

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	1. DISTRICT ADDRESS & PHONE NUMBER 407-475-4700 US Food and Drug Administration Florida District office 555 Windorley Place, Suite 200 Maitland, FL 32751	
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2. NAME AND TITLE OF INDIVIDUAL Amy G. Denegri and Fred Joseph Denegri	3. DATE 07/24/09	4. SAMPLE NUMBER 528482
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5. FIRM NAME	6. FIRM'S DEA NUMBER
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7. NUMBER AND STREET [REDACTED]	8. CITY AND STATE (Include Zip Code) Gulf Breeze, FL 32576
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9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (h) of the Federal Food, Drug, and Cosmetic Act [21 USC 360i(h)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.
(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)

Sample consists of one (1) opened can of soda labeled in part: "~~XX~~ diet pepsi: ~~XX~~ 0 ~~XX~~ cal ~~XX~~ carb ~~XX~~ sug ~~XX~~ 12 FL OZ (355 mL) ~~XX~~." with the writing on the bottom of the can reading in part: "~~XX~~ 1417ES05259 ~~XX~~ SEP 07 09 ~~XX~~"

Sample also consists of an additional can opened of soda and labeled in part: "diet pepsi: ~~XX~~ 0 ~~XX~~ cal ~~XX~~ carb ~~XX~~ sug ~~XX~~ 12 FL OZ (355 mL) ~~XX~~." with the writing on the bottom of the can reading in part: "~~XX~~ 1417ES05259 ~~XX~~ SEP 07 09 ~~XX~~." Open/closed controls of whirlpak bags and sterile gloves were also collected. Sample collected and officially sealed with FDA #5 in whirlpak bag.
Sample provided at no cost to FDA.

7/24/09
AO 7/24/09

10. SAMPLES WERE <input checked="" type="checkbox"/> PROVIDED AT NO CHARGE <input type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)	11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> CASH <input type="checkbox"/> CHECK <input type="checkbox"/> VOUCHER <input type="checkbox"/> CREDIT CARD	12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.) Amy G. Denegri 7/24/09 Fred J. Denegri 7/24/09
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13. COLLECTOR'S NAME (Print or Type) Ronda M. Morris	14. COLLECTOR'S TITLE (Print or Type) Investigator	15. COLLECTOR'S SIGNATURE [Signature]
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AFFIDAVIT

SAMPLE NO.

520482

STATE OF

Florida

COUNTY OF

Volusia

Before me, Russell L. Morris an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Fred Joseph Denegri in the county and state aforesaid, who, being duly sworn, deposes and says:

I am Fred Joseph Denegri, with residence at [redacted], Ormond Beach, FL 32176. On 07/24/09, Russell L. Morris, Investigator with the U.S. Food and Drug Administration came to my residence to follow up on a complaint #A93105 that my wife and I had filed to the FDA on 07/23/09.

I explained to Investigator Morris that my wife and I purchased (1) one (36) thirty-six count case of Diet Pepsi Soda at Sams Club of Daytona Beach, FL at (386) 700-3380. The thirty-six count case of Diet Pepsi purchased were labeled in part: "XX diet pepsi XX OXX cal XX carb XX Sug XX 12 FL OZ (355 mL) XX." After I purchased the cans of Diet Pepsi I put them in a refrigerator in my garage that I use to store my sodas. I drank most of them and I have two other cases of Diet Pepsi in there that were bought at a different store. I have not commingled them and I only have one diet Pepsi left from the case I bought on 07/18/09. I was cooking outside on an evening of 07/23/09 and opened the can of diet pepsi and took a swallow. I noticed that it tasted bad. So I poured some of it out and noticed the liquid coming out was a lighter color than what diet pepsi is. I saw something slimy and mucous like inside that looked like a mouse. I shook it a little to try and get it out. It wouldn't come out. I took it in the house and showed it to my wife when she looked in the can and then tried to pour out on a plate. I did not go to a doctor. I feel fine.

I have shown investigator Morris the refrigerator in my garage where I kept the cans and gave him the other can that was from that same case of sodas that we purchased on 07/18/09. The can that remains is unopened and the label reads in part: "XX diet pepsi XX OXX cal XX carb XX Sug XX 12 FL OZ (355 mL) XX." The bottom of the can reads in part: "XX 1417ESOS 259 XX SEP 07 09 XX". I have not put anything in the can and I certify that the above information is true and correct to the best of my recollection and I was given a copy of and read the Federal Anti-Tampering Act in the presence of Investigator Morris and we discussed it.

7/24/09

AFFIANT'S SIGNATURE AND TITLE

[Signature] 7/24/09

FIRM'S NAME AND ADDRESS (Include ZIP/Code)

Fred Joseph Denegri

Subscribed and sworn to before me at Ormond Beach, FL (City and State)

this 24th day of July, 2009

[Signature]

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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I am Amy G. Denegri, with residence at 111 Ocean Grove Dr., Ormond Beach, FL 32176. On 07/24/09, Randall L. Morris, Investigator with the U.S. Food and Drug Administration came to my residence to follow-up on a complaint # 93105 that my husband and I had filed to the FDA on 07/23/09.

I explained to Investigator Morris that on 07/18/09 my husband and I purchased (1) one (36) thirty-six count case of Diet Pepsi Soda at Sams Club of Daytona Beach, FL at (386) 760-3380. The thirty-six count case of Diet Pepsi purchased were labeled in part: "X* diet peps: O** Cal** Carb** Sug** 12 FL OZ (355ml) **". On July 23, 2009, after my husband opened the can and took a sip and told me and showed me that his side had a bad taste and had something in it, I poured the contents of the can onto a paper plate. I shook the can to get out the contents out. I noticed something slimy, shiny and mucous appearing partially out of the opening of the can. I thought it might be a mouse. I never touched it with my hands and I took photos of the can and the contents that were observed protruding from the can opening. I placed the can in a Ziplock bag, sealed it, dated it (7-23-09 6:45 pm) then called Poison Control (1-800-262-3171). Poison Control asked about my husband and how he was feeling. I told them my husband was ok but grossed out. Poison Control told me that if my husband developed stomach cramping to go to the emergency room and told me that she knew it was gross but that you don't normally get deathly ill from this. I searched the internet and found a link from FDA and called 866-637-6272 and left a voicemail. I also called the non-emergency number for the Volusia Sheriff's Office. The dispatcher told me that it was a civil suit and to get a lawyer. I put the soda can in the bag into the freezer because the dispatcher told me to. I retrieved the soda can in the ziplock bag from the freezer to give the UPC code or lot number to the FDA the next morning when FDA called. I called Sams Club in Daytona Beach and told the operations manager, Eddie about it. I received a phone call from [redacted]. She said she was from Customer Relations and was a Senior Manager for Pepsi out of Somers, New York. Her number is [redacted] and her other number is 800-433-2652. Her email is [redacted]. She apologized to me and asked if Pepsi could send a representative to take it to their lab and figure out what it is. I told her no, I want to keep it in my possession for a while. I told her that I had pictures and she asked if I would send them to her. I sent them. I have not heard anything else from Pepsi. Then Mr. Bennett from FDA called me to tell me that he had contacted Pepsi.

AFFIANT'S SIGNATURE AND TITLE

Amy G. Denegri July 24, 2009

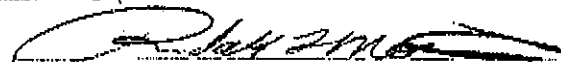
FIRM'S NAME AND ADDRESS (include ZIP Code)

Amy Denegri 111 Ocean Grove Dr. Ormond Beach, FL 32176

Subscribed and sworn to before me at

Ormond Beach, FL
(City and State)

this 24th day of July, 2009.


(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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I told him that I still had the can and I had sent photos to Papi's Mrs. Gromadski. I sent the photos to FDA and then you came here. I pulled the can out of the freezer when you called to tell me you were coming to see it.

I have shown Investigator Morris the can in the plastic bag and the extraneous material that was inside it.

Upon verification of the can inside the plastic bag, Investigator Morris turned the can over to pour out the contents and only some of the liquid inside and some of the extraneous material in the can ("a mouse") partially came out. The lot number on the bottom of the can was labeled in part: "XX 1417ES05259 XX SEP. 07 09 XX".

I provided Investigator Morris the opened can with the extraneous contents ("a mouse") and the plastic bag that I stored it in while in the freezer. I also gave him the paper plate that he tried to pour the contents out onto.

I certified that the above information is true and correct as to the best of my recollection and I was given a copy of and read the Federal Anti-Tampering Act in the presence of Investigator Morris and we discussed it.

AD 7/24/09
Btm 07/24/09

AFFIANT'S SIGNATURE AND TITLE

Amy G. Denegri July 24, 2009

FIRM'S NAME AND ADDRESS (include ZIP Code)

Amy G Denegri, [redacted], Ormond Beach, FL 32176

Subscribed and sworn to before me at Ormond Beach, FL

this 24th day of July, 2009.

[Signature]
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.