

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

ARMS#

12485



2 - LABEL SAMPLE

000001

TWINLAB
METABOLIC ENHANCER

RIPE
UP

60 Capsules

000002



LAB
ENHANCER

ED
TM



000003



Two Capsules Provide:

- MaHuang Extract
(standardized for 6% ephedrine)
- Guarana Extract
(standardized for 22% caffeine)
- L-Carnitine
- Chromium
(from Chromic Fuel* patented
chromium picolinate)
- *No U.S. RDA established

WARNING: Diabetics may use under
supervision because this product contains
picolinate which may enhance insulin

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



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Provide:

Extract 334mg
(for 6% ephedrine)
Extract 910mg
(for 22% caffeine)
..... 100mg

..... Fuel* patented
(picolinate) 200mg
..... established

Diabetics may use only under a physician's supervision because this product contains chromium which may enhance insulin sensitivity.

By
LABORATORIES, INC.
IRVINE, CA 92714 USA



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RECOMMENDED USE: As a dietary supplement, take before morning workout on an empty stomach. Take 2 capsules before afternoon and evening workouts. Do not exceed 6 capsules daily. Taking the recommended amount will not improve performance. Side effects may cause adverse reactions listed in the warnings. Begin use with one-half the recommended amount (one capsule three times per day) to assess tolerance. For best results, use as part of a diet and exercise program. Please note: This product contains caffeine and should not be used by those wishing to eliminate caffeine.

WARNINGS: Do not use if you are pregnant or nursing, at high risk or are being treated for high blood pressure, liver, thyroid or psychiatric disease, iron deficiency anemia, nervousness, anxiety, seizure disorder, stroke or difficulty in swallowing, or prostate enlargement. Consult your health care professional before use if you are taking any other prescription drug or supplement and consult your health care professional if you experience dizziness, lightheadedness, drowsiness, dizziness, sleeplessness, tremors, headache, heart palpitations or tingling. **NOT INTENDED FOR USE BY CHILDREN UNDER THE AGE OF 18. KEEP OUT OF REACH OF CHILDREN.**

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RECOMMENDED USE:

2 capsules before morning
stomach. Also, take 2 capsules
evening meals. Do not take
more than the recommended
results and may cause the
warning below. Begin use
recommended dose (one capsule)
assess your tolerance. For
a low-fat diet and exercise.
Guarana extract contains
be taken by those wishing
from the diet.

WARNING: Do not use if
or if you are at risk or are
pressure, heart, liver, thyroid,
diabetes, pernicious anemia,
depression, seizure disorder,
urination due to prostate
health care professional for
an MAO inhibitor or any
Discontinue use and consult
professional if dizziness,
nervousness, headache, or
sensations occur. **NOT FOR
PERSONS UNDER THE AGE OF 18
KEEP OUT OF REACH OF CHILDREN**

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| | | | | | | | |
|---|---|--|---------------------------------|--|---|---|--|
| 1. FLAG SURVEILLANCE <input checked="" type="checkbox"/> COMPLIANCE <input type="checkbox"/> | | | | 2. TYPE SAMPLE | | 3. SAMPLE NUMBER 97-790-066 | |
| 4. CENTRAL FILE NUMBER Pending | | 5. DATE COLLECTED 8/26/97 | | 6. PRODUCT CODE 54DC-99 | | 7. RESPONSIBLE FIRM M | |
| 10. RELATED SAMPLE None | | 11. PC 2 | 12. COLL NO. 234 | 13. SPLING DISTRICT LOS-DO | | 8. PROGRAM ASSIGNMT CODE 03R801 | 9. HOURS 3 |
| 15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) Metabolic Enhancer Ripped Fuel Capsules in previously opened brown tinted bottle measuring approximately 4.25" tall and 2.25" in diameter with black plastic screw top like lid. Black paper label with white and red print. Label reads in part: "****TWINLAB METABOLIC ENHANCER***60 Capsules***Two Capsules Provide: MaHuang Extract***Manufactured by: TWIN LABORATORIES, INC. Ronkonkoma, NY 11779 USA****" Clients attorney retained this bottle and placed 13 of 26 bottled capsules in clear plastic zip top like bag. Capsules are brown like in color and measure approximately 7/8" long. | | | | | | | |
| 16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or assignment No. if applicable.) for CFSAN Project # 12485. Check for Ephedrine Alkaloids. | | | | | | 17. MFG CODES (Labels, pkg, shipping containers) On neck of jar "Lot # 56491" | |
| 18. MANUFACTURER (Name, address & ZIP) TWIN LABORATORIES, INC. Ronkonkoma, NY 11779 USA | | | | 19. SHIPPER (Name, address & ZIP) (Retailer) | | 20. DEALER (Name, address, ZIP & TELEPHONE) Attorney for client | |
| 21. SIZE OF LOT FROM WHICH SAMPLED One previously opened bottle. Took sample from 26 remaining capsules. | | | 22. EST VALUE Unknown | | 23. RECEIPT ISSUED FDA472 FDA484 NONE X | | 24. DATE SHIPPED & DOC REF Unknown |
| 25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) Sample consists of one previously opened bottle of TWINLAB METABOLIC ENHANCER RIPPED FUEL. Client's attorney extracted 13 of the remaining 26 capsules and placed in a clear plastic zip top like baggie. | | | | | | | |
| HOW PREPARED Sample identified as in block #27. Sample placed in a whirlpack bag ard sealed and identified as in block #28. | | | | | | | |
| 27. COLLECTOR'S IDENT ON PKG AND/OR LABEL "97-790-066 8/26/97 NMC" | | | | 28. COLLECTOR'S IDENTIFICATION ON SEAL "97-790-066 8/26/97 Nianna M. Capalia" | | | |
| 29. SAMPLE DELIVERED TO Jan Bussey via Fed-Ex 22201 23rd Drive SE Bothell, WA 98021-4421 | | | | | 30. DATE DELIVERED 8/26/97 | | 31. LAB SEA-DO |
| | | | | | 32. LAB WITH SPLIT SAMPLE LOS-DO | | 33. ORIG C/R & RECORDS TO LOS-DO |
| 34. RCDS OBTAINED | a. INVOICE NO. AND DATE None | | | | b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavit, etc.) NO. AND DATE None | | |
| | c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE | | | | | | |
| 35. REMARKS (If additional space is needed, attach form FDA 464a, C/R Continuation Sheet) | | | | | | | |
| 36. CONSUMER COMPLAINT NO. OR RECALL NO. CFSAN #12485 | | 37. AMT. \$ N/C CRED CD C V B <input type="checkbox"/> <input 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) Nianna M. Capalia, CSO | |

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

COLLECTION REPORT

CIRCLE APPROPRIATE COPY:

SAMPLE RECORD COPY 1 (White) HOME DISTRICT COPY 2 (Pink) COLLECTING DISTRICT COPY 3 (Green)

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|--|---------------|---|-----------------------|
| 1 PRODUCT Ripped Fuel | | 2 SAMPLE NO 97-790-066 | |
| 3a SAMPLE CLASSIFICATION | | b LABORATORY CONCLUSIONS | |
| CODE | PAC NO | Sample consisted of 13 gelatin capsules. Analysis HPLC found: (3.3 mg/g) 2.6 mg/capsule ephedrine (9.0 mg/g) 7.2 mg/capsule pseudoephedrine trace methylephedrine trace methylpseudoephedrine Total Alkaloids = (12.3 mg/g) 9.8 mg/capsule | |
| 4 | 03R801 | | |
| | | | |
| | | | |
| 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

12485

97 SEP -9 A9:06

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

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