

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

ARMS#

13408



2 - LABEL SAMPLE

**000001**

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

**Collection Report**

**For Sample Number:** [REDACTED]

<b>Flag</b>	<b>Flag Remarks</b>				
<b>Episode Number</b>	<b>Origin</b>	<b>Basis</b>	<b>Sample Type</b>	<b>FIS Smpl Num</b>	<b>Status</b>
	Domestic	Surveillance	Documentary	99921368	Completed
<b>FEI</b>	<b>Date Collected</b>	<b>Product Code</b>	<b>Responsible Firm</b>	<b>PAC</b>	<b>Hours</b>
2421049	29-MAR-99	54FCE09	Manufacturer	09F800	4
<b>Related Smpl Num</b>	<b>Position Class</b>	<b>Sampling District</b>	<b>NDC Number</b>	<b>Permit Number</b>	<b>Storage Rqrmnt.</b>
	INV	FLA-DO			
<b>Dealer is Consumer</b>	<b>Crx/DEA Schedule</b>	<b>Recall Num</b>	<b>Consumer Compl. Num</b>	<b>Brand Name</b>	
No			[REDACTED]	TWINLAB	

**Product Description**

dietary supplement/metabolic enhancer product containing ephedra alkaloids

**Product Label**

See continuation.

**Reason for Collection**

No analysis-documentary sample only. Sample was collected in response to CFSAN/HFS-636 assignment dated 3/19/99 [REDACTED] requesting F/U on adverse event report and labeling collection.

**MFG Codes**

Lot "85544" imprinted on the bottle neck

**Expiration Date**

**Firm Legal Name**

Twin Labs Inc

**Address**

2120 Smithtown Ave Ronkonkoma, NY  
11779 US

**Type of Firm**

Manufacturer

**Firm FEI**

2421049

**FCE**

**Size of Lot**

unknown

**Est. Value**

**Rcpt Type**

None

**Date Shipped & Doc. Ref.**

**Description of Sample**

Sample consists of stripped product label and photographs of product label.

**Method of Collection**

See continuation.

**How Prepared**

Label and photographs identified with Collector's Identification. Photographs were taken on 4/6/99. Bottle was purchased on 3/29/99.

**Collector's Identification on Package and/or Label**

Photos "DOC46060 4/6/99 SJH" and Label "DOC46060 3/29/99 SJH"

**Collector's Identification on Seal**

None

**Sample Delivered To**

[REDACTED]

**Date Delivered**

**Orig C/R & Records To**

FLA-DO

**Lab w/Split Sample**

Lab

**Document Number**

**Document Date**

**Document Type**

**Document Remarks**

None

**Remarks**

See continuation.

**Payment Amount**

\$12.80

**Payment Method**

Cash

**704(d) Sample**

No

**702(b) Portion**

No

**Collector's Name**

Shari J Hromyak

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

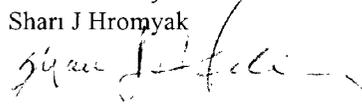
**Collection Report**

**For Sample Number:** [REDACTED]

**Name of Signer**

Shari J Hromyak

Shari J Hromyak



**Date & Time of Signature**

04/09/1999 02:04 PM ET

04/08/1999 02:22 PM ET

**Meaning**

Collector

Collector

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

**Collection Report**

**For Sample Number:** [REDACTED]

**Continuation:**

**Product Label**

Product contained in a dark glass bottle with a multi-colored label which read in part:"\*\*TWINLAB\*\*METABOLIC ENHANCER\*\*RIPPED FUEL\*\*THERMOGENIC FORMULA\*\*60 CAPSULES\*\*Manufactured by: TWIN LABORATORIES INC., Ronkonkoma, NY 11779\*\*". Bottle was also labeled in part:"\*\*LOT 85544\*\*".

**Method of Collection**

One bottle was collected from retail shelf at [REDACTED] Bottle photographed at [REDACTED]  
[REDACTED]. Label stripped from bottle at [REDACTED] Actual product destroyed at [REDACTED] on 4/8/99.

**Remarks**

Consumer portion was unavailable. Actual product was discarded and lost prior to FDA follow-up. Sample bottle was purchased at a local dealer store. Consumers, Mrs. [REDACTED] confirmed sample bottle was same brand and formulation of suspect product. Suspect lot number is unknown.



DOC 46060  
3 26 99  
SIII

PHOTOCOPY OF  
STRIPPED BOTTLE  
LABEL

000000

**RECOMMENDED USE:** As a dietary supplement, take 2 capsules before morning workout on an empty stomach. Also, take 2 capsules before afternoon and evening meals. Do not exceed 6 capsules daily. Taking more than the recommended amount will not improve results and may cause adverse reactions listed in the warning below. Begin use with one-half the recommended dose (one capsule three times per day) to assess your tolerance. Improper use may be hazardous to a person's health. For best results, use as part of a low-fat diet and exercise program. The maximum recommended dosage of ephedrine for a healthy adult human is no more than 100 mg in a 24 hour period for not more than 12 weeks. Please note: Guarana extract contains caffeine and should not be taken by those wishing to eliminate caffeine from the diet.

**WARNING:** Do not use if you are pregnant or nursing or if you are at risk or are being treated for high blood pressure, heart, liver, thyroid or psychiatric disease, diabetes, pernicious anemia, nervousness, anxiety, depression, seizure disorder, stroke or difficulty in urination due to prostate enlargement. Consult your health care professional before use if you are taking an MAO inhibitor or any other prescription drug. Discontinue use and consult your health care professional if dizziness, sleeplessness, tremors, nervousness, headache, heart palpitations or tingling sensations occur. **NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18.**

THEMOGENIC  
FORMULA

# TWINLAB® METABOLIC ENHANCER RIPPED® FUELED

60 Capsules



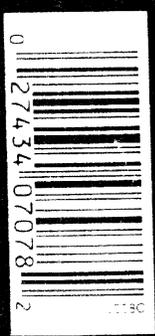
Two Capsules Provide:

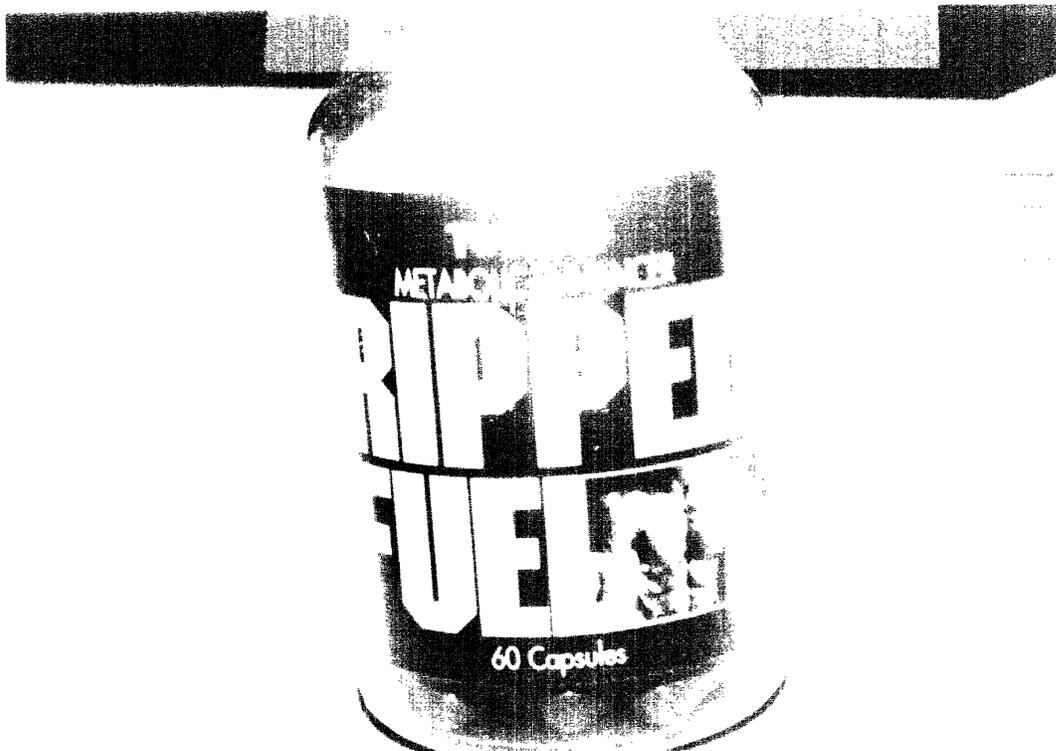
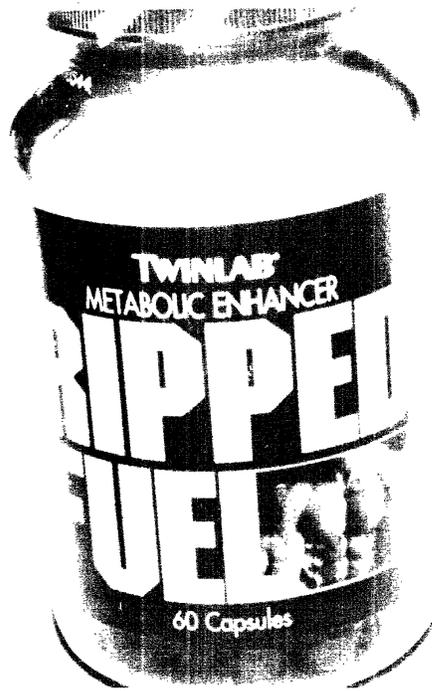
Mohhuang Extract (standardized for 20 mg ephedra alkaloids)	334 mg	% U.S. RDA
Guarana Extract (standardized for 22% caffeine)	910 mg	
L-Carnitine	100 mg	
Chromium (from Chromic Fuel <sup>®</sup> patented chromium picolinate)	200 mcg	

\*No U.S. RDA established

**KEEP OUT OF REACH OF CHILDREN.**

Manufactured by:  
TWIN LABORATORIES INC., Ronkonkoma, NY 11779 USA

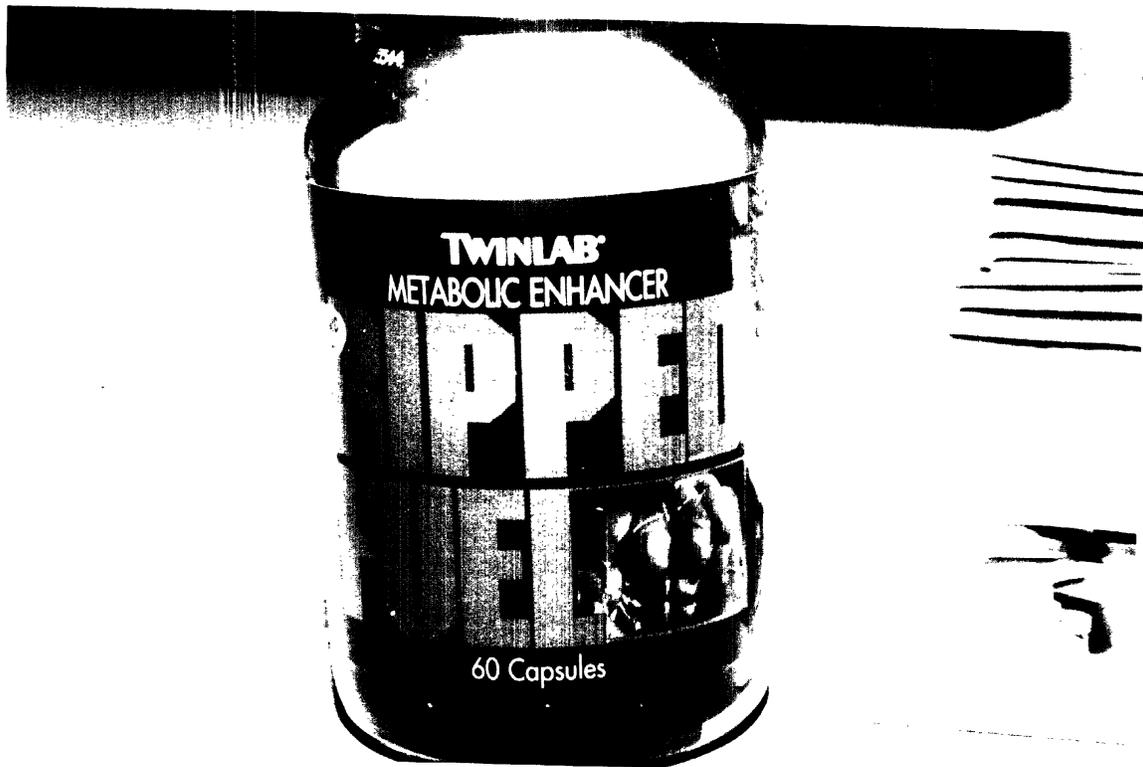




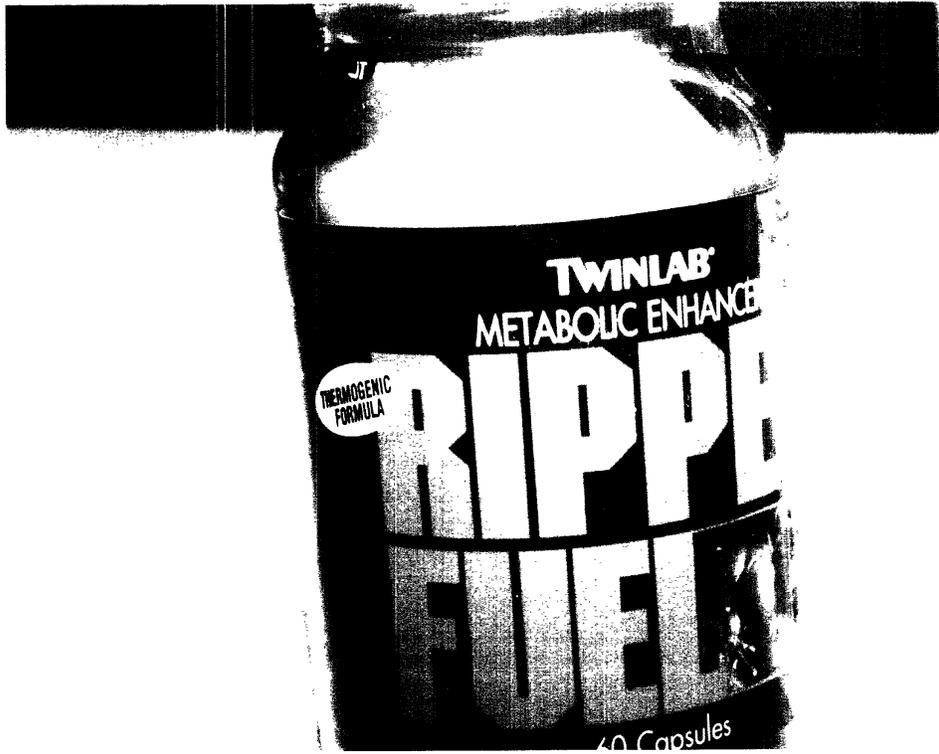
DOC 46060

4/6/99

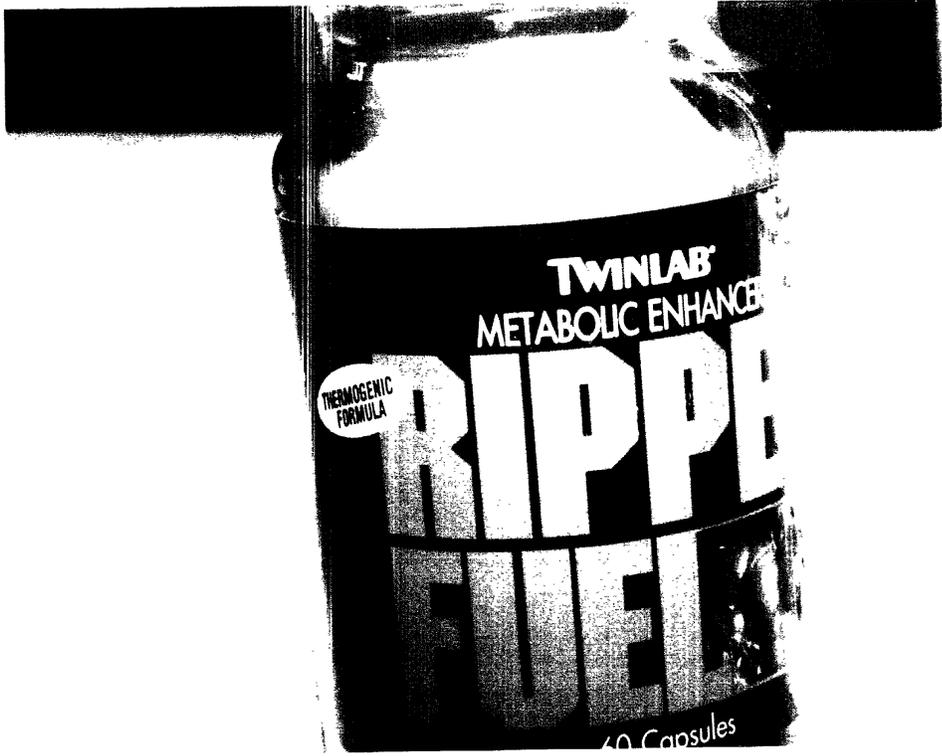
SJH



000008



000009



000010

DOC 46060

4/6/99

SJH

Best Quality  
FSA

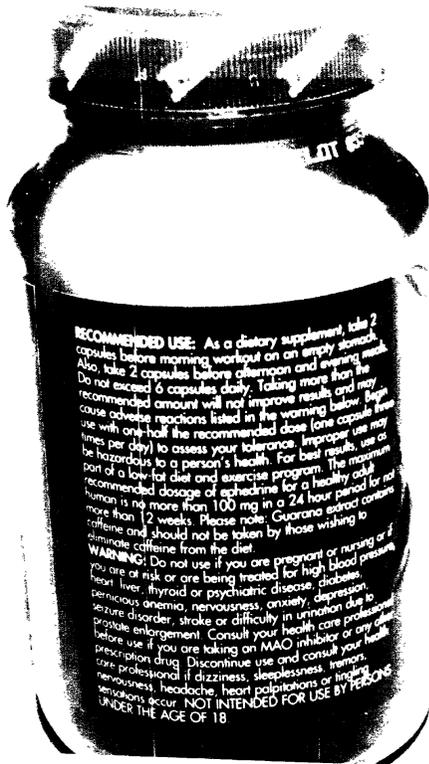


000011

Not to be used



For Quality  
FDA



**RECOMMENDED USE:** As a dietary supplement, take 2 capsules before morning workout on an empty stomach. Also, take 2 capsules before afternoon and evening meals. Do not exceed 6 capsules daily. Taking more than the recommended amount will not improve results and may cause adverse reactions listed in the warning below. Begin use with only half the recommended dose (one capsule three times per day) to assess your tolerance. Improper use may be hazardous to a person's health. For best results, use as part of a low-fat diet and exercise program. The maximum recommended dosage of ephedrine for a healthy adult human is no more than 100 mg in a 24 hour period for no more than 12 weeks. Please note: Guarana extract contains caffeine and should not be taken by those wishing to eliminate caffeine from the diet.

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000013

Not Quality  
FDA



000014

Best Quality  
USA

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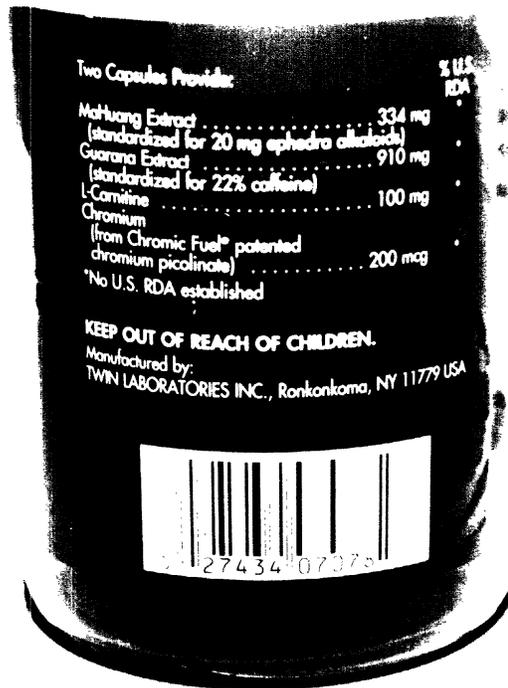


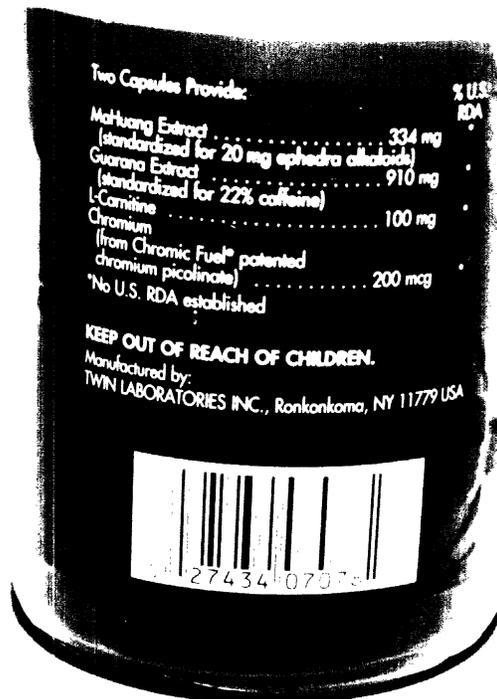
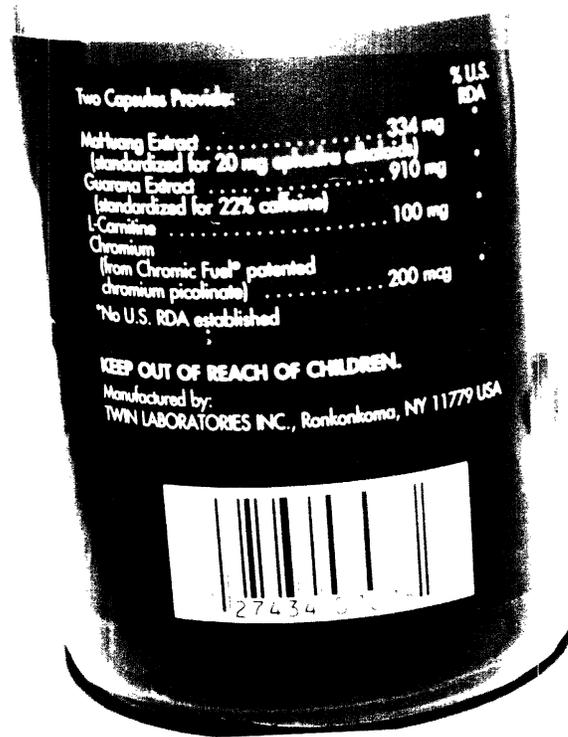
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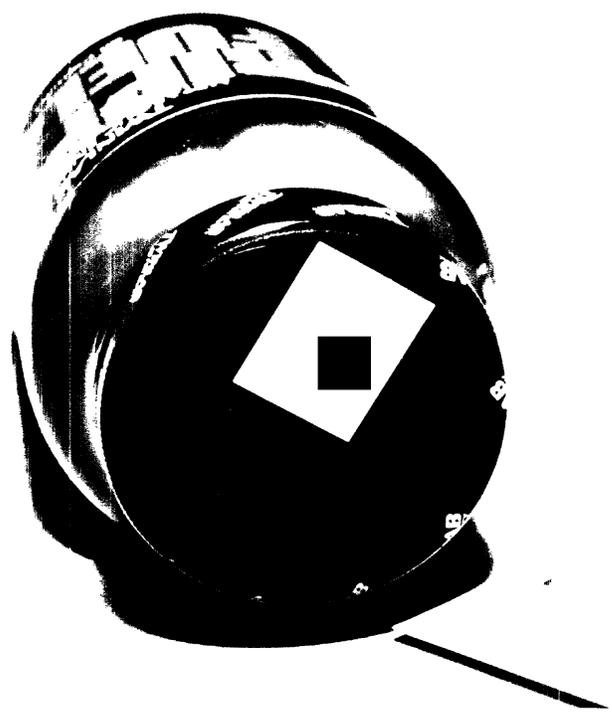
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Small circular logo or mark.



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