Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12720

2 - LABEL SAMPLE

SaBA 12-24-97

1. FLAG	SURVEILLANCE ☒ COMPLIANCE ☐	2. TYPE SAMPLE	3. SAMPLE NUMBER
[redacted] Death Creatine Investigation			**98-571-612**

4. CF NO	5. DATE COLLECTED	6. PRODUCT CODE	7. RESP FIRM	8. PROGRAM ASSIGN	9. HOURS
	12/18/97	54DY-99	M	1. 21B800	1. 4
				2.	2.
				3.	3.

10. RELATED SPL	11. PC	12. COLL NO.	13. SPLING DIST	14. COLL DIST
98-571-613	2	732	Min-DO	Min-DO

15. PRODUCT NAME AND IDENTIFICATION *(Quote pertinent labeling including firm name and address)* Creatine in paperboard can labeled in part: " JBN "Just Be Natural" 100% Pure Creatine Monohydrate CREATINE Pure! [redacted] Tested 1.1 lbs. *** 7,000 milligrams per serving! *** JBN ENTERPRISES 3864 Courtney Street Bethlehem, PA 18017 *** 1-800-487-2111 *** Ingredients: 100% pure Creatine Monohydrate. *** Usage: *** Warning: Keep tightly closed in a cool, dry place away from children. ****

16. REASON FOR COLLECTION *(Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.)* Death investigation of [redacted] Hold at Min-DO until analysis determined by CFSAN-DEIO.

17. MFG CODES *(Labels, pkg, shipping containers)* sticker label on bottom of can "5022 12"

18. MANUFACTURER *(Name, address & ZIP)*
JBN Enterprises
3864 Courtney Street
Bethlehem, PA 18017
1-800-487-2111

19. SHIPPER *(Name, address & ZIP)*
same

20. DEALER *(Name, address, ZIP & telephone)* [redacted] student and former roommate of deceased [redacted]

21. SIZE OF LOT FROM WHICH SAMPLED	22. EST VALUE	23. RECEIPT ISSUED			24. DATE SHIPPED & DOC REF
		FDA472	FDA484	NONE	
one previously opened partially used 1.1 lb. can	unknown		✓		unknown

25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION *(Number and size of units, etc.)* One previously opened partially used 1.1 lb. can of product collected from [redacted] former roommate.

26. HOW PREPARED Sample ident. as in 27. Sample placed in cdbd. box & off. sld. as in 28. Official seals used to maintain the integrity of sample from 12/18/97 to 12/19/97 and 12/19/97 to 12/23/97 while product locked in desk attached.

27. COLL IDENT ON PKG AND/OR LABEL "98-571-612 12-18-97 wek"

28. COLLECTOR'S IDENTIFICATION ON SEAL "98-571-612 12-23-97 William E. Keer"

29. SAMPLE DELIVERED TO Federal Express.. [redacted]

30. DATE DELIVERED 12/23/97

31. LAB Min DO

32. LAB W/SPLIT SAMPLE ----------

33. ORIG C/R & RECORDS TO Min DO

34. RCDS

a. INVOICE NO AND DATE

b SHIPPING RECORD *(B/L, F/B, Waybill, Affidavits, etc.)* NO. AND DATE

c OTHER DOCUMENTS *(Affidavits from dealers, etc.)* SIGNER'S NAME AND DATE Affidavit signed by [redacted] former roommate dated 12-19-97

35 REMARKS *(If additional space is needed, attach Form FDA 464a, C/R Continuation Sheet)*

36. CONSUMER COMPLAINT NO. OR RECALL NO.	37. AMOUNT n/c	38. 704(d) SPL	39. COLLECTOR *(Typed name and signature)*
	CRED. CD. ☐ C ☐ V ☐ B ☐	YES ☐ NO ☒	William E. Keer William E. Keer

FORM FDA 464 (11/86) PREV ED MAY BE USED.

COLLECTION REPORT

COPY: ORIGINAL COLLECTOR, DPU, FISCAL, MONITOR, SAMPLE

FLAG

ANALYST WORKSHEET	1. PRODUCT "CREATINE Pure!"		2. SAMPLE NUMBER 98-571-612
3. SEALS ☒ INTACT ☐ NONE ☐ BROKEN	4. DATE REC'D 12-29-97	5. RECEIVED FROM [redacted]	6. DISTRICT OR LABORATORY MIN

7. DESCRIPTION OF SAMPLE One cardboard box officially sealed "98-571-612 12-23-97 William E. Keer" containing one labeled paperboard can (previously opened) identified "98-571-612 12-18-97 WeK"!

8. NET CONTENTS	☐ NOT APPLICABLE ☒ NOT DETERMINED ___ UNITS EXAMINED	DECLARE/UNIT ___ AMOUNT FOUND ___ % OF DECLARED ___	9. LABELING	___ ORIGINAL(S) SUBMITTED 3 COPIES SUBMITTED ☐ NONE

10. SUMMARY OF ANALYSIS

Container: Paperboard can: 4 5/8" tall x 4" diameter with a translucent white plastic lid 4 1/8" diameter.

Code: "5022 12" ink stamped on paper sticker on metal lid base.

Product: White granular powder with a faint odor (plastic scoop in product) Can 1/3 full of product.

Analysis: No Analysis Performed

Labeling Submitted for Review

11. RESERVE SAMPLE One cardboard box officially sealed "98-571-612 12-29-97 E. Clifford Netz" containing one labeled paperboard can approximately 1/3 full of product.

12. a. ANALYST SIGNATURE (Broke Seal ☒) E. Clifford Netz	13. WORK-SHEET CHECK	a. BY Susan M. Warren
b.		b. DATE 12/30/97
c.	14. DATE REPORTED 12-29-97	

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FORM FDA 431 (5/84) PREVIOUS EDITION IS OBSOLETE. PAGE 1 OF 1 PAGES

☆U S Government Printing Office: 1990-253-903

1. PRODUCT	2. SAMPLE NO.
Juice Drink	98-571-612

3a. SAMPLE CLASSIFICATION (Insert classification code for each PAC No. represented by sample.)	b. LABORATORY CONCLUSIONS
	Label review only. No analysis performed

CODE	PAC NO.
3	21B800

c. NAME AND TITLE	d. SIGNATURE	e. DATE
Susan M. Warren, acting SB	Susan M. Warren	12/30/97

4a. DISTRICT CONCLUSIONS

b. NAME AND TITLE (District)	c. SIGNATURE	d. DATE

FORM FDA 465 (8/85) PREVIOUS EDITION MAY BE USED. *U.S. GPO: 1985-342-332/81862 SAMPLE SUMMARY

Best Quality FDA

Ingredients: 100% pure Creatine Monohydrate.

Usage: Each heaping scoop supplies 7,000mg* of Creatine Monohydrate. Mix one (1) heaping scoop in 8 ounces of water, juice or protein drink.

**No USRDA has been established for Creatine.*

Warning: Keep tightly closed in a cool, dry place away from children.

Creatine Monohydrate is a naturally-occurring, organic compound found primarily in red muscle tissue. Creatine is needed by muscle cells ADP & ATP for energy consumption. Each scoop of Creatine Pure! is certified pure by independent laboratory analysis[1]. Each scoop provides the amount of creatine found in 2.2 lbs. of uncooked red meat. Creatine Pure! is tasteless and an efficient way to provide Creatine Monohydrate as a dietary supplement at levels used in clinical studies[2,3].

1] Clinical Studies: 83-367-74 1992
2] Clinical Studies: 84-565-71 1993
3] AMJ Physiol: 266-E725 1994

100% Pure Creatine Monohydrate

JBN "Just Be Natural"

CREATINE Pure!

University Tested

1.1 lbs. [1/2 kilo]
500 grams [50,000mg]
7,000 milligrams per serving!

Loading Principle: Take one (1) heaping scoop equalling 7 grams and mix it into 8 oz. of either water, juice or a protein drink. Drink 5 times daily for ten days [loading dosage]. Thereafter, take one (1) heaping scoop 2 times daily for eleven days and beyond; preferably before and after workouts [maintenance dosage].

Creatine Loading (days 1 through 10):
Take one (1) heaping scoop 5 times daily.
Creatine Level Maintenance (day 11 & beyond):
Take one (1) heaping scoop 2 times daily.

JBN ENTERPRISES
3864 Courtney Street • Bethlehem, PA 18017
Fax: 610-882-9666
1-800-487-2111
Call Toll Free For Immediate Service!

Photocopy of Can labeling

000005

CCN

Lab A 12-24-97

1. FLAG SURVEILLANCE ☒ COMPLIANCE ☐	2. TYPE SAMPLE	3. SAMPLE NUMBER
[redacted] death - Creatine Investigation		**98-571-613**

4. CF NO	5. DATE COLLECTED	6. PRODUCT CODE	7. RESP FIRM	8. PROGRAM ASSIGN	9. HOURS
	12/18/97	54CH-99	M	1. 21B800	1. 4
				2.	2.
				3.	3.

10. RELATED SPL	11. PC	12. COLL NO.	13. SPLING DIST	14. COLL DIST
98-571-612	2	732	Min-DO	Min-DO

15. PRODUCT NAME AND IDENTIFICATION (*Quote pertinent labeling including firm name and address*) Powdered protein drink in plastic jug labeled in part: " *** TWINLAB *** THERMOGENIC PROTEIN DRINK *** RIPPED FUEL FOR THE MAXIMUM PRESERVATION OF LEAN BODY MASS NET WT 23.6 OZ. *** NUTRITIONAL INFORMATION PER SERVING *** EACH SERVING CONTAINS: RIPPED FUEL THERMOGENIC HERBS MaHuang *** Guarana Extract *** INGREDIENTS: *** Manufactured by TWIN LABORATORIES, INC RONKONKOMA, NEW YORK ***"

16. REASON FOR COLLECTION (*Indicate analysis needed & document assignment. Include CP No and/or Assignment No. if applicable.*) Death investigation of [redacted] Hold at Min-DO until analysis determined by CFSAN-DEIO.

17. MFG CODES (*Labels, pkg, shipping containers*) 71047 printed on the labeling

18. MANUFACTURER (*Name, address & ZIP*) Twin Laboratories, Inc.

Ronkonkoma, New York

19. SHIPPER (*Name, address & ZIP*) same as 18

20. DEALER (*Name, address, ZIP & telephone*) [redacted], student and former roommate of deceased [redacted]

21. SIZE OF LOT FROM WHICH SAMPLED	22. EST VALUE	23. RECEIPT ISSUED FDA472	FDA484	NONE	24. DATE SHIPPED & DOC REF
one previously operned partially used 23.6 oz jug	unknown		✓		unknown

25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (*Number and size of units, etc.*) One previously opened partially used 23.6 oz. jug collected from [redacted] former roommate.

26. HOW PREPARED Sample ident. as in 27. Sample placed in cdbd. box & off. sld. as in 28. Official seals used to maintain the integrity of sample from 12/18/97 to 12/19/97 and 12/19/77 to 12/23/97 while product locked in desk attached to 98-571-612.

27. COLL IDENT ON PKG AND/OR LABEL	28. COLLECTOR'S IDENTIFICATION ON SEAL
98-571-613 12-18-97 wek"	"98-571-613 12-23-97 William E. Keer"

29. SAMPLE DELIVERED TO	30. DATE DELIVERED	31. LAB
Federal Express.. [redacted]	12/23/97	Min-DO
	32. LAB W/SPLIT SAMPLE	33. ORIG C/R & RECORDS TO
	----------	Min-DO

34. RCDS

a. INVOICE NO. AND DATE

b. SHIPPING RECORD (*B/L, F/B, Waybill, Affidavits, etc.*) NO AND DATE

c. OTHER DOCUMENTS (*Affidavits from dealers, etc.*) SIGNER'S NAME AND DATE Affidavit signed by [redacted] former roommate dated 12-19-97

35. REMARKS (*If additional space is needed, attach Form FDA 464a, C/R Continuation Sheet*)

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36. CONSUMER COMPLAINT NO. OR RECALL NO	37. AMOUNT n/c CRED. CD ☐ C ☐ V ☐ B ☐	38. 704(d) SPL YES ☐ NO ☒	39. COLLECTOR (*Typed name and signature*) William E. Keer William E. Keer

FORM FDA 464 (11/85) PREV ED MAY BE USED.

COLLECTION REPORT

COPY: ORIGINAL COLLECTOR DPU FISCAL MONITOR SAMPLE

1. PRODUCT	2. SAMPLE NO.
Juice Drink	98-571-613

3a. SAMPLE CLASSIFICATION	b. LABORATORY CONCLUSIONS
(Insert classification code for each PAC No. represented by sample.)	Label review only. No analysis performed.

CODE	PAC NO.
3	213800

c. NAME AND TITLE	d. SIGNATURE	e. DATE
Susan M. Warren, acting SB	Susan M. Warren	12/30/97

4a. DISTRICT CONCLUSIONS

b. NAME AND TITLE (District)	c. SIGNATURE	d. DATE

FORM FDA 465 (8/85) PREVIOUS EDITION MAY BE USED. *U.S. GPO: 1985-540-302/61002 SAMPLE SUMMARY

FLAG

ANALYST WORKSHEET	1. PRODUCT "RIPPED FUEL" "THERMOGENIC PROTEIN DRINK"	2. SAMPLE NUMBER 98-571-613
3. SEALS ☒ INTACT ☐ NONE ☐ BROKEN	4. DATE REC'D 12-29-97 / 5. RECEIVED FROM [redacted]	6. DISTRICT OR LABORATORY MIN

7. DESCRIPTION OF SAMPLE One cardboard box officially sealed "98-571-613 12-23-97 William E. Keer" containing one labeled plastic jug (previously opened) identified "98-571-613 12-18-97 WEK".

8. NET CONTENTS			9. LABELING	
	☐ NOT APPLICABLE	DECLARE/UNIT		___ ORIGINAL(S) SUBMITTED
	☒ NOT DETERMINED	AMOUNT FOUND		3 COPIES SUBMITTED
	___ UNITS EXAMINED	% OF DECLARED		☐ NONE

10. SUMMARY OF ANALYSIS

Container: Plastic jug, white, 7" tall x 4 5/8" diameter with a black plastic screw on lid 2 3/8" diameter.

Code: "LOT 71047" ink stamped on plastic jug.

Product: Tan powder with a slight odor (plastic scoop in product) Jug half full of product.

Analysis: No Chemical Analysis Performed
Labeling Submitted for Review.

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11. RESERVE SAMPLE One cardboard box officially sealed "98-571-613 12-29-97 E. Clifford Nel" containing one labeled plastic jug approximately half full of product.

12. a. ANALYST SIGNATURE (Broke Seal) E. Clifford Nel	13. WORK-SHEET CHECK	a. BY
b.		b. DATE
c.	14. DATE REPORTED 12-29-97	

FORM FDA 431 (5/84) PREVIOUS EDITION IS OBSOLETE. PAGE 1 OF 1 PAGES

☆U S Government Printing Office 1990-253-903

Proj # 12720

1. PRODUCT	2. SAMPLE NO.
Ripped Fuel Protein Drink	7465 (98-571-613)

3a. SAMPLE CLASSIFICATION	b. LABORATORY CONCLUSIONS
(Insert classification code for each PAC No. represented by sample.)	Sample consisted of one (1) previously opened bottle of a brown powder with chocolate odor. No analysis was performed. Labeling submitted.

CODE	PAC NO.
4	21R800

c. NAME AND TITLE	d. SIGNATURE	e. DATE
Mihaly S. Ligmond, Chemist		6-12-98

4a. DISTRICT CONCLUSIONS

b. NAME AND TITLE (District)	c. SIGNATURE	d. DATE

FORM FD 465 (4/78) PREVIOUS EDITION IS OBSOLETE. ☆U.S. GPO: 1985—461-364/37051 SAMPLE SUMMARY

'98 JUN 29 P12:25

RECEIVED
CLINICAL PHARMACOLOGY
& REVIEW/OSN HFS-25

000009

FLAG

ANALYST WORKSHEET	1. PRODUCT Ripped Fuel protein drink		2. SAMPLE NUMBER 7465 (98571613)
3. SEALS ☑ INTACT ☐ NONE ☐ BROKEN	4. DATE REC'D 5/13/98	5. RECEIVED FROM [redacted]	6. DISTRICT OR LABORATORY SEA-DO

7. DESCRIPTION OF SAMPLE: One box, officially sealed "98-571-613 12-29-97 E. Clifford Netz", previous seal "98-571-613 12-23-97 William E. Keel" broken "ECN 12-29-97", containing one open bottle of product id'd "98-571-613 12-18-98 WEK". Received at room temperature.

8. NET CONTENTS	✓ NOT APPLICABLE ___ NOT DETERMINED ___ UNITS EXAMINED	DECLARED/UNIT ___ AMOUNT FOUND ___ % OF DECLARED ___	9. LABELING	___ ORIGINALS SUBMITTED ✓ COPIES SUBMITTED ___ NONE

10. SUMMARY OF ANALYSIS

container : opaque white plastic bottle, 180mm high x 125mm diameter, with black plastic screw cap, 112mm diameter

labeling : commercially printed paper label; label has been previously removed and it attached to bottle with rubber band

code : "LOT 71047" stamped directly onto bottle

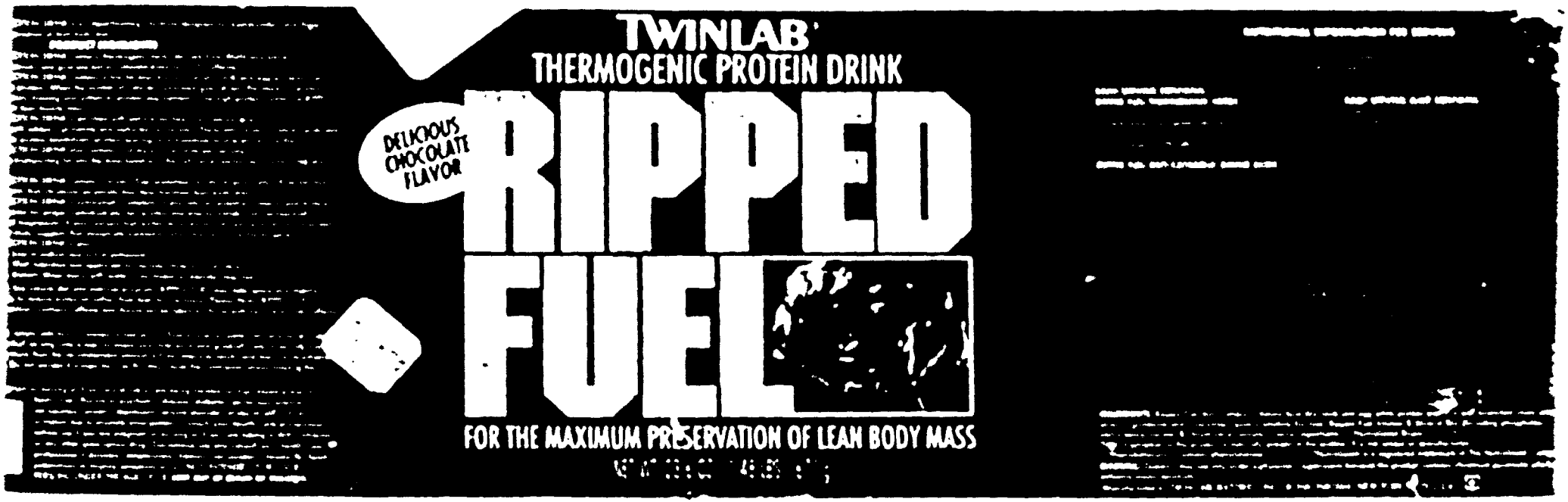
product : light brown chocolate smelling powder

Analysis : NO analysis performed per CFSAN request (Dr. William Obermeyer)

11. RESERVE SAMPLE: In original box, officially sealed "7465 6/11/98 JLBussey", one open bottle of product as received. Returned to sample custodian.

12. a. ANALYST SIGNATURE (☑ BROKE SEAL) JLBussey	13. WORK SHEET CHECK	a. BY
b.		b. DATE 6-12-98
c.	14. DATE REPORTED 11 June 98	

FORM FDA 431 ATTACHMENTS : none



Copy of labeling on Plastic Jug

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Best Quality FDA