

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 528482

This is an accurate reproduction of the original electronic record as of 07/30/2009

Flag	Flag Remarks				
Complaint Sample	CC # 93105				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Investigational	09132276	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
1014171	07/24/2009	29BET50	Manufacturer	03R801	7
Compliance Num	Country of Origin				
	United States				
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	FLA-DO			Refrigerated
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No			93105	Diet Pepsi	

Product Description

Two Diet Pepsi Soda Cans, one open and one closed, one paper plate and one plastic zip lock bag

Product Label

Label reads in part: "****diet pepsi**0**cal***carb***sug***12 FL OZ (355mL)****" and printed code on bottom of can: "****1417ES05259***SEP 07 09****"

Reason for Collection	MFG Codes	Expiration Date
Collected Per FACTS Assignment ID #1073460, OP ID # 4280583 under PAC 03R801 for follow up to CC # 93105. Complainant alleged a foreign material inside can of drink soda. Please analyze per CP 7303.803 for filth and micro.	1417ES05259	07 09

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Pepsi Bottling Group, LLC	1700 Directors Row Orlando, FL 32809-6226 US	Manufacturer	1014171	

Size of Lot	Est. Value	Rept Type	Carrier Name	Date Shipped
1 case/36 Cans, 12 FL OZ (355mL)	\$ [REDACTED]	FDA484		

Description of Sample

See continuation.

(b)(4)

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"INV528482 07-24-09 RLM Sub 1-2/Open/Closed Controls"

Collector's Identification on Seal

"INV 528482 07-27-09 Randall L. Morris"

Sample Delivered To

Fed-Ex Tracking Number: 796808286823

Date Delivered

07/27/2009

Orig C/R & Records To

FLA-DO

Lab w/Split Sample

0

Lab

SRL

Document Number	Document Date	Document Type	Document Remarks
1	07/24/2009	Affidavit	Affidavit, Form FDA 463a, 2 pages, Read and signed by [REDACTED] 07/24/09.
2	07/24/2009	Affidavit	Affidavit, Form FDA 463a, 1 page, Read and signed by [REDACTED] on 07/24/09.

Date: 07/30/2009

Page: 1 of 3

(b)(6)

**Food and Drug Administration Office of Regulatory Affairs
Collection Report**

For Sample Number: 528482

This is an accurate reproduction of the original electronic record as of 07/30/2009

3	07/18/2009	Other	Sales receipt copy, provided by consumer for purchase of 36 count, case of Diet Pepsi from [REDACTED], dated, 07/18/09.
4	07/24/2009	Other	Email cover page, dated 07/24/09, 1 page and Photographs not dated, provided by consumer complainant on 7/24/2009 to Consumer Complaint Coordinator of FLA-DO via email attachment, 5 pages. (b)(6)
5	07/27/2009	Other	FDA-415a, broken seal. Seal broken on 07/27/09 to relabel Whirl Pak bags with "INV" prefix.

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	Yes	No	Randall L Morris
Name of Signer		Date & Time of Signature		Meaning
Randall L Morris		07/29/2009	05:34 PM ET	Collector

**Food and Drug Administration Office of Regulatory Affairs
Collection Report**

For Sample Number: 528482

This is an accurate reproduction of the original electronic record as of: 07/30/2009

Continuation:

Description of Sample

Sample consists of 1(one) opened, can, Diet Pepsi, 12 FL OZ (355mL), 1 (one) paper plate, and 1 (one) plastic zip lock bag labeled by complainant "7-23-09 6:45 pm"; 1 (one) unopened, can, Diet Pepsi, 12 FL OZ (355mL), opened controls-Whirlpak bag and sterile gloves, closed controls-Whirlpak bag and sterile gloves.

Method of Collection

1 (one) opened can of "Diet Pepsi", 1 (one) plastic bag it was stored in, and 1 (one) paper plate used to view contents of can, were aseptically collected from the complainant's kitchen counter, after complainant removed it from freezer. Also collected 1 (one) unopened can of "Diet Pepsi", volume 12 FL OZ (355mL) of the same lot, from the refrigerator in complainant's garage. Also collected opened controls and closed controls of gloves and whirlpak bags.

How Prepared

Sample coll.7/24/09, in WhirlPak, subs labeled w/sample ID, coll. date, coll. initials, sub no. Placed in Lg. WhirlPak, labeled w/sample ID, coll. date, initials, sub 1-2/Open/Closed Controls & sealed w/FDA415a. Safeguarded in sample prep room refrig. On 07/27/09, FDA415a broken-relabeled WhirlPaks w/"INV" prefix. Sealed w/FDA415a. Shipped to SRL via Fed-Ex, 07/27/09, in cooler w/gel packs.

Remarks

Sample consists of 1 (one) opened, can, Diet Pepsi, 12 FL OZ (355mL), 1 (one) paper plate, 1 (one) plastic bag labeled by complainant as "7-23-09 6:45 pm"; 1 (one) unopened, can, Diet Pepsi, 12 FL OZ (355mL), opened controls-Whirlpaks & sterile gloves, closed-controls-Whirlpak & sterile gloves; Samples were placed in Whirl Pak bags labeled with sample no., coll. date, coll. initials, and sub no. Both Sub Samples and open and closed controls were then placed in Lg. WhirlPakbags, taped shut, and sealed with FDA415a. Seal broken 7/27/09 to relabel each sub and controls with "INV". Resealed w/FDA 415a. FDA 525 placed over seal, placed in cooler with gel packs and shipped via Fed-Ex to SRL-LAB on 7/27/09. Sample safeguarded in sample prep room in refrigerator until shipment on 07/27/09.***Complainant requested copy of laboratory analysis-[704(d)]. Please send copy to consumer, addressed to attention of: [REDACTED]

(b)(6)

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 528482

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 08/07/2009

Sample Class: Normal Everyday Sample **Sample Origin:** Domestic **Sample Basis:** Compliance
Sample Flag: Complaint Sample **Sample Type:** Investigational **Collecting District:** FLA-DO
Home District: **Orig C/R and Records To:** FLA-DO **Collection PACs:** 03R801

Product Name: Soft Drink, Cola, Carbonated; Metal; Packaged Food (Not Commercially Sterile)

Product Description: Two Diet Pepsi Soda Cans, one open and one closed, one paper plate and one plastic zip lock bag

Collection Reason: Collected Per FACTS Assignment ID #1073460, OP ID # 4280583 under PAC 03R801 for follow up to CC # 93105. Complainant alleged a foreign material inside can of drink soda. Please analyze per CP 7303.803 for filth and micro.

Lab: SRL	Split Num 0	Date Received: 07/28/2009	Date Out of Lab: 08/05/2009
District		District Conclusion	District
Conclusion:		Made By:	
Disposition		Disposition	Disposition
Reason:		Authorized By:	Authorized Date

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SRL-CH1DF	03R801	C	NAR		4 - No Classification Required	Completed

Lab Conclusion

Sample was collected as part of consumer complaint # 93105. Sample was examined for the presence of foreign objects and to identify the foreign object submitted. One small animal appearing to be a frog or toad was removed from sub 1 (previously opened can). The animal was lacking internal organs normally found in the abdominal and thoracic cavity. No foreign objects were found in sub 2 (intact can).

Lab Conclusion Date **Lab Conclusion Made By**

08/05/2009 Love Harris, Cheryl L

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SRL-MBTG	03R801	M	ACD		1 - In Compliance	Original Completed

Lab Conclusion

Lab Conclusion Date **Lab Conclusion Made By**

08/07/2009 Hunsucker, Jeffrey C

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SRL-MBTG	03R801	M	MIC		1 - In Compliance	Original Completed

Lab Conclusion

One intact can examined had normal product odor and appearance. pH was 2.90, no microbes observed in direct smear and no growth recovered from culture media. Yeast and Mold count and Aerobic plate counts were both < 10 org/ml.

Lab Conclusion Date **Lab Conclusion Made By**

08/07/2009 Hunsucker, Jeffrey C

Date: 08/07/2009

Page: 1 of 1

RECEIVED
AUG 24 2009
FLA COMPLIANCE

FLAG Consumer Complaint - Original Analysis

ANALYST WORKSHEET		1. PRODUCT Two Diet Pepsi Soda Cans		2. SAMPLE NUMBER JAW528482	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 7-30-09	5. RECEIVED FROM Jacquelyn Welch		6. DISTRICT OF LABORATORY SRL
7. DESCRIPTION OF SAMPLE One plastic bag officially sealed "528482 7-30-09 Jacquelyn A. Welch" containing one whirlpak bag with broken Investigator's seal "INV528482 07-27-09 Randall L. Morris" affixed and identified "INV528482 07-24-09 RLM" containing two plastic whirlpak bags identified "INV528482 07-24-09 RLM" marked as subs 1 and 2. Sub 1 contains one plastic ziplock bag identified "7-23-09 6:45 RLM" containing one opened product can and a folded paper plate; Sub 2 contains one opened product can identified "528482 7-30-09 JAW" and three 4-oz. plastic specimen cups identified "528482 7-30-09 JAW" all marked as Sub 2, each cup containing product. Sample received intact, in good condition. Additional information on broken Investigator's seal: "INV 7/30/09".					
8. NET CONTENTS	<input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED UNITS EXAMINED	DECLARE/UNIT AMOUNT FOUND % OF DECLARED	9. LABELING	12 fl. oz. / 355ml ORIGINAL(S) SUBMITTED 1 COPIES SUBMITTED <input type="checkbox"/> NONE	
10. SUMMARY OF ANALYSIS Containers: 1) Investigator's plastic bag and whirlpak bags; Analyst's plastic specimen cups. 2) Consumer's plastic ziplock bag and paper plate. 3) aluminum can with pop-top lid measuring approx. 6.5cm dia. x 12cm H. Labeling: 1) none on plastic bag, whirlpak bags or specimen cups. 2) none on ziplock bag or paper plate. 3) aluminum can commercially printed. Code: "SEP 07 09 / 1417ES05259" printed on bottom of two cans. Product: a dark brown colored carbonated liquid and foreign object. Analysis: 1) identify foreign object. 2) examine product and empty product can for filth and foreign objects. Method: 1) macroscopic and microscopic examination. 2) AOAC 18 th ed. online Official Method 970.66B(a), Wet Sieving Technique. Each subsample washed on an 8" dia. No. 140 sieve. Retains from No. 140 sieve transferred to ruled filter paper and examined microscopically. Results: One small animal appearing to be a frog or toad, approx. 12.5 cm in length, removed from inside consumer's product can. The animal was lacking internal organs normally found in the abdominal and thoracic cavity. See Photos attached. No foreign material found in product from can received intact at laboratory.					
11. RESERVE SAMPLE Official seal was removed in order to access product, see attached. One plastic bag officially sealed "INV528482 7-30-09 Diana P. Zepp" containing one plastic whirlpak bag with broken Investigator's seal "INV528482 07-27-09 Randall L. Morris" affixed and identified as in #7 above containing two whirlpak bags as described in #7 above marked as subs 1 and 2. Sub 1 contains items as described in #7 above and one plastic petri dish identified "INV528482 7-30-09 DPZ" marked as sub 1; Sub 2 contains one opened product can identified "528482 7-30-09 JAW". Sample returned to Sample Custodian on 7-30-09. Additional information on broken Investigator's seal: "JAW 7/30/09".					
12. ANALYST SIGNATURE (Broken Seal)		13. WORK-SHEET CHECK		a. BY b. DATE	
Diana P. Zepp Julia A. Barron Confirmed Amphibian		[Signature]		8-3-2009	
c.		14. DATE REPORTED 8-3-2009			

A, B, C, D, E, F, G, H

Official Seals Attached - Attachments G, H

Two Diet Pepsi Soda Cans

INV528482

7-30-09

DPZ

Analysis/Method: See front of Page 1.

Results:

Sub1 - opened product can examined, an object was noted inside can. Upon removal of object from can, object was determined to be an apparent frog or toad, approx. 12.5cm in length. The animal was lacking internal organs normally present in the abdominal + thoracic cavity.

- No additional foreign material was recovered when can was rinsed with water.
- a paper plate saturated with liquid was observed inside plastic Ziplock bag.

Sub2 - No foreign material found in product or product can.

Confirmed Amphibian
Julia A. Baron
7/30/09

TWO Diet Pepsi Soda Cans

INV 528482

Reagents/Solutions used:

Tap Water

Deionized Water

Equipment used:

Whatman Schleicher & Schuell #8 ruled filter paper, 9cm dia. Lot 8016819

No. 230 sieve, 8" dia., ID # DZ-2 - sieve visually examined for defects prior to use. 7-30-09

Olympus SZ61 Dissecting Scope, Serial # 8F04136

Lenses and eyepieces on microscope cleaned at time of use. (V 7-30-09)

Digital Camera: HP Photosmart 945 Digital Camera, Serial # CN42HE107P

Photo Printer: HGP Business Inkjet 1200n, Serial # TH4BB110MH

Environmental Control: Petri dish lined with ruled filter paper moistened with water left open to environment by microscope during examination of sample. Results: Negative Positive: _____

Analyst(s)

Diana R Zapp

Page

2

of

2

pages

FLAG Consumer Complaint - *Additional Analysis*

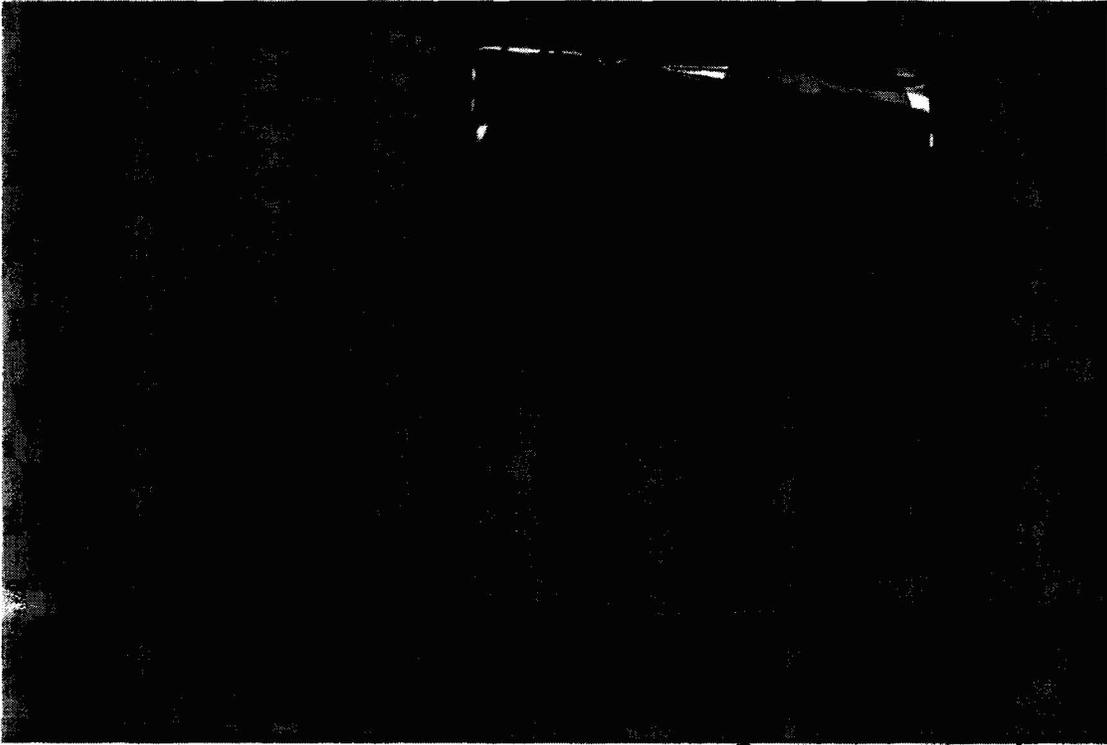
ANALYST WORKSHEET		1. PRODUCT Two Diet Pepsi Soda Cans		2. SAMPLE NUMBER INV528482	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> NONE <input checked="" type="checkbox"/> BROKEN		4. DATE REC'D 7-31-09		5. RECEIVED FROM Frank Goffigan	
6. DISTRICT OF LABORATORY SRL					
7. DESCRIPTION OF SAMPLE One plastic bag officially sealed "INV528482 7-30-09 Diana P. Zepp" containing one whirlpak bag with broken Investigator's seal "INV528482 07-27-09 Randall L. Morris" affixed and identified "INV528482 07-24-09 RLM" containing two plastic whirlpak bags identified "INV528482 07-24-09 RLM" marked as subs 1 and 2. Sub 1 contains one empty product can, one plastic ziplock bag identified "7-23-09 6:45 PM" containing a folded paper plate and one plastic petri dish identified "INV528482 7-30-09 DPZ" marked as sub 1; Sub 2 contains one opened product can identified "528482 7-30-09 JAW". Sample received intact and refrigerated. <i>Additional information on broken Investigator's seal: "JAW 7/30/09"</i>					
8. NET CONTENTS <input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED UNITS EXAMINED _____		DECLARE/UNIT AMOUNT FOUND _____ % OF DECLARED _____		9. LABELING ORIGINAL(S) SUBMITTED _____ COPIES SUBMITTED <u>1</u> <input type="checkbox"/> NONE	
10. SUMMARY OF ANALYSIS Containers: 1) Investigator's plastic bag and whirlpak bags; Analyst's plastic petri dish. 2) Consumer's plastic ziplock bag and paper plate. 3) aluminum can with pop-top lid measuring approx. 6.5cm dia. x 12cm H. Labeling: 1) none on plastic bag, whirlpak bags or petri dish. 2) none on ziplock bag or paper plate. 3) aluminum can commercially printed. Code: "SEP 07 09 / 1417ES05259" printed on bottom of two cans. Product: a dark brown colored carbonated liquid and foreign object. Analysis: 1) obtain additional photographic evidence of sample. 2) document product labeling. Method: 1) digital photographs taken of product can. 2) labeling from can documented by typing information printed on can and having information verified. Results: <i>see original worksheet.</i>					
11. RESERVE SAMPLE <i>Official seal removed in order to Access product, see attached.</i> One cardboard carton officially sealed on top and bottom "INV528482 7-31-09 Diana P. Zepp" containing one plastic whirlpak bag with broken Investigator's seal "INV528482 07-27-09 Randall L. Morris" affixed and identified as in #7 above containing two whirlpak bags as described in #7 above marked as subs 1 and 2. Sub 1 contains items as described in #7 above and one plastic petri dish identified "INV528482 7-30-09 DPZ" marked as sub 1; Sub 2 contains one opened product can identified "528482 7-30-09 JAW". Sample returned to Sample Custodian on 7-31-09. <i>Additional information on broken Investigator's seal: "JAW 7/30/09"</i>					
12. ANALYST SIGNATURE (Broken Seal) <i>Diana P. Zepp</i>		13. WORK-SHEET CHECK		a. BY <i>[Signature]</i> b. DATE <i>8-3-2009</i>	
c.		14. DATE REPORTED <i>8-3-2009</i>			

Attachment - A

INV528482

7-30-09

DPZ



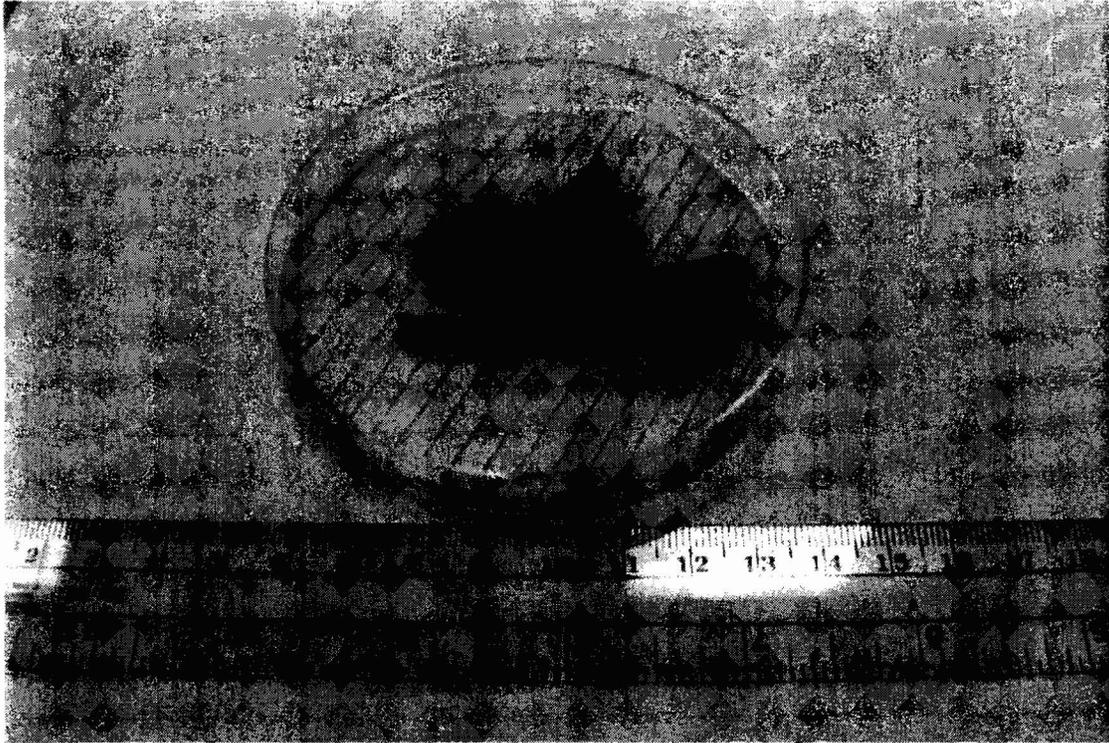
Sub 1 - Consumer's car and foreign object



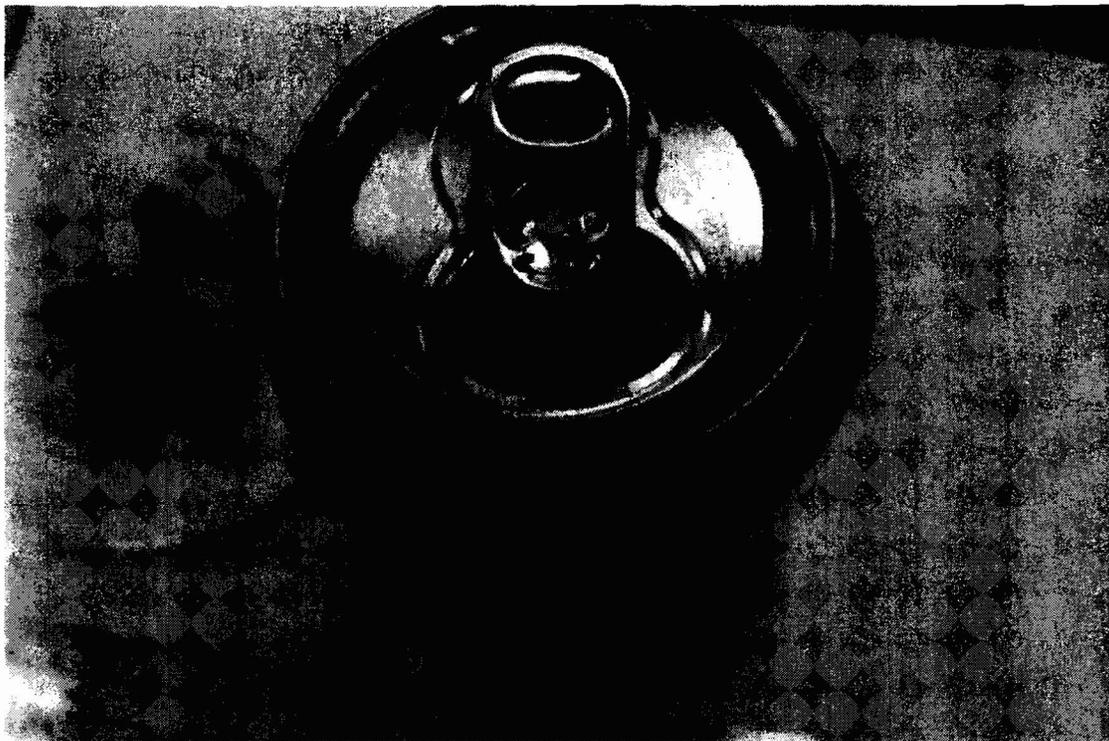
Sub 1 - Consumer's product car

Attachment-B

INV528482
7-30-09
DPZ



Sub 1 - Foreign object from Consumer's car



Sub 1 - Top of consumer's car + foreign object

Attachment - C

INV 528482

7-30-09

DPZ



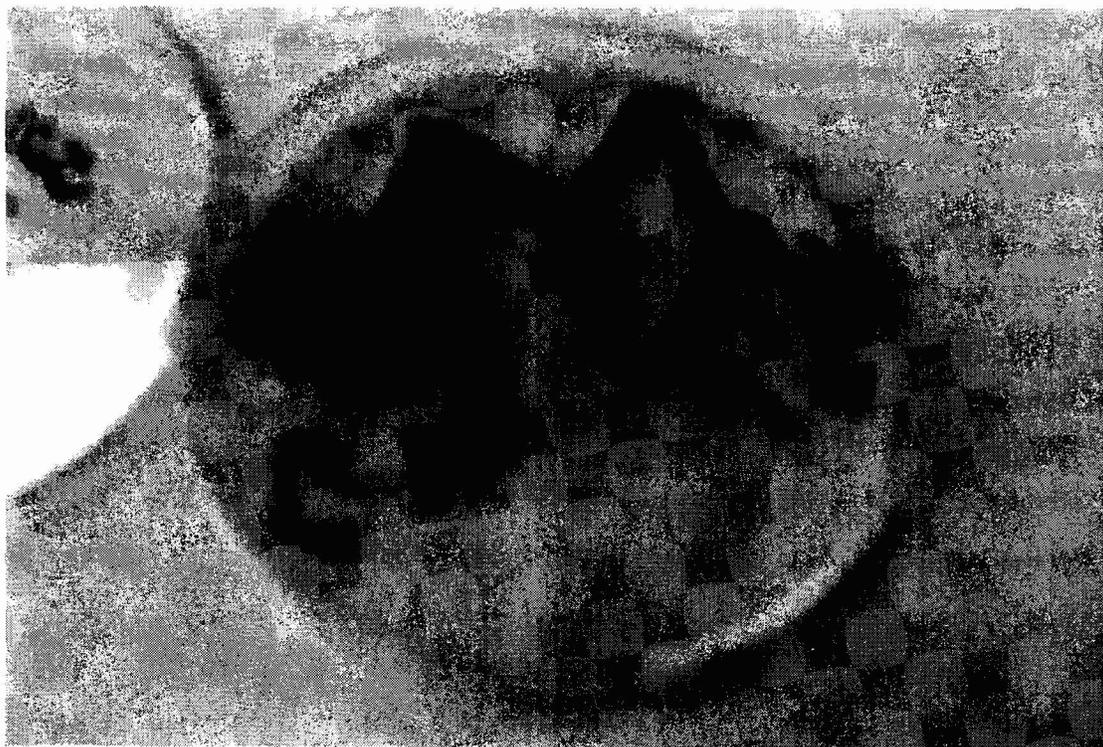
Sub 1 - Consumer's car and foreign object,
extended to show size

Attachment-D

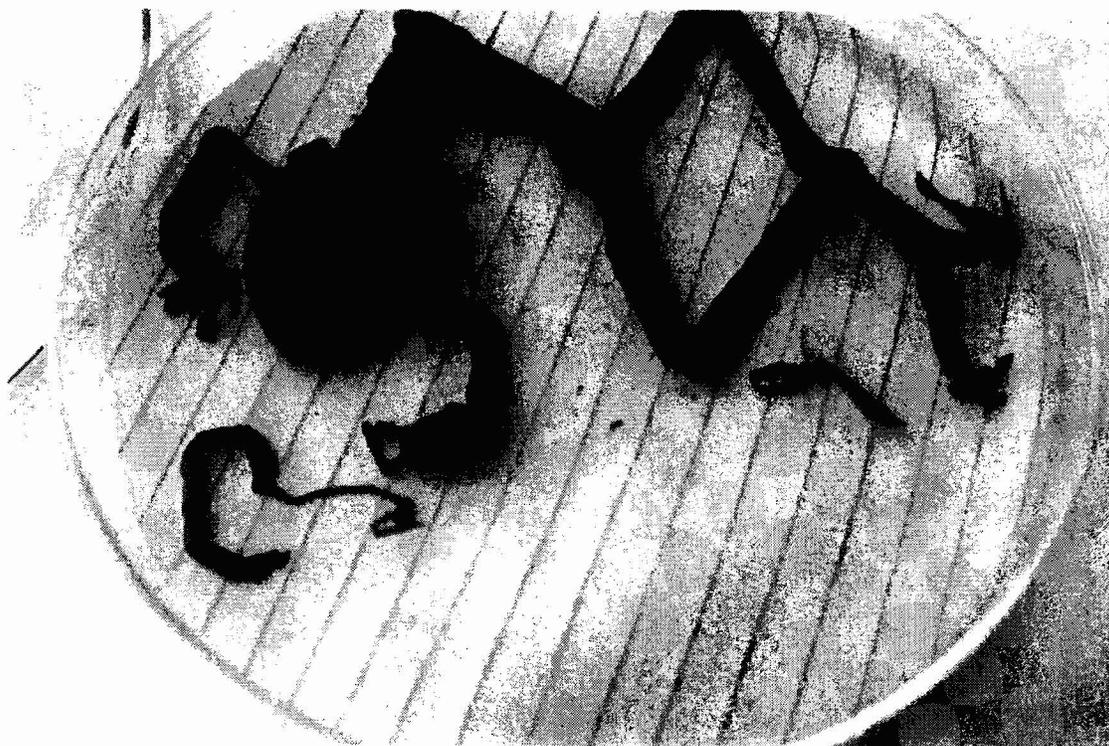
INV528482

7-30-09

DPZ



Sub 1 - Foreign object - Poor quality photo, see below



Sub 1 - Foreign object

Attachment-E

INV528482

7-30-09

DPZ



Sub 1 - Consumer's paper plate



Sub 2 - Consumer's paper plate

Attachment-F1

INV528482
7-31-09
DPZ



Sub 2 - Can Label



Subs 1 and 2 - Can codes

"SEP 07 09 / 1417ES05259"

Attachment - F2

INV528482
8-18-09
DPZ

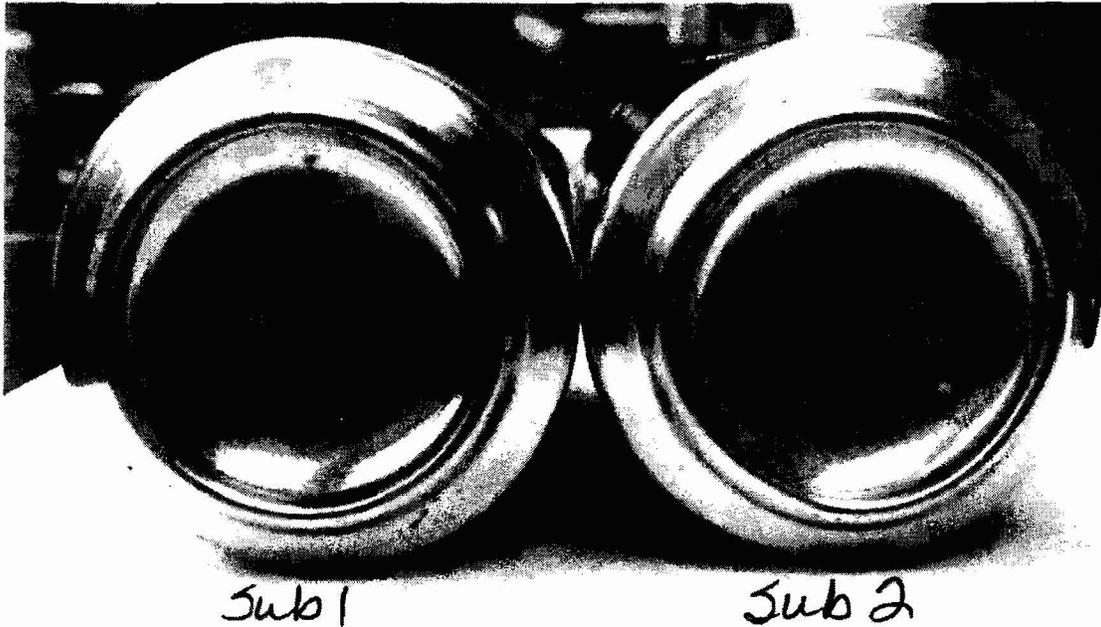


Photo of can codes in Attachment F1
Brightness adjusted for visual clarity

Attachment - G

INV 528482

7-30-09

DPZ

Analyst's Official Seal

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	 FDA	SAMPLE NO. 528482
		SIGNATURE <i>Jacquelyn A. Webb</i>
		PRINT NAME & TITLE (Investigator, Inc) Jacquelyn A. Webb

DATE 7-30-09		607E-6	FDA-115a (2/83)
Inspector (Analyst, etc.)			

Attachment-H

111V528482
7-30-09
DPZ

Analyst's Official Seal

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		 FDA	SAMPLE
SRL			SIGNATURE
			PRINT DIX

NO. 111V528482	DATE 7-30-09	 7-31-09	FDA-415a (2/83)
SIGNATURE Diana G. Papp			
NAME & TITLE (Investigator, Inspector, Analyst, etc.) Diana P. Papp Entomologist			

Labeling

INV528482

7-31-09

DPZ

Diet Pepsi Can Label:

"SUGAR FREE • VERY LOW SODIUM, 35MG or less per 240 ml (8 fl oz).

Nutrition Facts

Serving Size 1 Can

Amount Per Serving

Calories 0

	% Daily Value*
Total Fat 0g	0%
Sodium 35mg	1%
Total Carb. 0g	0%
Sugars 0g	
Protein 0g	

Not a significant source of other nutrients.

*Percent Daily Values are based on a 2,000 calorie diet.

CARBONATED WATER, CARAMEL COLOR, ASPARTAME, PHOSPHORIC ACID, POTASSIUM BENZOATE (PRESERVES FRESHNESS), CAFFEINE, CITRIC ACID, NATURAL FLAVOR.

PHENYLKETONURICS: CONTAINS PHENYLALANINE.

CAFFEINE CONTENT: 35mg/12 fl oz.

WWW.PEPSI.COM

Product questions? 1-800-433-2652

MANUFACTURED BY INDEPENDENT BOTTLERS ^{7-31-09 BAE} UNDER THE AUTHORITY OF PEPSICO, INC, PURCHASE, NY 10577.

PEPSI and the Pepsi Globe are trademarks of PepsiCo, Inc.

PLEASE RECYCLE

BEST TASTE

DRINK BY DATE ON BOTTOM OF CAN

24-101

9 05 08 N 4 MA

12 FL OZ
(355 mL)"

verified by Christine P Cosh
Christine P Cosh

date: July 31, 2009

FLAG Consumer Complaint, Additional Analysis # 2

ANALYST WORKSHEET		1. PRODUCT Two Diet Pepsi Soda Cans		2. SAMPLE NUMBER INV528482	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 8-4-09		5. RECEIVED FROM Frank Goffigan	
7. DESCRIPTION OF SAMPLE One cardboard carton officially sealed on top and bottom "INV528482 7-31-09 Diana P. Zepp" containing one whirlpak bag with broken Investigator's seal "INV528482 07-27-09 Randall L. Morris, 7-30-09 JAW" affixed and identified "INV528482 07-24-09 RLM" containing two plastic whirlpak bags identified "INV528482 07-24-09 RLM" marked as subs 1 and 2. Sub 1 contains one empty product can, one plastic ziplock bag identified "7-23-09 6:45 PM" containing a folded paper plate and one plastic petri dish identified "INV528482 7-30-09 DPZ" marked as sub 1; Sub 2 contains one opened product can identified "528482 7-30-09 JAW". Sample received intact and refrigerated.					
8. NET CONTENTS <input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED UNITS EXAMINED _____		DECLARE/UNIT AMOUNT FOUND % OF DECLARED		9. LABELING ORIGINAL(S) SUBMITTED COPIES SUBMITTED - with <input checked="" type="checkbox"/> NONE Original worksheet	
10. SUMMARY OF ANALYSIS Containers: 1) Analyst's cardboard carton and plastic petri dish; Investigator's whirlpak bags. 2) Consumer's plastic ziplock bag and paper plate. 3) aluminum can with pop-top lid measuring approx. 6.5cm dia. x 12cm H. Labeling: 1) none on carton, petri dish or whirlpak bags. 2) none on ziplock bag or paper plate. 3) aluminum can commercially printed. Code: "SEP 07 09 / 1417ES05259" printed on bottom of two cans. Product: a dark brown colored carbonated liquid and foreign object. Analysis: display sample for FDA Commissioner's visit to laboratory. Method: sample removed from carton and displayed in laboratory. Results: See Original Worksheet.					
11. RESERVE SAMPLE One cardboard carton officially sealed on top "INV528482 8-4-09 Diana P. Zepp" and bottom "INV528482 7-31-09 Diana P. Zepp" and identified "INV528482 7-31-09 DPZ" with broken Analyst's seal "INV528482 7-31-09 Diana P. Zepp, 8-4-09 DPZ" affixed containing one plastic whirlpak bag with broken Investigator's seal "INV528482 07-27-09 Randall L. Morris, 7-30-09 JAW" affixed and identified as in #7 above containing two whirlpak bags as described in #7 above marked as subs 1 and 2. (Continued on Page 2).					
12.a. ANALYST SIGNATURE (Broken Seal) <i>Diana P. Zepp</i>		13. WORK-SHEET CHECK		a. BY <i>Christina P. C.</i>	
b.				b. DATE <i>8/4/09</i>	
c.		14. DATE REPORTED <i>8-4-09</i>			

GENERAL CONTINUATION SHEET

PRODUCT

TWO DIET PEPSI SODA CANS

SAMPLE NO.

INV 528482

11. (Continued): Sub 1 contains items as described in #7 above and one plastic petri dish identified "INV528482 7-30-09 DPZ" marked as sub 1; Sub 2 contains one opened product can identified "528482 7-30-09 JAW". Sample returned to Sample Custodian on 8-4-09.

Analyst(s)

Diana Z Bepp

Page

2

of

2

pages

FLAG

ANALYST WORKSHEET		1. PRODUCT Diet Pepsi	2. SAMPLE NO. 528482
3. SEALS <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> NONE <input type="checkbox"/> BROKEN	4. DATE RECEIVED 7/30/09	5. RECEIVED FROM Dexter Smith	6. DIST OR LABORATORY SRL

7. DESCRIPTION OF SAMPLE
 One plastic bag FDA 525 attached "INV528482 07/27/2009 Randall L. Morris" containing one plastic bag FDA sealed "INV528482 07-27-09 Randall L. Morris" containing two whirlpak bags id in part "528482 07-24-09 RLM" and Sub 1-2; Sub 1 containing one Ziploc bag containing one manufacturer's empty can of product plus a folded paper plate; Sub 2 contained one intact manufacturer's can of product weighing approx. 355 net grams received refrigerated and in good condition from Dexter Smith, SRC, on 7/30/09. Investigator's controls included open/closed gloves and whirlpak bags.

8. NET CONTENTS	<input type="checkbox"/> NOT APPLICABLE	DECLARED/UNIT	9. ORIGINALS SUBMITTED
	<input checked="" type="checkbox"/> NOT DETERMINED	AMOUNT FOUND	LABEL <input type="checkbox"/> COPIES SUBMITTED
	<input type="checkbox"/> UNITS EXAMINED	% OF DECLARED	-ING <input checked="" type="checkbox"/> SEE CHEMISTRY WORKSHEET

10. SUMMARY OF ANALYSIS **Analysis began on 7/30/09.**

CONTAINER: Aluminum can measuring approx. 6.5 cm diam. X 12 cm ht.

LABELING: Multi-colored ink commercially printed on aluminum can.

CODE: "SEP 07 09
1417E805259" stamped in black ink on bottom of can.

PRODUCT: Bubbly brown fluid resembling cola.

ANALYSIS: One sub analyzed for yeast and mold count, aerobic plate count, pH, direct product smear, and cultural enrichment. Positive and negative controls analyzed concurrently.

METHOD: See pages 2, 4, 6

RESULTS: Yeast and mold count less than 10 YM/ml; APC less than 10 APC/ml; pH 2.90; no microorganisms noted in direct product smear nor recovered in culture; product had a normal odor and appearance.

11. RESERVE SAMPLE
 One plastic bag FDA 525 attached as above and FDA sealed "528482 7-30-09 Jacquelyn A. Welch" containing one plastic bag with the broken investigator's seal containing two whirlpak bags; Sub 1 id as above and intact as received; Sub 2 id as above and "528482 7-30-09 JAW" containing one empty manufacturer's can and 3 specimen cups id "528482 7-30-09 JAW" of product weighing a total of approx. 300 grams transferred to Diana Zepp, SRL chemist, on 7/30/09 for filth analysis.

12. a. ANALYST SIGNATURE (BROKE SEAL) <i>JAW</i> Jacquelyn A. Welch <i>Jacquelyn A. Welch</i>	13. WORK SHEET CHECK	a. BY <i>J. H. ...</i>
b.		b. DATE 8/2/09
c.	14. DATE REPORTED	8-6-09

YEASTS AND MOLDS
PREP AND QCR SHEET

PRODUCT:
Diet Pepsi

SAMPLE NO.
528482

SAMPLE PREPARATION FOR YEASTS AND MOLDS:

Product decimal dilutions of 10^{-1} to 10^{-2} were prepared by removing 10 ml from previous dilution to 90 ml of peptone water and shaking vigorously.

PLATING OF SAMPLE:

JAW SPREAD-PLATE METHOD: Aseptically pipet 0.1 ml of product and each subsequent product dilution, in triplicate, on pre-poured, solidified DRBC agar plates and spread plates evenly with sterile bent glass rod. Note: DG18 agar is preferred when the water activity of the sample is less than 0.95.

NA POUR-PLATE METHOD: Aseptically pipet 1.0 ml of each dilution, in triplicate into petri plates and immediately add 20-25 ml tempered DG18 agar. Mix contents by gently swirling. Note: After adding sample dilution, add agar within 1-2 min, otherwise dilution may begin to adhere to dish bottom.

INCUBATION: Incubate plates in the dark at 25°C. Do not stack plates higher than 3 and do not invert. Count plates after 5 days of incubation. If there is no growth at 5 days, re-incubate for another 48 hrs.

METHOD: BAM, On-Line Version.

METHOD MODIFICATION:

RESULTS: No yeast or mold (less than 10 YU/ml) recovered in one of one sub examined. Positive control tested positive; negative controls tested negative.

MEDIA AND EQUIPMENT:

BLENDER _____ STERILE SPOON _____
INCUBATOR: 35°C SRL# 8, 10, 20 25°C SRL# F20 Refrigerator: 4°C SRL# 11
BALANCE # _____ WEIGHT CHECK _____ YES _____ NO _____
EXPOSURE PLATES; _____
0.1% PEPTONE WATER (R-56): 450 ML _____ 90 ML _____
DICHLORAN ROSE BENZYL CHLORAMPHENICOL (DRBC) AGAR (M-183) _____
DICHLORAN 18% GLYCEROL (DG18) AGAR (M-184) _____
MALT AGAR (MA) (M-185) _____
POTATO DEXTROSE AGAR (PDA) (M-127) _____
TSA-YE 2011003
POSITIVE CONTROLS
C-24 *Candida albicans* C-25 *Saccharomyces cerevisiae* JAW
C-26 *Aspergillus niger*

N.A. = Not Applicable

ANALYST(S)

Jacqueline G. Melchior

PAGE 2 OF 8 PAGES

FROZEN/PREPARED
FOODS ANALYSIS

PRODUCT:
Diet Pepsi

SAMPLE NUMBER.
528482

SAMPLE PREPARATION:

Decimal dilutions of 10^{-1} to 10^{-2} prepared by adding 10 mls of sample and previous dilution to 90 mls of sterile buffer.

DETERMINATION:

JAW APC: 0.1 ml from sample and appropriate dilutions pipetted to duplicate TSA-YE plates and spread evenly with a sterile spreader.

NA Coliforms and/or E. coli Most Probable Number/g (MPN/g): One ml from appropriate dilutions pipetted to three/five tubes of sterile LST.

NA S. aureus:

- One ml from appropriate dilutions pipetted to triplicate tubes of sterile TSB with 10% salt and 1 % sodium pyruvate.
- One ml from appropriate dilutions spread on triplicate plates of Baird-Parker Agar (0.3, 0.3, 0.4 ml).

METHODS:

JAW APC: AOAC, On-Line Version, Section 966.23C.

NA Coliforms: AOAC, On-Line Version Section 966.23, Chilled, Frozen, Precooked or Prepared Foods; Section 966.24, Tree Nut Meats.

— E. coli: AOAC, On-Line Version, Section 966.23 Chilled, Frozen, Precooked or Prepared Foods; Section 966.24 Tree Nut Meats.

— E. coli: BAM, On-Line Version, Chapter 4, LST-MUG Method for Detecting E. coli in Chilled or Frozen Foods Exclusive of Bivalve Molluscan Shellfish.

— S. aureus: MPN - BAM, On-Line Version, Chapter 12, Most Probable Number Method.

↓ S. aureus: Direct Plating - BAM, On-Line Version, Chapter 12, Direct Plate Count Method.

MODIFICATIONS: 0.1% peptone water used as diluent in conjunction with yeast and mold plate count.

RESULTS: Less than 10 APC/ml in one of one sub examined. Positive control tested positive; negative controls tested negative.

N.A. - Not Applicable

ANALYST (S)

Jaqueline A. Melby

PAGE 4 OF 8 PAGES

CANNED FOOD ANALYSIS

PRODUCT:

Diet Pepsi

SAMPLE NO.

528482

SAMPLE PREPARATION : Exterior of cans were examined for damage and defects. Containers were cleaned and sanitized prior to opening. Containers were opened with flame sterilized bacteriological can opener. For swollen cans, portion of headspace gas was tested for presence of carbon dioxide and hydrogen gas. One gm/ml of product was transferred to duplicate sterile tubes of the following:

NA CM and BCP for 35°C incubation JAW AB and ME for 30°C incubation
NA CM and BCP for 55°C incubation JAW AB for 55°C incubation

Remaining product used for direct smear, pH, organoleptic evaluation and aseptic reserve.

NA cans incubated for ___ days at 35°C.

JAW cans examined by hand and eye for defects. NA micro-leak tests performed using NFDA vacuum leak test. NA cans double seams measured and evaluated using micrometer and seam scope. NA Headspace Gas tested using Fisher Model 1200 Gas Partitioner.

METHOD: BAM, On-Line Version, JAW Chapter 21A- Examination of Canned Foods; NA Chapter 21B- Modification of Headspace Gas Analysis Methodology, Using the SP4270 Integrator; NA Chapter 22A-Examination of Metal Containers for Integrity; NA Chapter 22B-Examination of Glass Containers for Integrity; NA Chapter 22C- Examination of Flexible and Semirigid Containers for Integrity; JAW Chapter 22D-Examination of Containers for Integrity: Glossary and References.

MODIFICATIONS:

RESULTS:

Product had a normal odor and appearance with a pH of 2.90. No microorganisms noted in direct smear nor recovered in culture. Positive controls tested positive; negative controls tested negative.

N.A. = Not Applicable

ANALYST

Joseph A. Welch

PAGE 6 OF 8 PAGES

SUBSAMPLE NUMBER		1	C-25	C-30	media	system	investigator's			
CODE		SEP 07 09 1417E805259				Control	Control			
CONTAINER CONDITION	C/R DESCRIPTION	NA								
	BEFORE INCUBATION									
	AFTER INCUBATION									
	NO. DAYS INCUBATED									
	INTERNAL		Normal							
	SEAM EXAMINATION		NA							
PRODUCT	MICRO-LEAK									
	pH	2.90								
	ODOR AND APPEARANCE	Normal								
	SMEAR	no microorganisms noted								
GAS		NA								
CULTURE TESTS	COOKED LIVER (Cooked Meat)	35°C	NA							
		55°C								
	BROM-CRESOL PURPLE BROTH	35°C								
		55°C								
	ACID BROTH	30°C		NG	NG	G	NG	NG	NG	
		55°C		NG	NG	G	NG	NG	NG	
MALT EXTRACT	30°C	NG	NG	G	NG	NG	NG			
MICROSCOPIC EXAMINATION		NA								
SUMMARY		pH: 2.90 Product had a normal odor and appearance. No microorganisms noted in direct smear nor recovered in culture.		Positive controls tested positive.		Negative controls tested negative.				

ANALYST(S)

Jacqueline A. Welch

PRODUCT:

Diet Pepsi

PAGE 7 OF 8 PAGES

SAMPLE NUMBER
528482

NA = not applicable



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161

August 12, 2009

[Redacted]

(b)(6)

Re: FDA Sample No. 528482
Consumer Complaint: 93105

Dear [Redacted]

(b)(6)

We have examined One (1), Intact can of Diet Pepsi examined for yeast and mold count, aerobic plate count, pH, direct product smear, and cultural enrichment, collected from you on 7/24/09 by FDA Investigator, Randall L. Morris.

The product had a normal odor and appearance. No microorganisms recovered in culture.

You may be sure that prompt investigation is made when a product appears to be in violation of the law. Thank you for taking the time to report your experience to us. Reports from concerned consumers, as yourself, are an invaluable asset to our regulatory efforts.

If you have any questions regarding this letter, please write or call the Director of Compliance, Florida District Office, and refer to sample number 528482.

Jim Walthall
Food and Drug Administration
655 Winderley Pl, Room 200
Maitland, FL 32751
(407) 475-4734

Sincerely,

Lurlene G. Effatt
Director of Microbiology

cc: FLA-DO
w/Sample ✓
HFR-SE670
JAW /JAC/08/12/09



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Southeast Regional Laboratory
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1160
FAX: 404-253-1208

 COPY

August 17, 2009



(b)(6)

RE: Our Sample Number: 528482
Diet Pepsi Soda

We have examined the samples collected on 07/24/2009 by FDA Investigator, Randall L. Morris, in connection with your recent complaint. We tested the opened and unopened cans of product for foreign objects. Our analysis detected a foreign object, that appears to be a frog or toad, in the opened can of product. We did not detect any foreign objects in the unopened product container.

If you have any further questions or concerns regarding these samples, please call or write:

Jimmy Walthall
Director Compliance Branch
U. S Food and Drug Administration
Florida District Office
555 Winderley Place, Room 200
Maitland, FL 32751
407-475-4734

The remaining portion of the samples will be destroyed 30 days from the above date unless instructions are received from you to return it.

We wish to thank you for your interest in providing assistance for the protection of the consumer.

Sincerely,

Edwin C. Phifer
Director, Chemistry I Branch

CC: HFR-SE660