


**DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration**

REPORT OF SAMPLE ANALYSIS

FROM: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION SOUTHEAST FOOD & FEED LABORATORY 60 8TH STREET, N.E. ATLANTA, GEORGIA 30309	 REFERENCE TO THE REPORT OF ANALYSIS IS PROHIBITED IN LABELING, ADVERTISING, OR OTHER SALES PROMOTION.
TO: Kevin R. Corbett, Plant Manager RedBarn Pet Products, LLC 30 SE 10 th Rd. Great Bend, KS 67570	FDA SAMPLE NUMBER DI960005
	DATE SAMPLE COLLECTED 2/8/2018
	COLLECTING INSPECTOR Monica M. McClure

DESCRIPTION OF SAMPLE
 Sample consists of 10 whirl-pak bags of bulk 5" dried Bully Sticks.


ESTABLISHMENT WHERE SAMPLE COLLECTED (If other than addressee)

REASON FOR SUBMISSION OF REPORT	<input checked="" type="checkbox"/> SECTION 704(d) OF THE FEDERAL "FOOD, DRUG, AND COSMETIC ACT" <input type="checkbox"/> OTHER--In Cooperation with growers
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REPORT OF ANALYSIS

Analysis	Results
One (1) - ten (10) sub composite analyzed for Salmonella spp.	Salmonella spp. poly A recovered in one (1) - ten (10) sub composite analyzed.

If you have any questions concerning this letter, please call Miguel Hernandez, Director of Compliance, Kansas District Office at (913)-495-5101.

SIGNATURE 	TITLE Steven B. Simpson, Director of Microbiology	DATE 2/28/18
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SFFL Microbiology Routing Sheet

FACTS# RI960005

Route Worksheet To:

Email/Scanned

HAFW2

Miguel Hernandez

KAN District

8050 Marshall Drive, Suite 205
Lenexa, Kansas 66214

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 960005

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 03/01/2018

Sample Class: Normal Everyday Sample **Sample Origin:** Domestic/Import **Sample Basis:** Compliance
Sample Flag: Dealer Voluntarily Holding **Sample Type:** Official **Collecting District:** HAFW2
Home District: **Orig C/R and Records To:** KAN-DO **Collection PACs:** 71003E

Product Name: Pizzles, Beef, Pet Chews (Non-Nutritive); Flex Plastic; Ntrl/Artfcl Dried

Product Description: Bulk 5" dried Bully Sticks stored in cardboard combo's

Collection Reason: Collected during RFR/Recall follow up inspection of dealer 2/7-8/18; analysis; micro - Salmonella sp

Lab: SFFL	Split Num: 0	Date Received: 02/12/2018	Date Out of Lab: 03/01/2018
District		District Conclusion	District
Conclusion:		Made By:	
Disposition Reason:		Disposition Authorized By:	Disposition Authorized Date:

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SFFL-MB-K	71003E	M	MIC		3 - Adverse Findings	Completed

Lab Conclusion

Salmonella Poly A recovered from 1/10 sub composite examined.

Lab Conclusion Date **Lab Conclusion Made By**

02/27/2018 Suktankar, Vilasini S

Lab: SFFL	Split Num: 1	Date Received:	Date Out of Lab:
District		District Conclusion	District
Conclusion:		Made By:	
Disposition Reason:		Disposition Authorized By:	Disposition Authorized Date:

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SFFL-MB-K	71003E	M	MIC			Assigned

Lab Conclusion

Lab Conclusion Date **Lab Conclusion Made By**

Lab: SFFL	Split Num: 2	Date Received:	Date Out of Lab:
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Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 960005

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 03/01/2018

District Conclusion:				District Conclusion Made By:		District
Disposition				Disposition		Disposition
Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SFFL-MB-D	71003E	M	MIC			Assigned
Lab Conclusion						
Lab Conclusion Date				Lab Conclusion Made By		

Lab: ARKL	Split Num:3			Date Received:		Date Out of Lab:
District Conclusion:				District Conclusion Made By:		District
Disposition Reason:				Disposition Authorized By:		Disposition Authorized Date:

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
ARKL	71003E		MIC			Pending
Lab Conclusion						
Lab Conclusion Date				Lab Conclusion Made By		

FLAG

ANALYST WORKSHEET		1. PRODUCT Bulk 5" dried Bully Sticks		2. SAMPLE NUMBER DI960005	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 2/14/2018		5. RECEIVED FROM Jessie Oliver	
6. DISTRICT OF LABORATORY SFPL					
7. DESCRIPTION OF SAMPLE One brown cardboard box with attached form FDA-525 identified "960005 2/8/18 M. McClure" containing one clear plastic bag officially sealed "960005 2/8/18 Monica M McClure, Investigator" further identified "960005 2/8/18 MMM" containing 10 subs of product identified "960005 2/8/18 MMM" subs numbered 1-10. Subs weigh approximately 260g each. Also containing closed whirl-pak bag and closed gloves identified "960005 2/8/18 MMM" subs a and b respectively as investigator controls. Sample was received intact, in good condition, at room temperature from Jessie Oliver (SRC) on 2/24/2018. <i>Discrepancy: CR states collector's identification</i>					
8. on Seal as "960005 2/8/18 Monica M. McClure, Investigator" Sample should also be identified as DI for domestic/import.					
NET CONTENTS <input checked="" type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> NOT DETERMINED UNITS EXAMINED _____		DECLARE/UNIT _____ AMOUNT FOUND _____ % OF DECLARED _____		LABELING ____ ORIGINAL(S) SUBMITTED ____ COPIES SUBMITTED <input checked="" type="checkbox"/> NONE	
10. SUMMARY OF ANALYSIS Analysis began on 2/14/2018					
CONTAINER: Whirl pak bag measuring approximately 37cm long x 19cm wide.					
LABELING: None.					
CODE: None noted by analyst.					
PRODUCT: Thin dark brown to black cylindrical objects with a meaty odor, resembling 5" dried Bully Sticks.					
ANALYSIS: One (1) - ten (10) sub composite analyzed for <i>Salmonella</i> spp. Positive and negative controls analyzed concurrently. Investigator controls analyzed.					
METHOD: See page 2.					
RESULTS: <i>Salmonella</i> spp. poly A recovered from one (1) - ten (10) sub composite analyzed. Positive controls tested positive. Negative and investigator controls tested negative. See page 2.					
11. RESERVE SAMPLE One brown cardboard box identified as in #7 above and further identified "DI960005 2/14/18 APO" containing one clear plastic bag officially sealed "DI960005 2/14/18 Ashley P. O'Neill, Analyst" and identified as in #7 above and further identified "DI960005 2/14/18 APO" containing 10 subs of product identified as in #7 above and further identified "DI960005 2/14/18 APO". Approximately 223.4g remain in all subs. Sample was kept in a locked cabinet from 2/14/2018 to 2/23/2018 and then returned to Frank Goffigan (SRC) for room temperature storage on 2/23/2018. Official broken seal identified "960005 2/8/18 Monica M McClure, Investigator APO 2/14/18" was retained with the sample. Three TSA-YE plates and one BHI slant identified "DI960005 MTTXLD-2 SLM Poly A 2/23/2018 APO" transferred to SFPL for PFGE, whole genome sequencing, VITEK MS, and to SFPL QA department for isolate retention. One BHI slant officially sealed "DI960005 2/26/2018 Ashley P. O'Neill, Analyst" and further identified "DI960005 MTTXLD-2 SLM Poly A 2/23/2018 APO" transferred to ARKL for further serotyping.					
12. a. ANALYST SIGNATURE (Broke Seal) <i>Ashley P. O'Neill</i> <input checked="" type="checkbox"/>		DATE 2-23-18		13. WORK-SHEET CHECK a. BY <i>[Signature]</i> b. DATE 2/27/18	
b. <i>[Signature]</i>		c. <i>[Signature]</i>		14. DATE REPORTED 2/27/18	

TCB - transferred to M-broth. ran VIDAS for
Salmonella. struck BS, HE, and XLD plates.

DI 960005

2/23/18

APD

MEB - Read 24hr BS, HE, and XLD plates. Inoculated
TSI, LIA, and urea tubes.

VT - Read 48hr BS plates. Read TSI, LIA, and
urea tubes.

All other work performed by APD.

Ashley P. O'Neill

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SALMONELLA ANALYSIS SHEET	PRODUCT: Bulk 5" dried Bully Sticks	SAMPLE NO: DI960005
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SAMPLE PREPARATION:

APO COMPOSITE: 1 Composite unit(s) examined. A composite unit was prepared by aseptically removing 37.5grams of product from each of 10 subs and placed into a sterile container; total weight of composite 375 grams. A total of 3375 mls sterile broth was added.

N/A INDIVIDUAL: Individual unit(s) examined. A unit was prepared by aseptically removing grams of product into mls of sterile broth and homogenated for 2 minutes at high speed.

METHOD: AOAC Official Method 2004.03. *Salmonella* in Foods, Enzyme-Linked Fluorescent Assay (ELFA) Screening Method. Official Methods of Analysis of AOAC International, current edition. Bacteriological Analytical Manual Online: Chapter 5.
<http://www.cfsan.fda.gov/~ebam/bam-toc.html>

MODIFICATIONS: None.

RESULTS: *Salmonella* spp. poly A was recovered from one (1) - ten (10) sub composite analyzed.
Positive controls tested positive.
Negative and investigator controls tested negative as indicated by absence of growth.

N.A.=NOT APPLICABLE

ANALYST(S) 	PAGE <u>2</u> OF <u>12</u> PAGES
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SALMONELLA RECORD

PRODUCT: Bulk 5" dried Bully Sticks

SAMPLE NO. DI960005

SUMMARY OF RESULTS

Negative control negative as indicated by absence of growth.

Investigator control negative as indicated by absence of growth.

Investigator control negative as indicated by absence of growth.

Table with columns for various tests: POLY-O, INDOLE, VITEK SEE PG., UREASE, OXIDASE, LIA (GAS, H2S, BUTT, SLANT), TSI (GAS, H2S, BUTT, SLANT), SELECTIVE AGAR (BS, HE, XLD).

A=ACID R=RED T=TYPICAL AT=ATYPICAL NT=NOT TYPICAL K=ALKALINE NG=NO GROWTH G=GROWTH += POSITIVE -=NEGATIVE

Vertical text on the left margin: 12/18/18, 217-8468, APC, INITIAL/DATE: 2/14/18

VIDAS See Page, VIDAS/M-BROTH (RESULTS, DATE/TIME, INITIAL), SELECTIVE ENRICH (RV, TT), PRE-ENRICH (LB, TSB, NFDM, UPB, BG), SUB/COMP. (Bag, A-C-bag, B-C-gloves)

ANALYST (S) Ash P. O'Connell, Adamee Bay, Signature

SALMONELLA RECORD

PRODUCT: Bulk 5" dried Bully Sticks

SAMPLE NO. DI960005

SUMMARY OF RESULTS

Salmonella spp. poly Arecovered.

Positive control positive.

Positive control positive.

Table with columns for test results including POLY-O, A-I + Vi, POLY-H a-z, INDOLE, VITEK SEE PG., UREASE, OXIDASE, LIA (GAS, H2S, BUTT, SLANT), TSI (GAS, H2S, BUTT, SLANT), and SELECTIVE AGAR (BS, HE, XLD). Includes handwritten '8' and '11' in the VITEK SEE PG. column.

A=ACID R=RED T=TYPICAL AT=ATYPICAL NT=NOT TYPICAL K=ALKALINE NG=NO GROWTH G=GROWTH += POSITIVE -=NEGATIVE

VIDAS See Page

RESULTS (Circle One): POSITIVE NEGATIVE DATE/TIME VIDAS WAS RUN ___/___/___ am/pm Initial DATE/TIME TRANSFERRED TO M-BROTH ___/___/___ am/pm Initial

RESULTS (Circle One): POSITIVE NEGATIVE

RESULTS (Circle One): POSITIVE NEGATIVE

SELECTIVE ENRICH RV TT

RV TT

RV TT

RV TT

PRE-ENRICH LB TSB NFDM UPB BG

LB TSB NFDM UPB BG

LB TSB NFDM UPB BG

LB TSB NFDM UPB BG

SUB/COMP. 1

C-62

C-94

ANALYST(S)

Ashy P. O'Neil Melanie Ray

Bulk 5" dried Bully Sticks

DI960005
2/12/18
APO

FDA Southeast Food&Feed Laboratory
VIDAS A1 (5134696); A2 (5040202)

Salmonella (SLM - I1) - DSVID R4.7.1 DSPTC R6.1

VIDAS : 1 - section(s) 904, 905
Technician : tcb
Lot number : 180717-0

Completed :
Feb 16 2018 3:35:07 PM

Standard used for this analysis :
Completed : Feb 11 2018 1:41:45 PM
S1 RFV : 3364

Negative < 0.23

Positive >= 0.23

Position	Sample ID	Test		Test Value	Interpretation
		BKG	RFV		
A-1	1040909 ELJ	141	195	0.05	Negative
A-2	1040883 TYW	139	227	0.06	Negative
A-3	1040899 MEB	140	188	0.05	Negative
A-4	1040501-1 CAZ	138	200	0.05	Negative
A-5	1040501-2 CAZ	139	202	0.06	Negative
A-6	1021169-1 RA	137	184	0.05	Negative
B-1	1021169-2 RA	139	228	0.06	Negative
B-2	DI960005 APO	139	12001	3.56	Positive
B-3	C-81	138	11139	3.31	Positive

B-2: Sample DI 960005

B-3: Lab positive control C-81

All other positions do not pertain to this sample.

APO 2/12/18
Page 1 of 1

Ashley Nozull
Jamayo Barnes

Page 7 of 12 pages

Bulk 5" dried Bully Sticks

FDA Southeast Food & Feed Laboratory

DI960005
2/22/18
APO

bioMerieux Customer: 1011618
System #: 506185

Laboratory Report

Printed Feb 22, 2018 11:00 GMT-05:00
Autoprint
Report Version: 1 of 1

Isolate Group: DI960005 TTXLD1-1

Card Type: GN Testing Instrument: 00000B4B8863 (FDA)

Isolate TTXLD-1

Bionumber: 0417610443566210

Organism Quantity:

Comments:	

Identification Information	Card: GN	Lot Number: 2410273203	Expires: Aug 26, 2018 12:00 GMT-05:00
	Completed: Feb 22, 2018 11:13 GMT-05:00	Status: Final	Analysis Time: 4.00 hours
Selected Organism	99% Probability Salmonella enterica ssp diarizonae		
	Bionumber: 0417610443566210	Confidence: Excellent identification	
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages: Confirm by serological tests			
Contraindicating Typical Biopattern(s)			

Biochemical Details																	
2	APPA	-	3	ADO	-	4	PyrA	-	5	IARL	-	7	dCEL	-	9	BGAL	+
10	H2S	+	11	BNAG	-	12	AGLTp	-	13	dGLU	+	14	GGT	+	15	OFF	+
17	BGLU	-	18	dMAL	+	19	dMAN	+	20	dMNE	+	21	BXYL	-	22	BALap	-
23	ProA	-	26	LIP	-	27	PLE	-	29	TyrA	-	31	URE	-	32	dSOR	+
33	SAC	-	34	dTAG	-	35	dTRE	+	36	CIT	+	37	MNT	+	39	5KG	(-)
40	ILATk	+	41	AGLU	-	42	SUCT	+	43	NAGA	-	44	AGAL	+	45	PHOS	+
46	GlyA	-	47	ODC	+	48	LDC	+	53	IHISa	-	56	CMT	+	57	BGUR	-
58	O129R	+	59	GGAA	-	61	IMLTa	-	62	ELLM	-	64	ILATa	-			

Installed VITEK 2 Systems Version: 07.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Ashley P. O'Neil

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APO 2/22/18
Page 1 of 1

Bulk 5'' dried Bully Sticks

DI 960005
2/22/18
APO

FDA Southeast Food & Feed Laboratory

bioMerieux Customer: 1011618
System #: 506185

Laboratory Report

Printed Feb 22, 2018 11:59 GMT-05:00
Autoprint
Report Version: 1 of 1

Isolate Group: DI960005 MTTXLD2-1

Card Type: GN Testing Instrument: 00000B4B8863 (FDA)

Isolate MTTXLD-2

Bionumber: 0017611545567210
Organism Quantity:

Comments:	

Identification Information	Card: GN	Lot Number: 2410273203	Expires: Aug 26, 2018 12:00 GMT-05:00
	Completed: Feb 22, 2018 12:12 GMT-05:00	Status: Final	Analysis Time: 5.00 hours
Selected Organism	98% Probability Salmonella spp		Confidence: Excellent identification
SRF Organism	Bionumber: 0017611545567210		
Analysis Organisms and Tests to Separate:			
Analysis Messages: Confirm by serological tests			
Contraindicating Typical Biopattern(s) Salmonella spp 5KG(24),			

Biochemical Details																	
2	APPA	-	3	ADO	-	4	PyrA	-	5	IARL	-	7	dCEL	-	9	BGAL	-
10	H2S	+	11	BNAG	-	12	AGLTp	-	13	dGLU	+	14	GGT	+	15	OFF	+
17	BGLU	-	18	dMAL	+	19	dMAN	+	20	dMNE	+	21	BXYL	-	22	BAlap	-
23	ProA	+	26	LIP	-	27	PLE	-	29	TyrA	+	31	URE	-	32	dSOR	+
33	SAC	-	34	dTAG	-	35	dTRE	+	36	CIT	+	37	MNT	-	39	5KG	+
40	ILATk	+	41	AGLU	-	42	SUCT	+	43	NAGA	-	44	AGAL	+	45	PHOS	+
46	GlyA	+	47	ODC	+	48	LDC	+	53	IHISa	-	56	CMT	+	57	BGUR	-
58	O129R	+	59	GGAA	-	61	IMLTa	-	62	ELLM	-	64	ILATa	-			

Installed VITEK 2 Systems Version: 07.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Ashley P. O'Zall

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Bulk 5" dried Bully Sticks

DI 960005
2/22/18
APO

FDA Southeast Food & Feed Laboratory

bioMerieux Customer: 1011618
System #: 506185

Laboratory Report

Printed Feb 22, 2018 12:57 GMT-05:00
Autoprint
Report Version: 1 of 1

Isolate Group: Lab Control C81-1

Card Type: GN Testing Instrument: 00000B4B8863 (FDA) Lab Positive Control C-81

Bionumber: 0015610545566610
Organism Quantity:

Comments:	

Identification Information	Card: GN	Lot Number: 2410273203	Expires: Aug 26, 2018 12:00 GMT-05:00
	Completed: Feb 22, 2018 13:12 GMT-05:00	Status: Final	Analysis Time: 6.00 hours
Selected Organism	95% Probability Salmonella spp		Confidence: Very good identification
SRF Organism	Bionumber: 0015610545566610		
Analysis Organisms and Tests to Separate:			
Analysis Messages: Confirm by serological tests			
Contraindicating Typical Biopattern(s) Salmonella spp 5KG(24),BGUR(3),			

Biochemical Details																	
2	APPA	-	3	ADO	-	4	PyrA	-	5	IARL	-	7	dCEL	-	9	BGAL	-
10	H2S	+	11	BNAG	-	12	AGLTp	-	13	dGLU	+	14	GGT	-	15	OFF	+
17	BGLU	-	18	dMAL	+	19	dMAN	+	20	dMNE	+	21	BXYL	-	22	BAlap	-
23	ProA	-	26	LIP	-	27	PLE	-	29	TyrA	+	31	URE	-	32	dSOR	+
33	SAC	-	34	dTAG	-	35	dTRE	+	36	CIT	+	37	MNT	-	39	5KG	+
40	ILATk	+	41	AGLU	-	42	SUCT	+	43	NAGA	-	44	AGAL	+	45	PHOS	+
46	GlyA	-	47	ODC	+	48	LDC	+	53	IHISa	-	56	CMT	+	57	BGUR	+
58	O129R	+	59	GGAA	-	61	IMLTa	-	62	ELLM	-	64	ILATa	-			

Installed VITEK 2 Systems Version: 07.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Ashley P. O'Neil

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APO 2/22/18
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Bulls dried Bully Sticks

DI960005
2/22/18
AP0

FDA Southeast Food & Feed Laboratory

bioMerieux Customer: 1011618
System #: 506185

Laboratory Report

Printed Feb 22, 2018 11:00 GMT-05:00
Autoprint
Report Version: 1 of 1

Isolate Group: Lab Control C62-1

Card Type: GN Testing Instrument: 00000B4B8863 (FDA)

Lab Positive Control C-62

Bionumber: 0415610543026610

Organism Quantity:

Comments:	

Identification Information	Card: GN	Lot Number: 2410273203	Expires: Aug 26, 2018 12:00 GMT-05:00
	Completed: Feb 22, 2018 11:12 GMT-05:00	Status: Final	Analysis Time: 4.00 hours
Selected Organism	99% Probability Salmonella enterica ssp diarizonae Bionumber: 0415610543026610 Confidence: Excellent identification		
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages: Confirm by serological tests			
Contraindicating Typical Biopattern(s)			

Biochemical Details																	
2	APPA	-	3	ADO	-	4	PyrA	-	5	IARL	-	7	dCEL	-	9	BGAL	+
10	H2S	+	11	BNAG	-	12	AGLTp	-	13	dGLU	+	14	GGT	-	15	OFF	+
17	BGLU	-	18	dMAL	+	19	dMAN	+	20	dMNE	+	21	BXYL	-	22	BAlap	-
23	ProA	-	26	LIP	-	27	PLE	-	29	TyrA	+	31	URE	-	32	dSOR	+
33	SAC	-	34	dTAG	-	35	dTRE	+	36	CIT	+	37	MNT	+	39	5KG	-
40	ILATk	-	41	AGLU	-	42	SUCT	-	43	NAGA	-	44	AGAL	+	45	PHOS	-
46	GlyA	-	47	ODC	+	48	LDC	+	53	IHSa	-	56	CMT	+	57	BGUR	+
58	O129R	+	59	GGAA	-	61	IMLTa	-	62	ELLM	-	64	ILATa	-			

Installed VITEK 2 Systems Version: 07.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

AP0 2/22/18
Page 1 of 1

Ash & P. O'Neil

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**SALMONELLA
QUALITY CONTROL RECORD**

PRODUCT:
Bulk 5" dried Bully Sticks

SAMPLE NUMBER:
DI960005

EQUIPMENT AND SUPPLIES

PLASTIC JUG _____ BLENDER JAR _____
BLENDER CAP/CUTTER _____ STERILE SPOON _____
STERILE TUBES 16 X150 mm 320V001 x: 5/16/18; 13 X100 mm 355V001 x: 4/21/18
BALANCE # 38 WEIGHT CHECK X YES _____ NO _____
EXPOSURE PLATES: TSA 024W003 x: 3-25-18 - no growth 2/16/18 APO

REAGENTS AND CHEMICALS

1N NaOH (R-73) 079V004 x: 3/21/18 1N HCl (R-36) _____
TRITON X-100 (R-86) _____ TERGITOL ANIONIC 7 (R-78) _____

MEDIA

LACTOSE BROTH (M-74) 040W006 x: 6/10/18 NONFAT DRY MILK (M-111) _____
TSB (M-154) _____ mBPW _____
UNIVERSAL PREENRICHMENT BROTH _____
STERILE WATER _____ 1% BG (R-8) _____
RV MEDIUM (M-132) 038W002 x: 3/10/18
TT BROTH (M-145) 029W001 x: 5/29/18
IKI SOLN (M-145) 157V003 x: 6/6/18 0.1% BG SOLN (M-145) 079V003 x: 3/21/18
M-Broth (AOAC, 993.07(g)) 023W002 x: 5/24/18
VIDAS SLM Test Kit 184803 x: 7/17/18
XLD AGAR (M-179) 022W003 x: 3/22/18 HEK AGAR (M-61) 023W004 x: 2/23/18 BS AGAR (M-19) 191556 x: 2/16/18
LIA AGAR (M-89) 347V001 x: 4/13/18 TSI AGAR (M-149) 362V003 x: 4/28/18
UREA BROTH (M-171) 026W004 x: 7/27/18
STERILE WATER _____ NORMAL SALINE (R-63) 346V006 x: 12/13/18
0.45% SALINE 181830 x: 4/27/19
VITEK GNI CARDS LOT NO. 177148 x: 8/26/18
TSA-YE SLANTS (M-153) _____
10% FERRIC CHLORIDE (R-25) _____ OXIDASE REAGENT (R-54) 169115 x: 1/31/19
KOVAC'S REAGENT (R-38) _____ MINERAL OIL (R-46) _____
alpha-NAPHTHOL (R-89 soln 1) _____ 40% KOH (R-89 soln 2) _____
TSTB BROTH (M-160) 032W004 x: 6/2/18 BHI BROTH (M-24) _____
FORMALIZED SALINE 511V003 x: 1/18/18 x: 11/8/18 APO 2/27/18
H ANTISERUM POLY a-z 183112 x: 7/14/19
O ANTISERUM:
POLY A-I & Vi 186440 x: 7/27/19 POLY A 160823 x: 5/19/19
POLY B _____ POLY C 160836 x: 4/16/18
POLY D _____ POLY E 46796 x: 4/29/19
POLY F _____ POLY G _____
MALONATE BROTH (M-92) _____ KCN BROTH (M-126) _____
0.5% DULCITOL (M-121) _____ BHI AGAR SLANTS (M-24) 016W004 x: 7/17/18
TSA plates; 024W003 x: 3/25/18 TSA-YE plates; 032W001 x: 4/11/18

POSITIVE CONTROLS

SRL C-81 *Salmonella gaminara* APO
SRL C-94 *Proteus hauseri* (vulgaris) APO
SRL C-62 *Salmonella diarizonae* APO
SRL C-31 *Pseudomonas aeruginosa* APO

EQUIPMENT CONTROLS

Incubator: 35°C SRL# 8, 10, 21, 56, 57 Refrigerator: 4°C SRL# 11, 60, 50
Freezer: -17°C SRL# 23
VIDAS EQUIPMENT: A #1-FDA# 5134696; A #2-FDA# 5040202; B #1-FDA# 5134695; B #2-FDA# 5134694;
C #1-FDA# 5147082; C #2-FDA# 5147081
VITEK2 EQUIPMENT: FDA#5146121 APO
Waterbaths: 42°C SRL# 38 43°C SRL# _____ 50°C SRL# 12 (W01) APO

NOTE: All references are BAM, On-Line Version, except as noted otherwise

ANALYST (S)

Ady P. O'Connell *Jamaya Bann*

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

For Sample Number: 960005

This is an accurate reproduction of the original electronic record as of 02/22/2018

Flag
Dealer Voluntarily Holding

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic/Import	Compliance	Official	18281874	In Progress

FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
1928015	02/08/2018	72FGH20	Dealer	71003E	

Compliance Num	Country of Origin
	Colombia

Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	HAFW2			Ambient

Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name
No				Bulk Product Sampled - No Brand Name

Product Description

Bulk 5" dried Bully Sticks stored in cardboard combo's

Product Label

See continuation.

Reason for Collection	MFG Codes	Expiration Date
Collected during RFR/Recall follow up inspection of dealer 2/7-8/18; analysis; micro - Salmonella sp	11/28/17	

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Redbarn Pet Products	30 SE 10 Rd Great Bend, KS 67530-9601 US	Dealer	1928015	
Redbarn Pet Products	30 SE 10 Rd Great Bend, KS 67530-9601 US	Repacker	1928015	
(b) (4)	(b) (4)	Manufacturer	(b) (4)	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
(b) (4)kg	\$ (b) (4)	FDA484	(b) (4)	10/13/2017

Description of Sample

See continuation.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"960005 2/8/18 MMM" subs 1-10 a-b

Collector's Identification on Seal

"960005 2/8/18 Monica M. McClure, Investigator

Sample Delivered To

Hand delivered to UPS Tracking #1ZA49E034495770734

Date Delivered	Orig C/R & Records To
02/09/2018	KAN-DO

Lab w/Split Sample	Lab
0	SFFL

Document Number	Document Date	Document Type	Document Remarks
1	02/08/2018	Other	Photographs of handwritten identification on combo boxes samples were collected from
2	10/13/2017	Other	Invoice and Packing Slip showing (b) (4) kg (b) (4) cartons) of dehydrated pizzles were ordered and

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 960005

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packed from (b) (4) for RedBarn
Pet Products, Great Bend, KS
Shipping Records showing (b) (4) cartons of bull pizzas
were shipped from (b) (4) via
(b) (4) to RedBarn Pet Products, Great Bend, KS
Finished Product Bag Label for 7" Bully Sticks

10/20/2017 Other
Other

Remarks

See continuation.

Payment Amount
\$0.00

Payment Method
No Charge

704(d) Sample
Yes

702(b) Portion
Yes

Collector's Name
Monica M McClure

Name of Signer

Date & Time of Signature

Meaning

ET

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 960005

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Continuation:

Product Label

Samples were collected from Bulk Combos with no product labels available. Photos of handwritten identification on the combos is attached. Each box was id'd with BC 11-28-17 5" Bully and the amount in each combo in kgs; (b) (4) kg, (b) (4) kg, (b) (4) kg, and (b) (4) kg.

A copy of a Finished Product Label collected for 7" Bully Sticks attached; labels for bagged 5" sticks would be the same except for size.

Description of Sample

Sample consists of 10 approx. 200 g subs of dried beef pizzles in clear whirlpak bags. Closed Controls submitted as subs a and b. Photos of bulk labeling and I/S records included.

Method of Collection

Under my direction, all (4) combos of 5" bully sticks were removed from shelves in the raw material warehouse and placed on the floor in the warehouse. 10 subs containing approx 200 g were randomly collected from the 4 combos aseptically using sterile whirl-pak bags. Firm collected side-by-side samples from the same 4 combos.

How Prepared

Subs aseptically put in sterile whirl-pak bags, bags folded down and ends bent in, bags id'd as noted, subs held in unused paper bag, locked in GOV and returned to WCH RP. At RP, subs put in 2nd sterile whirl-pak bag, put in unused clear plastic bag with controls, bag taped closed, id'd and sealed as noted. FDA 525 taped over seal. Bag put in cardboard box with styro peanuts and prepared for ship

Remarks

***Dealer is holding product until results are recieved. Send Results to:

Kevin R. Corbett, Plant Manager
RedBarn Pet Products, LLC
30 SE 10th Rd
Great Bend, KS 67570

Sample 960005 consist of 10 subs 1-10 and Controls a and b:

- Sub 1: Collected from Combo #1 (b) (4)kg)
- Sub 2: Collected from Combo #2 (b) (4)kg)
- Sub 3: Collected from Combo #3 (b) (4)kg)
- Sub 4: Collected from Combo #4 (b) (4) kg)
- Sub 5: Collected from Combo #1 (b) (4) kg)
- Sub 6: Collected from Combo #2 (b) (4) kg)
- Sub 7: Collected from Combo #3 (b) (4) kg)
- Sub 8: Collected from Combo #4 (b) (4) kg)
- Sub 9: Collected from Combo #2 (b) (4) kg)
- Sub 10: Collected from Combo #4 (b) (4) kg)

Sub a: Unopened sterile whirl-pak bag

Sub b: Sterile Aloetouch 12? Powder-Free Nitrile Exam Gloves, Date of Manufacture 2011-07 LOT PAN105363344