

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

ARMS#

12486



2 - LABEL SAMPLE

000001

DIETARY SUPPLEMENT:

60 Doses (10 drops each)

INGREDIENTS:

Water, L-Carnitine, Green Tea Extract,
Choline, Atractylodes, Propylene Glycol
, Citric Acid, Sodium Benzoate,
Chromium Picolinate (150mcg per
dose), B12 Dibenzozide.

Exp. Date : 7040480
EXP4/* *date illegible

* [*label incomplete]
LIQUA THIN™

LIQUA
THIN™

1 FLUID OZ. (30ML.)

DOSAGE AND *

Shake well before eac* [*label incomplete]
Take 10 drops, 2-3 times*
day with meals.

Agite bien antes de usar. Tome 10
gotas, 2 a 3 veces por día junto
con las comidas.

CAUTION:

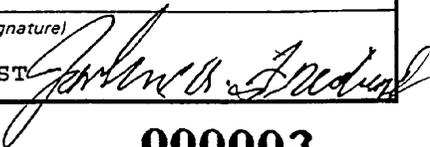
*Keep out of reach of children. Do not use
product if you are presently taking a pre-
scription drug, if you have high blood pres-
sure, depression, or while pregnant or lac-
tating, without first consulting your doctor.*

E'OLA LIFE LINES

Formulated exclusively for E'OLA™ PRODUCTS
St. George, Utah 84790

Verified
9-4-97
S. L. (signature)

KDS 07/08/97

1. FLAG SURVEILLANCE <input type="checkbox"/> COMPLIANT Consumer Complaint			2. TYPE SAMPLE Inv		3. SAMPLE NUMBER 97-452-941					
4. CENTRAL FILE NUMBER 1722358		5. DATE COLLECTED 7-7-97		6. PRODUCT CODE 54FCL99		7. RESPONSIBLE FIRM M		8. PROGRAM ASSIGNMT CODE 56R801		9. HOURS 1.5
10. RELATED SAMPLE 97-452-942		11. PC 1	12. COLL NO. 538	13. SPLNG DISTRICT DEN-DO		14. COLL DISTRICT DEN-DO				
15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) PRODUCT IS LIQUID IN A WHITE PLASTIC BOTTLE WITH WHITE PLASTIC SCREW ON CAP. BOTTLE LABELED IN PART:"***"LIQUA THIN 1 FLUID OZ (30 ML.)Formulated exclusively for E'OLA PRODUCTS St.George, Utah 84790***"										
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) CONSUMER COMPLAINT LABEL REVIEW FOR COMPLIANCE; ASSAY FOR EPHEDRINE							17. MFG CODES (Labels, pkg, shipping containers) "LOT #7040460 EXP 4/98 (CONSUMER COMPLAINT)"			
18. MANUFACTURER (Name, address & ZIP) EOLA PRODUCTS 945 N 1300 W ST GEORGE, UT 84790				19. SHIPPER (Name, address & ZIP) UNKNOWN			20. DEALER (Name, address, ZIP & TELEPHONE) 			
21. SIZE OF LOT FROM WHICH SAMPLED ONE BOTTLE 1 FLUID OZ (30 ML.)				22. EST VALUE 0.00		23. RECEIPT ISSUED FDA472 FDA484 NONE X		24. DATE SHIPPED & DOC REF SEE REMARKS		
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) 1 BOTTLE 30 ML - PURCHASED FROM CONSUMER										
26. HOW PREPARED BOTTLE LABEL IDENTIFIED AS ON LINE #27 PLACED IN A PLASTIC BAG, SEALED AND SHIPPED.										
27. COLLECTOR'S IDENT ON PKG AND/OR LABEL "97-452-941 7-7-97 JAF"				28. COLLECTOR'S IDENTIFICATION ON SEAL "97-452-941 7-7-97 JOHN A. FREDERICK"						
29. SAMPLE DELIVERED TO FED EX SALT LAKE CITY, UT					30. DATE DELIVERED 7-9-97			31. LAB DEN-DO		
					32. LAB WITH SPLIT SAMPLE NONE			33. ORIG C/R & RECORDS TO DEN-DO		
34. RCDS OBTAINED	a. INVOICE NO. AND DATE SEE REMARKS				b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavit, etc.) NO. AND DATE SEE REMARKS					
	c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE NONE				Attachment #2.1 E'Ola Products (DEN-3841) Saint George, UT 84790 MEMO, 8/8/97 James E. Moore II					
35. REMARKS (If additional space is needed, attach form FDA 464a, C/R Continuation Sheet) REF ITEM #24&34 NO IS INFORMATION OR DOCUMENTATION AVAILABLE										
28. Placed under temporary seal included under permanent seal.										
36. CONSUMER COMPLAINT NO. OR RECALL NO. DEN-3841		37. AMT. \$ 19.00 CRED CD C V B <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		38. 704(d) SPL YES NO <input type="checkbox"/> <input checked="" type="checkbox"/>		39. COLLECTOR (Typed name and signature) JOHN A. FREDERICK, CST 				

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

COLLECTION REPORT

000003

CIRCLE APPROPRIATE COPY:

SAMPLE RECORD COPY 1 (White)
SAMPLE RECORD COPY 4 (Salmon)

HOME DISTRICT COPY 2 (Pink)
COLLECTING DISTRICT MONITOR COPY 5 (Blue)

COLLECTING DISTRICT COPY 3 (Green)
COLLECTOR'S COPY 6 (Yellow)

Attachment #2

1 PRODUCT Liqua Thin		2 SAMPLE NO 97-452-941	
		# 12486	
3a SAMPLE CLASSIFICATION		b LABORATORY CONCLUSIONS Sample consisted of one bottle of a brown free flowing liquid. Analysis HPLC found: No ephedrine alkaloids found.	
CODE	PAC NO		
4	56R801		
c NAME AND TITLE Janet L. Burke, Chemist		d SIGNATURE <i>Janet L. Burke</i>	DATE 9/5/97
4a DISTRICT CONCLUSIONS			
b NAME AND TITLE		c SIGNATURE	d DATE

FORM FD 465 (4/78)

SAMPLE SUMMARY

97 NOV 19 AM 11:44

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

000004

DIETARY SUPPLEMENT:

160 Doses (5 drops each)

INGREDIENTS:

Water, Ma Huang (Ephedra standardized to Ephedrine), DMAE, White Willow Extract, Guarana Extract, Licorice Root, Atractylodes Extract, Propylene Glycol, Benzoic Acid, B-12.

DOSAGE AND USE:

Recommended dosage is five drops, not to exceed 30 drops in a 24 hour period. For adults 18 years and older. Shake well before each use.

La dosis recomendada es cinco gotas, no exceda 30 gotas en un período de 24 horas. Para adultos de 18 años y mayor. Agite bien antes de usar.

Each dose contains 15mg. of Ephedrine.

Lot # 7040510
Exp. Date : EXP4/98

[note: lot and exp. have been partially rubbed off and are difficult to read.]

E'OLA™
AMP II PRO DROPS

Amp II
Pro Drops™

1 FLUID OZ. (30ML.)

WARNING:

Do not use if you have heart disease, high blood pressure, thyroid disease, diabetes, been hospitalized for asthma, or have difficulty urinating due to enlargement of the prostate gland. Some users of the product may experience loss of appetite, nervousness, tremor, sleeplessness, or nausea. If this occurs, or if symptoms are not relieved within one hour or become worse, do not continue to use product but seek medical assistance.

CAUTION:

Keep out of reach of children. Do not use product if you are presently taking a prescription drug, if you have high blood pressure, depression, or while pregnant or lactating, without first consulting your doctor.

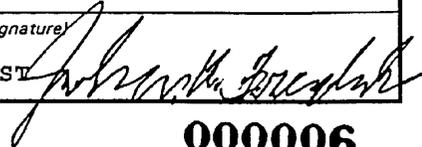
E'OLA LIFE LINES

Formulated exclusively for E'OLA™ PRODUCTS
St. George, Utah 84790

Verified
9-4-97
JL
initials signed

000005

KDS 07/08/97

1. FLAG SURVEILLANCE <input type="checkbox"/> COMPLIANT Consumer Complaint			2. TYPE SAMPLE Inv		3. SAMPLE NUMBER 97-452-942					
4. CENTRAL FILE NUMBER 1722358		5. DATE COLLECTED 7-7-97		6. PRODUCT CODE 54FCL09		7. RESPONSIBLE FIRM M		8. PROGRAM ASSIGNMT CODE 56R801		9. HOURS 1.5
10. RELATED SAMPLE 97-452-941		11. PC 1	12. COLL NO. 538	13. SPLING DISTRICT DEN-DO		14. COLL DISTRICT DEN-DO				
15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) PRODUCT IS LIQUID IN A WHITE PLASTIC BOTTLE WITH WHITE PLASTIC SCREW ON CAP. BOTTLE LABELED IN PART: "***AMP II PRO DROPS 1 FLUID OZ (30 ML.) Formulated Exclusively for E'OLA PRODUCTS St. George, Utah 84790***"										
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) CONSUMER COMPLAINT LABEL REVIEW FOR COMPLIANCE; ASSAY FOR EPHEDRINE							17. MFG CODES (Labels, pkg, shipping containers) "LOT #7040510" EXP 4798" (CONSUMER COMPLAINT)			
18. MANUFACTURER (Name, address & ZIP) EOLA PRODUCTS 945 N 1300 W ST GEORGE, UT 84790				19. SHIPPER (Name, address & ZIP) UNKNOWN			20. DEALER (Name, address, ZIP & TELEPHONE) 			
21. SIZE OF LOT FROM WHICH SAMPLED ONE BOTTLE 1 FLUID OZ (30 ML.)				22. EST VALUE 0.00		23. RECEIPT ISSUED FDA472 FDA484 NONE X		24. DATE SHIPPED & DOC REF SEE REMARKS		
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) 1 BOTTLE 30 ML. - PURCHASED FROM CONSUMER										
26. HOW PREPARED BOTTLE LABEL IDENTIFIED AS ON LINE #27 PLACED IN A CLEAR PLASTIC BAG, SEALED AND SHIPPED.										
27. COLLECTOR'S IDENT ON PKG AND/OR LABEL "97-452-942 7-7-97 JAF"					28. COLLECTOR'S IDENTIFICATION ON SEAL "97-452-942 7-8-97 JOHN A. FREDERICK"					
29. SAMPLE DELIVERED TO FED EX SALT LAKE CITY, UT					30. DATE DELIVERED 7-9-97			31. LAB DEN-DO		
					32. LAB WITH SPLIT SAMPLE NONE			33. ORIG C/R & RECORDS TO DEN-DO		
34. RCDS OBTAINED	a. INVOICE NO. AND DATE SEE REMARKS					b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavit, etc.) NO. AND DATE SEE REMARKS				
	c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE NONE					Attachment #2.2 E'Ola Products (DEN-3841) Saint George, UT 84790 MEMO, 8/8/97 James E. Moore II				
35. REMARKS (If additional space is needed, attach form FDA 464a, C/R Continuation Sheet) REF ITEM #24&34 NO IS INFORMATION OR DOCUMENTATION AVAILABLE										
28. PLACED UNDER TEMPORARY SEAL INCLUDED UNDER PERMANENT SEAL.										
36. CONSUMER COMPLAINT NO. OR RECALL NO. DEN-3841		37. AMT. \$ 19.00 CRED CD C V B ^ X X X			38. 704(d) SPL YES NO ^ X		39. COLLECTOR (Typed name and signature) JOHN A. FREDERICK, CST 			

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

COLLECTION REPORT

000006

CIRCLE APPROPRIATE COPY:

- SAMPLE RECORD COPY 1 (White)
- HOME DISTRICT COPY 2 (Pink)
- COLLECTING DISTRICT COPY 3 (Green)
- SAMPLE RECORD COPY 4 (Salmon)
- COLLECTING DISTRICT MONITOR COPY 5 (Blue)
- COLLECTOR'S COPY 6 (Yellow)

1 PRODUCT Amp II Pro Drops		2 SAMPLE NO 97-452-942	
		# 12486	
3a SAMPLE CLASSIFICATION		b LABORATORY CONCLUSIONS Sample consisted of one bottle of a brown free flowing liquid. Analysis HPLC found: (63.0 mg/g) 16.2 mg/dose ephedrine or 108% declared. [one dose is 5 drops] A trace of pseudoephedrine was also found.	
CODE	PAC NO.		
4	56R801		
c NAME AND TITLE Janet L. Burke, Chemist		d SIGNATURE <i>Janet L. Burke</i>	DATE 9/5/97
4a DISTRICT CONCLUSIONS			
b NAME AND TITLE		c SIGNATURE	d DATE

FORM FD 465 (4/78)

SAMPLE SUMMARY

RECEIVED
 CLINICAL RESEARCH
 & REVIEW/OSN HFS-452
 97 NOV 19 AM 11:44

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