



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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Date: January 18, 2013
To: File
From: Emily L. Harvey
Re: *Salmonella* Bredeney associated with peanut butter, 1208MLJBX-1,
August-September 2012
WGFIC: 2012-09-004
MAVEN ID: 101251388

Between 8/23/2012 and 9/10/2012, the Massachusetts Department of Public Health (MDPH) Epidemiology Program (EPI) received reports from the PulseNet laboratory at the Centers for Disease Control and Prevention (CDC) and the PFGE (Pulsed-Field Gel Electrophoresis) laboratory at the Hinton State Laboratory Institute (HSLI) that three isolates of *Salmonella Bredeney* submitted to HSLI were a genotypic match and identical to several other cases nationwide. The cluster code was designated as 1208MLJBX-1, with the pattern identified as JBXX01.0013/ JBXA26.0002. Nationally, as of September 10, there had been a total of 22 cases of *Salmonella Bredeney* infections reported from 13 states: CA(2), CT(2), LA(1), MA(3), MD(1), MU(1), MN(1), MO(1), NJ(2), PA(1), TX(3), VA(1), WA(3). Culture isolation dates ranged from 8/12-8/23/2012. Infected individuals ranged in age from two to 66 years old with a median age of five years; 81% of cases were younger than 18 years old. Forty percent of ill persons were female. According to the CDC, *Salmonella Bredeney* is a rare serotype reported in the United States. This recent clustering of cases was significantly above the expected baseline for this pattern. The median age was also significantly different than expected for this serotype (current cluster is five, expected median amongst all Bredeney isolates is 12 years). The sex distribution was also unusual (40% versus expected 47%).

While there had not been any non-human matches to this pattern specifically, a variety of meat products (boneless beef, ground turkey, and chicken breast) have yielded *Salmonella Bredeney* of several different PFGE patterns. A search of the literature also

showed that chicken and other meat products had been implicated in Bredeney outbreaks internationally. There had not been any Bredeney outbreaks identified in the United States historically.

By 11/30/2012 when the investigation officially closed, a total of 42 individuals infected with the outbreak strain of *Salmonella* Bredeney were reported from 20 states: Arizona (1), California (7), Connecticut (3), Illinois (1), Louisiana (1), Massachusetts (3), Maryland (1), Michigan (1), Minnesota (1), Missouri (2), New Jersey (2), New Mexico (1), New York (2), Nevada (1), North Carolina (3), Pennsylvania (2), Rhode Island (1), Texas (5), Virginia (2), West Virginia (2).

This investigation involved the Working Group on Foodborne Illness Control (WGFIC) in MA and CDC's Outbreak Response Team. As a result of the collaborative efforts of these groups, the likely vehicle of transmission for this outbreak was identified as Trader Joe's Valencia Creamy Salted Peanut Butter made with Sea Salt. The peanut butter was manufactured by Sunland, Inc. of Portales, New Mexico. Several recalls, including the first one issued by Trader Joe's¹, were eventually issued by this company and the FDA suspended its registration which basically halted production until certain requirements were met.²

CDC's final web update can be found here: <http://www.cdc.gov/salmonella/bredeney-09-12/index.html>

The remainder of this memo will focus on the three MA cases.

Because one of the earliest identified cases in a MD resident reported exclusively purchasing food from a Trader Joe's (TJs) market, all MA cases were specifically asked about grocery shopping venues. Ultimately, all were interviewed with a hypothesis generating questionnaire developed by CDC [Attachment 1]. All MA cases did report shopping at a TJs market, but weren't exclusive TJs shoppers. But, all reported purchasing TJs Valencia Creamy Salted Peanut Butter Made with Sea Salt (later determined to be the likely vehicle of transmission) at some time prior to onset. This type of peanut butter had also been consumed by several of the cases in other states. Because of this, on 9/21/2012, MDPH (along with several other state health departments involved in the investigation), issued a consumer alert warning consumers not to eat TJs Valencia Creamy Salted Peanut Butter Made with Sea Salt.² The investigation quickly expanded to include the Federal Food and Drug Administration (FDA).

In MA, cases ranged in age from 15 months to four years and two were male. Onset of symptoms ranged from 7/30/2012-8/26/2012 with a duration of three to five days, none were hospitalized. The cases were from the towns of Grafton, Barnstable and Amherst. It was because of the genetic linkages identified by the PFGE lab and CDC that brought attention to these otherwise geographically scattered cases.

Unfortunately, at the time of case identification and interview, none of the case families had any left over peanut butter from the jars that their children ate from prior to illness.

However, MDPH Food Protection Program collected a variety of TJs peanut and other nut butter spreads, including an opened jar of TJs Valencia Creamy Salted Peanut Butter made with Sea Salt from an additional suspected case's home; this case never tested positive for Salmonella sp. None of the products tested at the Hinton State Laboratory Institute (HSLI) tested positive for Salmonella sp. [Attachment 2]

¹<http://www.fda.gov/Safety/Recalls/ucm320579.htm>

²<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm329370.htm>

³<http://www.mass.gov/cohhs/gov/newsroom/press-releases/dph/consumer-alert-regarding-peanut-butter.html>

Focused Questionnaire for *Salmonella* Bredeney
PulseNet cluster code: 1208MLJBX-1

Section 1: INTERVIEWER INFORMATION

1. PulseNet ID #: _____ 2. State/Local/Other ID #: _____
3. Date of Interview: / / (if unknown, enter 99/99/9999)
4. Interviewer Information Name: _____ Contact phone number: (____) _____
 Agency or Organization: _____
5. Before this interview, how many times has the case been interviewed about their illness by a local, state, or federal public health representative? ☐ None ☐ Once ☐ Twice ☐ Three times
☐ Other (specify # times): _____ ☐ Unknown
6. Respondent was: ☐ Self ☐ Parent ☐ Spouse ☐ Other (Specify): _____

Section 2: DEMOGRAPHIC DATA: I'd like to begin by asking a few questions about yourself (your child) and your household.

1. What are your state, county, and zip code? State abbr. _____ County _____ Zip Code _____
2. Birth month and year / (if unknown, enter 99/9999)
3. Sex: ☐ Male ☐ Female ☐ Unknown
4. Hispanic or Latino origin? ☐ Yes ☐ No ☐ Unknown
5. How would you describe your race? ☐ White ☐ Black/ African American ☐ American Indian/Alaska Native ☐ Asian
☐ Native Hawaiian/Other Pacific Islander ☐ Other (specify): _____ ☐ Unknown

Section 3: CLINICAL INFORMATION: Now I have a few questions about your (your child's) illness.

1. What date did you first feel sick? / / (if unknown, enter 99/99/9999)
- | Yes | Maybe | No | Don't Know |
|--------------------------|--------------------------|--------------------------|--------------------------|
| ☐ | ☐ | ☐ | ☐ |
- Did/Were you (your child)
2. Have any diarrhea (defined as at least 3 loose stools in 24 hours)
- 2a. What day did it start / / (if unknown, enter 99/99/9999)
- | Yes | Maybe | No | Don't Know |
|--------------------------|--------------------------|--------------------------|--------------------------|
| ☐ | ☐ | ☐ | ☐ |
3. Hospitalized overnight?
4. Have any close contact with anyone with diarrhea or vomiting?
- 4a. When was this person ill ☐ less than 24 hours before you ☐ ≥ 24 hours before you ☐ Unknown
5. How many days total were you sick? _____ days (enter 999 if unknown) or ☐ Still ill

Section 4: SOURCES OF FOOD AT HOME: Now I have a few questions about the stores where you buy food for home.

- | Yes | Maybe | No | Don't Know |
|--------------------------|--------------------------|--------------------------|--------------------------|
| ☐ | ☐ | ☐ | ☐ |
- Did you (your child) eat foods purchased from the following stores in the month before you were sick?
1. Grocery stores or supermarkets
- | | Yes | No | Maybe | Unknown |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 1a. Whole Foods | ☐ | ☐ | ☐ | ☐ |
| 1b. Kroger | ☐ | ☐ | ☐ | ☐ |
| 1c. Safeway | ☐ | ☐ | ☐ | ☐ |
| 1d. Trader Joe's | ☐ | ☐ | ☐ | ☐ |
| 1e. Stop&Shop | ☐ | ☐ | ☐ | ☐ |
| 1f. Wegman's | ☐ | ☐ | ☐ | ☐ |
| 1g. Costco | ☐ | ☐ | ☐ | ☐ |
| 1h. Sam's Club | ☐ | ☐ | ☐ | ☐ |
| 1i. Walmart | ☐ | ☐ | ☐ | ☐ |
| 1j. Aldi | ☐ | ☐ | ☐ | ☐ |
| 1k. Other supermarket (specify: _____) | ☐ | ☐ | ☐ | ☐ |
- If person does not shop at Trader Joe's, complete this section and skip to Section 6

Yes	Maybe	No	Don't Know					
☐	☐	☐	☐	Did you (your child) eat foods purchased from the following stores in the <u>month</u> before you were sick?				
				2. Buy foods or groceries from an online retailer?				
				2a. Fresh Direct	☐ Yes	☐ No	☐ Maybe	☐ Unknown
				2b. Amazon	☐ Yes	☐ No	☐ Maybe	☐ Unknown
				2c. Netgrocer	☐ Yes	☐ No	☐ Maybe	☐ Unknown
				2d. Peapod	☐ Yes	☐ No	☐ Maybe	☐ Unknown
				2e. Ebay	☐ Yes	☐ No	☐ Maybe	☐ Unknown
				2f. Other online retailer or food company (specify: _____)	☐ Yes	☐ No	☐ Maybe	☐ Unknown
				2a1. You mentioned buying food/groceries from an online retailer. Did you purchase any Trader Joe's branded items from an online retailer? ☐ Yes ☐ No ☐ Maybe ☐ Unknown				
				2a2. Which online retailer: _____				
				2a3. What Trader Joe's branded items did you purchase from an online retailer? _____				
<i>If person buys TJ's brand items online, interview case with Trader Joe's Section 5</i>								
☐	☐	☐	☐	3. Try or sample any foods or drinks featured at any of the stores that you shopped at? If yes, what foods, which store: _____				
☐	☐	☐	☐	4. Do you have any receipts saved from the time period that you purchased food before you/your child's illness?				
				5a Receipts available from any of the abovementioned stores: (Name of stores) _____ _____				
☐	☐	☐	☐	5. Do you have any loyalty cards from any of the stores where you purchased food before you/your child's illness?				
				6a. Will you provide a list of loyalty card numbers for the stores where you shopped? _____ _____				

Section 5:

You mentioned that you had shopped at a Trader Joe's in the month before you/your child became ill. Now we would like to ask you some questions about the foods you purchased specifically at Trader Joe's

Yes	Maybe	No	Don't Know	
				1. At what Trader Joe's store location(s) do you shop? (include store #, if known) _____
				2. How often do you shop at a Trader Joe's? ☐ Rarely (only once in the past month) ☐ Occasionally (2 or 3 times in the past month) ☐ Weekly (4 or more times in the past month)
☐	☐	☐	☐	3. In the <u>7 days</u> before your illness began, did you eat any <u>peanut butter</u> purchased at Trader Joe's?
☐	☐	☐	☐	3a. Trader Joe's Creamy Salted Valencia Peanut Butter made with Sea Salt
☐	☐	☐	☐	3b. Trader Joe's Valencia PB made Roasted Flax Seeds
☐	☐	☐	☐	3c. Trader Joe's Creamy Salted PB
☐	☐	☐	☐	3d. Trader Joe's Crunchy Salted PB
☐	☐	☐	☐	3e. Trader Joe's Creamy Unsalted PB
☐	☐	☐	☐	3f. Trader Joe's Crunchy Unsalted PB
☐	☐	☐	☐	3g. Organic Trader Joe's Creamy Salted PB
☐	☐	☐	☐	3h. Organic Trader Joe's Crunchy Salted PB
☐	☐	☐	☐	3i. Organic Trader Joe's Creamy Unsalted PB
☐	☐	☐	☐	3j. Organic Trader Joe's Crunchy Unsalted PB
☐	☐	☐	☐	3k. Trader Joe's Almond Butter with Roasted Flax Seeds
☐	☐	☐	☐	3l. Better 'n' Peanut Butter 85% less fat, low sodium butter
☐	☐	☐	☐	3m. Other brand/variety at Trader Joe's: (specify) _____

Supplemental peanut butter section: If person reports more than one brand, fill out an additional supplemental for each peanut butter named. Supplementals at the end of this questionnaire

Which brand/variety does this section refer to? _____ (mark full product name)				
4. This peanut butter that you/your child were eating in the 7 days before you were sick, when did you purchase it ____/____/____				
5. How many times did you eat this as a meal or snack in the 7 days before you were sick? _____				
6. Do you keep this peanut butter refrigerated after opening? ☐ Yes ☐ No ☐ Maybe ☐ Unknown				
7. Do you still have the jar of peanut butter in your home? ☐ Yes ☐ No ☐ Maybe ☐ Unknown				
If more than one jar of the same variety/brand are in the home, use Jar #2 to record additional jar's information	Jar #1 Brand/detail on label: _____ Date of purchase: ____/____/____ "Use by" date: ____/____/____ Lot code: _____ UPC (10 digits): _____ Size of jar (ounces): _____ Available for testing by health department? ☐		Jar #2 Brand/detail on label: _____ Date of purchase: ____/____/____ "Use by" date: ____/____/____ Lot code: _____ UPC (10 digits): _____ Size of jar (ounces): _____ Available for testing by health department? ☐	
In this section of the interview, I will continue to ask you about the foods you ate that you may have purchased from Trader Joe's :				
☐	☐	☐	☐	8. Pre-packaged peanut butter crackers?
→				2a. Specify any details about the crackers (e.g., mini, cheese-and-peanut butter, etc):
☐	☐	☐	☐	9. Peanut butter filled pretzels?
				What variety: ☐ Salted ☐ Unsalted ☐ Chocolate-covered
☐	☐	☐	☐	10. Peanut butter containing foods (cookies, candies, ice cream, snack/energy bar etc.)?
→				10a. What was the type/variety: _____
				10b. What was the brand: _____
☐	☐	☐	☐	11. Peanut-based sauces or dressings, such as Asian or Thai-style sauce?
→				11a. What type/brand? _____
				11b. Location of purchase: _____
☐	☐	☐	☐	12. Whole peanuts from a package, jar, or can?
→				12a. ☐ Roasted ☐ raw, unroasted
				12b. What brand: _____
☐	☐	☐	☐	13. Ground nut butter or spread other than peanut butter (Nutella, almond butter)?
→				Type of spread:
				☐ Almond butter - brand: _____; any details: _____
				☐ Cashew butter - brand: _____; any details: _____
				☐ Sunflower butter - brand: _____; any details: _____
				☐ Chocolate spread - brand: _____; any details: _____
				☐ Cookie spread - brand: _____; any details: _____
				☐ Other: _____ any details: _____
☐	☐	☐	☐	14. Jams, jellies, or preserves?
→				14a. Flavor: ☐ Strawberry ☐ Raspberry ☐ Blackberry ☐ Grape ☐ Cherry
				☐ Other: _____
				14b. Brand: ☐ Trader Joe's ☐ Other brand: _____
☐	☐	☐	☐	15. Frozen chicken nuggets/drumettes
→				15a. Brand: ☐ Tyson's ☐ Trader Joe's ☐ Perdue ☐ Boca ☐ Other: _____
☐	☐	☐	☐	16. Frozen fish sticks
→				16a. Brand: ☐ Praeger's ☐ Trader Joe's ☐ Ian's ☐ Gorton's ☐ Other: _____
☐	☐	☐	☐	17. Frozen meals (including pizzas, dinners, entrees, snacks):
→				17a. Brand: ☐ Trader Joe's ☐ Other brand: _____
				17b. Type/flavor: _____
☐	☐	☐	☐	18. Milk or milk alternatives
→				18a. Type: ☐ Cow's ☐ Almond ☐ Rice ☐ Soy ☐ Other: _____
				18b. Brand: ☐ Blue Diamond/Breeze ☐ Silk ☐ Rice Dream
				☐ Store brand ☐ Organic Valley ☐ Horizon ☐ Other: _____
				18c. Was it sold in the: ☐ refrigerated section ☐ shelf-stable section (not refrigerated section)
☐	☐	☐	☐	19. Apples
→				19a. Type: ☐ Gala ☐ Fuji ☐ Granny Smith ☐ Red Delicious ☐ Other: _____

Please fill in any comments/notes from this section in the space provided below:

Section 6:

Next I have questions for you about the foods that you purchased at **other stores**, which you ate in the 7 days before your illness.

Yes	Maybe	No	Don't Know	In the 7 days before your illness started, did you (your child) eat any:		
☐	☐	☐	☐	20. Peanut Butter? (variety would be: Simply Jif, Sunland with Molasses, Low-Fat Peter Pan, etc)		
☐	☐	☐	☐	20a. Jif	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20b. Sunland	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20c. Arrowhead Mills Valencia Peanut Butter	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20d. Peter Pan	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20e. Smuckers	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20f. Skippy	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20g. Kirkland (Costco)	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20h. Archer Farms (Target)	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20i. Earth Balance	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20j. Fresh&Easy	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20k. Heinen's	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20l. Joseph's	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20m. Natural Value	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20n. Naturally More	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20o. Open Nature	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20p. Peanut Power Butter	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20q. SeriousFood SillyPrices	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20r. SnacLife	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20s. Sprouts	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural
☐	☐	☐	☐	20t. Other (brand: _____)	Variety: _____	☐ Creamy ☐ Crunchy ☐ Organic ☐ Natural

Supplemental peanut butter section: If person reports more than one brand, fill out an additional supplemental for each peanut butter named. Supplementals at the end of this questionnaire

Which brand/variety does this section refer to? _____ (mark full product name)

21. This peanut butter that you/your child were eating in the 7 days before you were sick, when did you purchase it ____/____/____

22. How many times did you eat this as a meal or snack in the 7 days before you were sick? _____

23. Do you keep this peanut butter refrigerated after opening? ☐ Yes ☐ No ☐ Maybe ☐ Unknown

24. Do you still have the jar of peanut butter in your home? ☐ Yes ☐ No ☐ Maybe ☐ Unknown

<i>If more than one jar of the same variety/brand are in the home, use Jar #2 to record additional jar's information</i>	<u>Jar #1</u> Brand/detail on label: _____ Date of purchase: ____/____/____ "Use by" date: ____/____/____ Lot code: _____ UPC (10 digits): _____ Size of jar (ounces): _____ Available for testing by health department? _____	<u>Jar #2</u> Brand/detail on label: _____ Date of purchase: ____/____/____ "Use by" date: ____/____/____ Lot code: _____ UPC (10 digits): _____ Size of jar (ounces): _____ Available for testing by health department? _____
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Yes	Maybe	No	Don't Know	
In the 7 days before your illness started, did you (your child) eat any:				
☐	☐	☐	☐	25. Pre-packaged peanut butter crackers?
}				25a. What brand: ☐ Keebler ☐ Austin ☐ Lance ☐ Ritz ☐ Toms ☐ Other: _____
				25b. Specify any details about the crackers (e.g., mini, cheese-and-peanut butter, etc): _____
☐	☐	☐	☐	26. Any peanut butter flavored or filled pretzels?
}				26a. What brand: ☐ Herrs ☐ Combos ☐ Snyder ☐ Other: _____
☐	☐	☐	☐	27. Whole peanuts from a package, jar, or can?
}				27a. ☐ Roasted ☐ raw, unroasted
				27b. What brand: _____
☐	☐	☐	☐	28. Peanut-based sauces or dressings, such as Asian or Thai-style sauce?
}				28a. What type/brand? _____
				28b. Location of purchase: _____
☐	☐	☐	☐	29. Peanut butter containing foods (cookies, sandwiches, candies, ice cream, snack/energy bar)?
}				29a. What was the type/variety: _____
				29b. What was the brand: _____
☐	☐	☐	☐	30. Ground nut butter or spread other than peanut butter (Nutella, almond butter)?
}				Type of spread:
				☐ Almond butter - brand: _____; any details: _____ ☐ Cashew butter - brand: _____; any details: _____ ☐ Sunflower butter - brand: _____; any details: _____ ☐ Chocolate spread - brand: _____; any details: _____ ☐ Cookie spread - brand: _____; any details: _____ ☐ Other: _____ any details: _____
☐	☐	☐	☐	31. Jams, jellies, or preserves?
}				31a. Flavor: ☐ Strawberry ☐ Raspberry ☐ Blackberry ☐ Grape ☐ Cherry ☐ Other: _____
				31b. Brand: ☐ Smuckers ☐ Polaner ☐ Bonne Maman ☐ Stonewall Kitchen ☐ Crofter's ☐ Other brand: _____
☐	☐	☐	☐	32. Frozen chicken nuggets/drumettes
}				32a. Brand: ☐ Tyson's ☐ Perdue ☐ Boca ☐ Other: _____
☐	☐	☐	☐	33. Frozen fish sticks
}				33a. Brand: ☐ Gorton's ☐ Praeger's ☐ Ian's ☐ Mrs. Paul's ☐ Other: _____
☐	☐	☐	☐	34. Frozen meals (including pizzas, dinners, entrees, snacks):
}				34a. Brand: ☐ Totinos ☐ Stouffer's ☐ Lean Cuisine ☐ Other: _____
				34b. Type/flavor: _____
☐	☐	☐	☐	35. Milk or milk alternatives
}				35a. Type: ☐ Cow's ☐ Almond ☐ Rice ☐ Soy ☐ Other: _____
				35b. Brand: ☐ Blue Diamond/Breeze ☐ Silk ☐ Rice Dream ☐ Store brand ☐ Organic Valley ☐ Horizon ☐ Other: _____
				35c. Location of purchase: _____
☐	☐	☐	☐	36. Apples
}				36a. Type: ☐ Gala ☐ Fuji ☐ Granny Smith ☐ Red Delicious ☐ Other: _____
				36b. Location of purchase: _____
☐	☐	☐	☐	37. Did your household use any peanut butter flavored pet treats or other peanut butter pet products for any reason in the 7 days before the onset of diarrhea?
}				37a. Did you use Dogsbutter with Flax Seed Peanut Butter? ☐ Yes ☐ No ☐ Unknown
				37b. Other brand PB treats: _____

Please fill in any comments/notes from this section in the space provided below:

Thank you for the interview. Those are all the questions I have for you right now. We may have to contact you again for additional information. Would that be OK?

Please email completed questionnaires to Thai-An Nguyen at ten9@cdc.gov. Alternatively faxed to 404.679.5073
For persons who ate several different brands of peanut butter in the 7 days before their illness (both sections 5 and 6), please print out this additional supplemental peanut butter section and complete for each different type of peanut butter.

Supplemental peanut butter section: If person reports more than one brand, fill out an additional supplemental for each peanut butter named.		
Which brand/variety does this section refer to? _____ (mark full product name)		
38. This peanut butter that you/your child were eating in the 7 days before you were sick, when did you purchase it ____/____/____		
39. How many times did you eat this as a meal or snack in the 7 days before you were sick? _____		
40. Do you keep this peanut butter refrigerated after opening? ☐ Yes ☐ No ☐ Maybe ☐ Unknown		
41. Do you still have the jar of peanut butter in your home? ☐ Yes ☐ No ☐ Maybe ☐ Unknown		
If more than one jar of the same variety/brand are in the home, use Jar #2 to record additional jar's information	Jar #1	Jar #2
	Brand/detail on label: _____	Brand/detail on label: _____
	Date of purchase: ____/____/____	Date of purchase: ____/____/____
	"Use by" date: ____/____/____	"Use by" date: ____/____/____
	Lot code: _____	Lot code: _____
	UPC (10 digits): _____	UPC (10 digits): _____
	Size of jar (ounces): _____	Size of jar (ounces): _____
Available for testing by health department? _____	Available for testing by health department? _____	

Please email completed questionnaires to Thai-An Nguyen at ten9@cdc.gov. Alternatively faxed to 404.679.5073

Attachment 2

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5553

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joes
1121 Washington St.
WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 4:00 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Valencia Peanut Butter with roasted flax seeds crunchy and salted. Best buy date: 03JUL13 16:29
Package Description	Screw cap plastic jar - intact
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-02
Lot Number	
Date Code	
Event Code	09202012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5554

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joes
1121 Washington St.
WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 9:35 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Valencia Peanut Butter with roasted flax seeds crunchy and salted. Best buy date: 03JUL13 16:29
Package Description	Screw cap plastic jar intact.
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-02
Lot Number	
Date Code	
Event Code	09202012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5555

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joes
1121 Washington St.
WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 4:00 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Valencia Peanut Butter with roasted flax seeds crunchy and salted. Best buy date: 03JUL13 16:29
Package Description	screw cap plastic jar - intact
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-02
Lot Number	
Date Code	
Event Code	09202012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5556

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joes
1121 Washington St.
WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 4:00 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Valencia Peanut Butter with roasted flax seeds crunchy and salted. Best buy date: 03JUL13 16:29
Package Description	screw cap plastic jar - intact
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-02
Lot Number	
Date Code	
Event Code	09202012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5557

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joes
1121 Washington St.
WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 4:00 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Valencia Peanut Butter with roasted flax seeds crunchy and salted. Best buy date: 03JUL13 16:29
Package Description	Screw cap plastic jar - intact
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-02
Lot Number	
Date Code	
Event Code	09202012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # **12EN5671**

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joe's
1121 Washington St

WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 4:00 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Almond Butter w/Roasted Flax Seeds Crunchy and Salted. Best Buy Date: 06JUL13 08:06
Package Description	Intact plastic screw cap jar.
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-01
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5672

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joe's
1121 Washington St

WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 4:00 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Creamy Salted Peanut Butter from unblanched peanuts. Best Buy Date: 4/30/13N 22:51
Package Description	Intact plastic screw cap jar.
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-03
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5673

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joe's
1121 Washington St
WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 4:00 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Sunflower Seed Butter. Sell by Aug 2013 Lot #12082414
Package Description	Intact plastic screw cap jar
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-04
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5674

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joe's
1121 Washington St
WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 4:00 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Creamy Unsalted Peanut Butter from unblanched peanuts
Package Description	Intact plastic screw cap jar
Arrival Temp	Room Temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-05
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5675

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joe's
1121 Washington St

WEST NEWTON MA 02465
Contact:

Date Received 09/19/2012
Time Received 9:09 pm
Received by efortes
Date Collected 09/19/2012

Sample Description	Trader Joe's Almond Butter Raw Creamy Unsalted. Use by 08 Sept 2013
Package Description	Intact glass screw cap jar
Arrival Temp	Room Temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	2012-09-06
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5676

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Norman H. Finkelstein
56 Greenleaf Circle

FRAMINGHAM MA 01701
Contact: 508-875-6419

Date Received 09/25/2012
Time Received 9:10 am
Received by CConley
Date Collected 09/25/2012

Sample Description	Trader Joe's Valencia Creamy Salted Peanut Butter made with Sea Salt. Lot # 22311543. Best Buy 26Jul13 09:58
Package Description	Opened 16oz plastic screw cap jar
Arrival Temp	on ice
Gross Weight	389.03g
Reason for Test	Outbreak Related

Inspector	E Mascoop
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # **12EN5677**

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Trader Joe's
1317 Beacon St.

Brookline MA
Contact: Lori Bourassa

Date Received 09/25/2012
Time Received 9:30 am
Received by kjepson
Date Collected 09/25/2012

Sample Description	Trader Joe's Valencia Peanut Butter w/Roasted Flax seeds Crunchy & Salted. Best Buy: 03Jul13 23:20
Package Description	Intact plastic screw cap jar
Arrival Temp	room temp
Gross Weight	16oz
Reason for Test	Outbreak Related

Inspector	1
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # **12EN5678**

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Norman H. Finkelstein
56 Greenleaf Circle

FRAMINGHAM MA 01701
Contact: 508-875-6419

Date Received 09/25/2012
Time Received 9:10 am
Received by CConley
Date Collected 09/25/2012

Sample Description	Trader Joe's Valencia Creamy Salted Peanut Butter made with Sea Salt. Lot # 22311543. Best Buy 26Jul13 09:58
Package Description	Opened 16oz plastic screw cap jar
Arrival Temp	on ice
Gross Weight	389.03g
Reason for Test	Outbreak Related

Inspector	E Mascoop
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

Foodborne Disease Surveillance Laboratory
State Laboratory Institute
Massachusetts Department of Public Health
305 South Street, Jamaica Plain, MA 02130
(617) 983-6608

Report Date: 9/28/2012

Lab # 12EN5679

Submitted by:
FOOD PROTECTION PROGRAM
HEALTH DIRECTOR
305 SOUTH STREET
JAMAICA PLAIN MA 02130
Contact: TARA HARRIS

Sample Collection Location:
Norman H. Finkelstein
56 Greenleaf Circle

FRAMINGHAM MA 01701
Contact: 508-875-6419

Date Received 09/25/2012
Time Received 9:10 pm
Received by CConley
Date Collected 09/25/2012

Sample Description	Trader Joe's Valencia Creamy Salted Peanut Butter made with Sea Salt, Lot # 22311543, Best Buy 26Jul13 09:58
Package Description	Opened 16oz plastic screw cap jar.
Arrival Temp	room temp
Gross Weight	389.03g
Reason for Test	Outbreak Related

Inspector	E Mascoop
Lot Number	
Date Code	
Event Code	09252012
FBIC#	2012-09-004

Test Performed	Result / Method Reference
Salmonella species	Bacteriological Analytical Manual Online, Chapter 5 Salmonella sp. NOT found

The Official Website of the Executive Office of Health and Human Services (EOHHS)

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GOVERNOR
TIM MURRAY
LIEUTENANT GOVERNOR
JUDYANN BIGBY, M.D.
SECRETARY
JOHN AUERBACH
COMMISSIONER

Media Contact

Anne Roach
Anne.Roach@State.MA.US
617-624-5006

For Immediate Release - September 21, 2012

Consumer Alert Regarding Peanut Butter Due to Possible Salmonella Contamination

Trader Joe's Valencia Creamy Salted Peanut Butter may be linked to outbreak

BOSTON – Friday, September 21, 2012 – The Massachusetts Department of Public Health (DPH) warns consumers that Trader Joe's Valencia Creamy Salted Peanut Butter Made with Sea Salt may be related to a multi-state outbreak of Salmonella infection. DPH is working in conjunction with the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration and many other state health departments to investigate an outbreak of *Salmonella* Bredeney that may be linked to the consumption of this product. Since June 11, twenty-nine cases of *S. Bredeney* have been detected nationally. Three of these cases have occurred in Massachusetts. DPH recommends discarding the product if it is in the home.

Salmonella are germs (bacteria) that cause an infectious disease (called "salmonellosis") of the bowel in humans and animals. The most common symptoms are stomach cramps, diarrhea, fever, nausea, and sometimes vomiting. Symptoms can take up to three days to show up, but most often begin 12 to 36 hours after the germs are swallowed. Symptoms generally last for several days. Some people with salmonellosis become sick enough to require hospitalization. Anyone with these symptoms who has consumed Trader Joe's Valencia Creamy Salted Peanut Butter Made with Sea Salt should consult their healthcare provider.

###

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Home Safety Recalls, Market Withdrawals, & Safety Alerts

Safety

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Trader Joe's Voluntarily Recalls Creamy Salted Valencia Peanut Butter Because of Possible Health Risk

Contact

Consumer:
(626) 599-3817

Media:
Alison Mochizuki
(626) 599-3779

FOR IMMEDIATE RELEASE - September 24, 2012 - Out of the utmost caution and care for our customers, Trader Joe's is voluntarily recalling its Creamy Salted Valencia Peanut Butter (sku 97111) because of potential contamination with *Salmonella*. Customers who have purchased this item are urged to not eat the product, and to dispose of it or return it to any Trader Joe's for a full refund. *Salmonella* is an organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis.

At this time the Food and Drug Administration (FDA), Centers for Disease Control and Prevention, and state health agencies are investigating whether there are direct links between this product and reported illnesses. Trader Joe's is fully cooperating with these authorities because there is nothing more important to us than the health and safety of our customers and crew, and the quality of our products.

In advance of this recall, Trader Joe's removed the product from all store shelves.

The recalled Creamy Salted Valencia Peanut Butter was distributed to Trader Joe's stores nationwide. The product comes in a 16 ounce, plastic jar with an expiration date of stamped below the lid.

All code dates are included in this recall—up to and including 26JUL13 (July 26, 2013).

Production and distribution of the item has been suspended while the FDA and the Valencia Peanut Butter supplier continue their investigations.

Customers with questions may contact Trader Joe's Customer Relations at (626) 599-3817 [Monday through Friday, 7:00 am to 5:00 pm Pacific Time].

###

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About FDA

Letter to Sunland Inc. Concerning Suspension of Food Facility Registration; Notice of Opportunity for Hearing



**DEPARTMENT OF HEALTH & HUMAN
SERVICES**

**Public Health Service
Food and Drug
Administration
Silver Spring, MD 20993**

November 26, 2012

Jimmie D. Shearer, President
Sunland Inc.
42593 U.S. Highway 70
Portales, NM 88130-9043

Dear Mr. Shearer:

The U.S. Food and Drug Administration (FDA) hereby suspends the registration for your food facility Sunland, Inc. (Sunland), located at 42593 U.S. Highway 70, Portales NM. Your food facility was registered with FDA pursuant to section 415(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 350d(a)] on November 24, 2003, and such registration was updated on July 11, 2012. Section 415(b)(1) of the FD&C Act provides in relevant part that if FDA determines that food manufactured, processed, packed, received, or held by a facility registered under section 415 has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility (1) that created, caused, or was otherwise responsible for such reasonable probability; or (2) that knew of, or had reason to know of such reasonable probability, and packed, received, or held such food.

As discussed further below, FDA has determined that food manufactured, processed, packed, received, or held by your facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, and that your facility created, caused, or was otherwise responsible for such reasonable probability. FDA is issuing this Order under section 415(b)(1) of the FD&C Act, and the Order is effective immediately upon your receipt. While this Order is in effect, pursuant to section 415(b)(4) of the FD&C Act, no person can import or export food into the United States from your facility, offer to import or export food into the United States from your facility, or otherwise introduce food from your facility into interstate or intrastate commerce in the United States. The introduction or delivery for introduction into interstate commerce in violation of this Order is a prohibited act under section 301(d) of the FD&C Act [21 U.S.C. 331(d)], subject to injunction proceedings under section 302 of the FD&C Act [21 U.S.C. 302] and certain penalties under section 303 of the FD&C Act [21 U.S.C. 333]. This Order also offers you an opportunity to request an informal hearing, as provided by section 415(b)(2) of the FD&C Act.

The basis for FDA's determination is as follows:

- In September 2012, the Centers for Disease Control and Prevention (CDC) and FDA collaborated to investigate a multistate outbreak of Salmonella Bredeney. Since that time, CDC has reported a total of at least 35 persons infected with the outbreak strain of Salmonella Bredeney from 19 states; eight of these persons were hospitalized as a result of their infection. Trader Joe's™ brand Valencia Creamy Salted peanut butter made with Sea Salt has been

identified by FDA and CDC as a likely source of this outbreak.

- Salmonella, including Salmonella Bredeney, is a pathogenic organism that has a reasonable probability of causing serious adverse health consequences or death to humans.
- Sunland is the sole manufacturer of Trader Joe's™ brand Valencia Creamy Salted peanut butter made with Sea Salt.
- As discussed in detail below, evidence collected by FDA in response to this outbreak, including your facility's own testing records, environmental and finished product samples analyzed by FDA, and observations made by FDA during an inspection of your facility, establishes the following:
 - Nut butter and nut products manufactured, processed, packed, and held by your facility are contaminated with Salmonella, or are at risk for contamination with Salmonella, based on the conditions in your facility. Your facility's testing records over the past 3 years include multiple positive Salmonella results throughout your facility and in finished product. Due to this contamination and/or risk for contamination, FDA has determined that these products have a reasonable probability of causing serious adverse health consequences or death to humans.
 - Your facility created, caused, or was otherwise responsible for this reasonable probability. Specifically, FDA has determined that the conditions within your facility (e.g., the presence of Salmonella in various locations throughout the facility and CGMP violations that could lead to cross-contamination between raw materials and finished product) caused this reasonable probability.

Sunland Samples:

- From September 17, 2012 to October 16, 2012, FDA inspected your facility, located at 42593 U.S. Highway 70, Portales NM. During this time, we primarily inspected two buildings at your facility - the building in which you manufacture, process, pack, and hold nut butter products (nut butter building) and the building in which you manufacture, process, pack, and hold shelled and in-shell peanut products (nut building). During the inspection, FDA investigators obtained copies of your testing records.
- FDA reviewed your testing records of finished product samples and environmental samples collected from your facility between June 2009 and September 2012. Your facility sent these finished product samples and environmental samples for analysis to (b)(4), a third party private laboratory. During this time, your records indicate that this third party testing identified the presence of Salmonella spp. in at least 40 finished products from 11 finished product lots of nut butter products consisting of multiple brands and eight (8) sets of environmental samples (generally 17 swabs each set) with at least one positive swab from each set. These results reveal that food manufactured, processed, packed, and held at your facility is contaminated with Salmonella.
- Your facility distributed at least a portion of eight (8) lots of peanut and almond butter consisting of multiple brands manufactured between March 01, 2010 and September 2012, after composite testing of those lots revealed the presence of Salmonella. Specifically, when composite testing of a lot was positive for Salmonella, individual containers of product from the positive tested lots were re-tested and portions, or all, of these lots were distributed based on the re-test (non-composite) testing. The initial Salmonella positive composite test results were disregarded. At least one of the batches from a lot with initial positive composite test results, manufactured on July 14, 2012, that was ultimately distributed, contained a Pulsed Field Gel Electrophoresis (PFGE) pattern that was indistinguishable from the clinical isolates for the outbreak strain Salmonella Bredeney. When a PFGE pattern of an isolate is indistinguishable from the pattern of another isolate from a common source, it is highly likely that the two isolates are the same strain of Salmonella Bredeney. These results demonstrate that food manufactured, processed, packed, and held by your facility has a reasonable probability of causing serious adverse health consequences or death to humans.

FDA Samples:

- As part of our inspection, FDA collected environmental samples from different areas of your facility, including the roasting room in your nut butter building and equipment located inside

the roasting room and various areas in your nut building. FDA performed analytical testing of those environmental samples, which identified 4 swabs that tested positive for *Salmonella* Bredeney and 24 swabs that tested positive for other *Salmonella* species, including samples that FDA collected from the roasting room and equipment located inside the roasting room in your nut butter building and samples that FDA collected from your nut building.

- Analysis using PFGE showed that *Salmonella* Bredeney isolates obtained from the FDA environmental samples collected on September 24, 2012, from the roasting room of your nut butter building were indistinguishable from the clinical isolates associated with the *Salmonella* Bredeney outbreak.
- In addition, as part of our inspection FDA collected samples of nut and nut butter finished products. FDA performed analytical testing of these finished product samples which identified thirteen peanut butter products and one raw peanut product that tested positive for *Salmonella*, including five peanut butter products that tested positive for *Salmonella* Bredeney. Analysis using PFGE showed that *Salmonella* Bredeney isolates obtained from four of the finished peanut butter product samples were indistinguishable from the clinical isolates associated with the *Salmonella* Bredeney outbreak. Some of these samples were collected from lots of product that were released for sale to the public. These results also indicate that the pervasive and widespread nature of *Salmonella* contamination in Sunland's peanut butter processing building and adjacent peanut plant caused *Salmonella* contamination in finished product, which indicates a reasonable probability of these products causing serious adverse health consequences or death in humans.

Current Good Manufacturing Practice (CGMP) Violations:

- During FDA's investigation, our investigators observed serious violations of our Current Good Manufacturing Practice (CGMP) regulation for food in your facility's food production environment. These violations cause your ready-to-eat nut butter and nut products to be adulterated within the meaning of section 402(a)(4) of the FD&C Act, in that the foods have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. Further, these conditions and practices create a reasonable probability that finished product that is manufactured, processed, packed, and held by your facility is contaminated with *Salmonella* and therefore that there is a reasonable probability of finished product causing serious adverse health consequences or death to humans.
- Specifically, our investigators observed the following:
 - A number of conditions and practices in your facility likely result in cross-contamination between raw peanuts and peanuts that have been roasted or brined. This is particularly problematic because raw peanuts are more likely to contain pathogenic bacteria, particularly *Salmonella*, and can introduce pathogenic bacteria into finished product. Specifically:
 - Your (b)(4) brand packaging equipment in the small packaging room of the nut building is not effectively cleaned to prevent contamination between raw and roasted peanuts.
 - Your facility's "(b)(4) Sacks," collapsible mesh totes used to store and transport nuts around the facility, are considered multi-use because they carry raw peanuts, roasted and/or brined peanuts, and peanut food waste. The "(b)(4) Sacks" are not cleaned and sanitized between uses. This is problematic because it likely results in cross-contamination between raw peanuts and peanuts that have been roasted or brined.
 - The nut building does not have any hand washing sinks in the production or packaging areas. Five employees were observed having bare hand contact with ready to package, roasted, in-shell peanuts in the Picking Room of the nut building. Hand washing sinks are essential in preventing cross-contamination between raw peanuts and peanuts that have been roasted or brined.
 - Your three compartment sink was observed leaking and water was observed accumulating onto the floor in the nut butter building.
 - Dead legs were observed on six pipe connections on your processing equipment in the nut butter building, which allows food material to accumulate. These areas act as collection points for debris and water, both of which facilitate the growth of pathogenic

bacteria that could spread to finished product.

- Uneven welds were observed on your processing equipment in the nut butter building. The welds were not smooth to facilitate cleaning and sanitizing of the equipment.

We acknowledge your written response to the FDA Form 483 that was issued at the end of our most recent inspection of your facility, received by FDA on November 9, 2012. In your response, you indicate a number of corrective actions that you plan to take in response to FDA's observations; however your response omits significant details regarding planned physical repairs and corrective actions, and the adequacy or effectiveness of these corrective actions cannot be determined based on the information provided in the response. It will be necessary for FDA to evaluate the completed corrective actions on site to assure their adequacy. Based upon the current condition of the facility and past management policies and actions, FDA concludes that unless and until Sunland has completed and implemented certain corrective actions, food manufactured, processed, packed, received, or held by Sunland has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

Opportunity for an Informal Hearing

Pursuant to section 415(b)(2) of the FD&C Act, your facility is being offered an opportunity for an informal hearing on the actions required for reinstatement of your facility's registration and why your facility's registration should be reinstated.

Section 415(b)(2) of the FD&C Act provides in relevant part that a registrant subject to an order of suspension under section 415(b) shall be provided with an opportunity for an informal hearing, to be held as soon as possible, but not later than two (2) business days after the issuance of the order. In order to request an informal hearing to be held within two (2) business days after the issuance of this Order, you must submit your request, in writing, to the FDA contact person identified in this Order within one (1) business day after the issuance of this Order.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or her delegate determines that no genuine and substantial issue of fact had been raised by the material submitted. A hearing will not be granted on issues of policy or law. Accordingly, your request for a hearing should include information that you believe shows that there is a genuine and substantial issue of fact that warrants a hearing, and must be submitted in writing to the FDA contact person identified in this Order.

Alternatively, section 415(b)(2) of the FD&C Act provides that an informal hearing may be held at some other time period, as agreed upon by FDA and the registrant. In order to request a hearing to be held at a later time, as agreed upon by the registrant and FDA, you must submit your request, in writing, to the FDA contact person identified in this Order within three (3) business days after issuance of this Order. If you do not submit a written hearing request within three (3) business days after the issuance of this Order, your facility will be deemed to have waived its right to the opportunity for an informal hearing.

If you request an informal hearing, a Presiding Officer (PO) as defined in 21 CFR 16.42 will be designated and you will be notified of that individual's identity and contact information. The PO may deny your request for a hearing if the PO determines that you have not raised a genuine or substantial issue of fact by the material submitted in your hearing request, or if you failed to request the hearing within the time frame stated in this Order. If the PO determines that a hearing is not justified, written notice of a determination will be given to the registrant and FDA explaining the reasons for denial of the hearing. If the PO grants your request for an informal hearing, at the informal hearing you will have the opportunity to address the actions required for reinstatement of your facility's registration and to explain why the registration should be reinstated. The informal hearing will be conducted in accordance with the procedures in 21 CFR part 16, Regulatory Hearing Before the Food and Drug Administration, to the extent that such procedures are not in conflict with the procedures specified in section 415(b) of the FD&C Act. The informal hearing will be closed to protect information not available for public disclosure, as provided by 21 CFR 16.60.

If you wish to request an informal hearing, but do not wish to request that the hearing be held orally, you should contact the FDA contact person identified in this Order and send a written

response containing the basis for your request to the FDA contact person within three (3) business days. Your submission should state that you waive your opportunity for an oral informal hearing and that you want your request to be based on your written response and other information available to the agency.

Under section 415(b)(4) of the FD&C act, if the registration of a facility is suspended under section 415(b), no person shall import or export food into the United States from such facility, offer to import or export food into the United States from such facility, or otherwise introduce food from such facility into interstate or intrastate commerce in the United States. Accordingly, until this Order is vacated and your facility's registration is reinstated, you or any other individual may not introduce food from your facility, which includes all of the buildings at your facility, into interstate or intrastate commerce in the United States. This prohibition includes food produced before your receipt of this Order that is currently still under your control. This Order does not affect your on-going recall of peanut and peanut butter products and shipments of such products back to your facility. However, once you have received the returned food products, you may not introduce such products from your facility into interstate or intrastate commerce.

If you do not wish to appeal this Order or request an oral informal hearing, but wish to have your registration reinstated in part by submitting a corrective action plan to FDA that demonstrates how you plan to correct the conditions found by FDA, please contact the FDA contact person identified in this Order.

You may submit your written request for an informal hearing or your written response containing the basis for your appeal of this Order by any mode of written communication (e.g., mail, email, delivery service, personal delivery) to, or may otherwise contact, the designated FDA contact person using the following contact information:

LaTonya M. Mitchell, District Director

Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087

LaTonya. Mitchell@fda.hhs.gov
303-236-3016

In your submission, you should include your mail address, phone number, email, and any other relevant contact information. You should promptly contact the FDA contact person by phone or email if you have any questions regarding this Order.

Sincerely,

/s/

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

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