in agreement to this statement.

The FACTS received complaint is attached.

RECALL PROCEDURES (DSM)

The firm has a written recall plan on file and conducts a mock recall yearly. Ms. McBride informed us that any document requests would need to be in writing.

The firm conducted a recall of the Influenza Sorbet Rx and/or Influenza Sorbet during the inspection. The firm voluntarily destroyed all remaining inventory of this product at the manufacturing location and at the firm owned retail scoop shops. Mr. Lowe informed me of this destruction after the fact with the product being destroyed prior to my knowledge. Attached are the 24 hour alert information and the recall recommendation forwarded to CIN-DO R&E Coordinator. According to Mr. Lowe and Ms. McBride, this product was only sold at the firm's scoop shops and through internet sales. Mr. Lowe indicated the product was under their control as it was only sold through their scoop shops and the internet. The firm voluntarily destroyed a total of approximately 287 pints of this sorbet. I (DSM) asked for a letter of voluntary destruction on 1/25/13 and as of the close out on 2/5/13, this was not provided. Other requested information for the recall notification was requested on 1/25/13, and on 1/28/13 I requested it again and Mr. Lowe stated they were working on it. As of the close out on 2/5/13, this was not provided.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE (DSM)

The FDA 483 was issued to John (NMI) Lowe, Chief Executive Officer. Present at the close out meeting for the firm were: John (NMI) Lowe, Chief Executive Officer, and Stephanie N. McBride, Director of Operations.

Observations listed on form FDA 483

OBSERVATION 1

Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.

Specifically, there is a buildup of condensate/ice on the ceiling in the large freezer located near the refrigeration units. We observed condensate/ice on the shipping containers of various finished ice cream products such as Queen City Cayenne Ice Cream packaged in pint sized containers.

Annotation:

Reference: 21 CFR 110.35(a)

Supporting Evidence and Relevance: **Exhibit 1** is a photograph of a portion of the ceiling and refrigeration unit of the large walk in freezer, used to store finished product, showing the condensate/ice buildup on the ceiling in proximity to the finished product.

Exhibit 2 is a photograph of the condensate/ice in contact with the finished product shipping containers that are stored on shelves below to refrigeration unit.

Discussion with Management: We asked Mr. Lowe if he had any questions and he stated no. Mr. Lowe also stated that this issue had been corrected. We informed Mr. Lowe and Ms. McBride that we acknowledged the firm had a maintenance person working on the freezer unit while we were at the firm, however due to the amount of condensation/ice buildup and the ice also on the shipping containers, this was still an objectionable condition.

REFUSALS (DSM)

No refusals of documents or records we were entitled to were encountered.

GENERAL DISCUSSION WITH MANAGEMENT (DSM)

The FDA 483 was issued to John (NMI) Lowe, Chief Executive Officer. Present at the close out meeting for the firm were: John (NMI) Lowe, Chief Executive Officer, and Stephanie N. McBride, Director of Operations.

There was 1 item discussed with the firm that was not on the FDA 483. This item was for the firm's product name and website content. The name of the product was "Influenza Sorbet Rx" and/or "Influenza Sorbet" and the firm's website had a statement on the product specific page that read ""Cures" what ails you".

See Documentary sample DOC794867 for firm provided website printouts for the homepage, product specific page, and ingredients and nutritional information page, dated 1/25/13.

At the beginning of the inspection, I (DSM) informed Mr. Lowe the product name (Influenza Sorbet Rx and/or Influenza Sorbet) and the firm's website content, including the product specific webpage that contained the phrase ""Cures" what ails you", are making drug claims about the product and corrections needed to be made.

This product can be ordered from its product specific webpage. There is a drop down feature to select the quantity desired to order. From here, you would be directed to a check out page to complete the order.

Mr. Lowe indicated he didn't think people would look at a pint of ice cream and think it would give them the flu or would actually cure the flu.

I (DSM) informed Mr. Lowe that the product could be determined to be misbranded by the FDA, based on the product name and website content.

Mr. Lowe left the room and after returning, informed me that the product name would be changed and the remaining product with the Influenza Sorbet Rx or Influenza Sorbet labeled name had already been destroyed at the manufacturing location and at all retail locations. This correction was made previous to informing me.

Attached to this report are the printouts of the firm's website for the homepage, for the "The Hot Toddy" product specific page, and representative social media websites for The Hot Toddy product, dated 1/28/13. I (DSM) printed this website information at the COL-RP and shows the firm's removal of the statement, "Cures" what ails you. The firm replaced this "Cures" statement with "[Formerly called "Influenza Sorbet," but we changed the name because we didn't want anyone to think that it actually cures the flu or contains the flu.]". I printed out the website information at COL-RP due to Mr. Lowe requiring a written request for any documents and Mr. Lowe indicating he had provided enough information, would not provide any more website information, and I could go on the website and look at it for myself.

Attached to this report are the printouts of the firm's website for the homepage, for the "The Hot Toddy" product specific page, and representative social media websites for The Hot Toddy product, dated 2/5/13. I (DSM) printed this website information at the COL-RP and to show the firm's continues to use the above "Formerly called "Influenza Sorbet,"" statement. I printed out the website information at COL-RP due to Mr. Lowe requiring a written request for any documents and Mr. Lowe indicating he had provided enough information, would not provide any more website information, and I could go on the website and look at it for myself.

On 1/25/13, I (DSM) provided Mr. Lowe with the FDA guidances for; Claims That Can Be Made for Conventional Foods and Dietary Supplements, and Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide. I also explained to Mr. Lowe, any recognized disease or disease claims would need to be removed from the firm's website and social media sites. We again explained this information to Mr. Lowe on 2/5/13 at the close out meeting.

At the close out of the inspection, 2/5/13, we informed Mr. Lowe that the website change made by the firm previously to include the "Formerly called "Influenza Sorbet," statement still had a recognized disease on the website and needed to be removed, along with any reference to the recognized disease, including the term "flu". We also explained that the website had pictures of the product with the previous Influenza Sorbet name and needed to be corrected.

We asked Mr. Lowe about any corrective actions for these labeling and website issues and Mr. Lowe explained that he had listened to us and "engaged in significant back and forth on the topic" and had no more comments.

Investigator Dymbrowski was not present at the firm for all of the discussions on this issue on 1/25/13, however was present for the closeout on 2/5/13.

ADDITIONAL INFORMATION (DSM)

When we requested to review documents or records, the firm did not provide any of these records for review such as processing records, product testing records, allergen program, complaint procedures, recall procedures, receiving records, and shipping records. Mr. Lowe stated that any requested records or documents needed to be requested in writing. Ms. McBride, and Mr. Boutros informed us that Mr. Lowe had instructed them to tell us that any document requests needed to be in writing.

SAMPLES COLLECTED (DSM)

Sample DOC794867 was collected to document labeling, drug claims, and website information for the Influenza Sorbet Rx and/or Influenza Sorbet product

VOLUNTARY CORRECTIONS (DSM)

The firm voluntarily destroyed approximately 287 pints of Influenza Sorbet Rx and/or Influenza Sorbet during the inspection and changed the name of the product to The Hot Toddy. See Recalls section of this report for more information.

EXHIBITS COLLECTED (DSM)

Exhibit 1: Photographs of the condensation/ice buildup in the freezer [2p]
Exhibit 2: FDA 252 [1p]

ATTACHMENTS (DSM)

FDA 482 dated 1/25/13 [3p]
FDA 483 dated 2/5/13 [1p]
Assignment email dated 1/24/13 [2p]
Firm website printouts dated 1/28/13 [56p]
Firm website printouts dated 2/5/13 [32p]
24 Hour Alert Information [1p]
Recall Recommendation Information [p]

Dell S. Moller, Investigator
CIN-DO/COL-RP

Kirk A. Dymbrowski, Investigator
CIN-DO/COL-RP