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

ARMS#

13265

2 - LABEL SAMPLE

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 48053

Flag	Flag Remarks				
Complaint Sample	F/U to DET-0789 Medwatch 13265				
Episode Number	**Origin**	**Basis**	**Sample Type**	**FIS Smpl Num**	**Status**
	Domestic	Compliance	Official	99919509	In Progress
FEI	**Date Collected**	**Product Code**	**Responsible Firm**	**PAC**	**Hours**
3002622506	02-MAR-99	54YCY99	Shipper	21R801	8
Related Smpl Num	**Position Class**	**Sampling District**	**NDC Number**	**Permit Number**	**Storage Rqrmnt.**
	INV	DET-DO			Ambient
Dealer is Consumer	**Crx/DEA Schedule**	**Recall Num**	**Consumer Compl. Num**	**Brand Name**	
Yes			DET-0789	Metabolife Dietary Supplement 356	

Product Description
Multi-ingredient dietary caplets in a white plastic bottle with a yellow self-adhesive label

Product Label
See continuation.

Reason for Collection
F/U to Consumer complaint DET-0789. Collect sample per CFSAN assignment # 13265. Analyze for Ephedra

MFG Codes
None

Expiration Date
None

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Garden State Nutritionals	100 Lehigh Drive Fairfield, NJ 07072 US	Manufacturer	2244049	
Metabolife International, Inc.	5070 Santa Fe Street San Diego, CA 92109 US	Shipper	3002622506	

Size of Lot	Est. Value	Rcpt Type	Date Shipped & Doc. Ref.
		FDA484	

Description of Sample
Metabolife Dietary Supplement 356

Method of Collection
See continuation.

How Prepared
Bottle was placed in a brown paper bag and identified and officially sealed as stated below.

Collector's Identification on Package and/or Label
"48053 03/05/99 RLR"

Collector's Identification on Seal
"48053 03/05/99 Renee L. Rice"

Sample Delivered To
Chuck Teschke

Date Delivered

Orig C/R & Records To
NWJ-DO

Lab w/Split Sample

Lab

Document Number	Document Date	Document Type	Document Remarks
	03/05/1999	Affidavit	Signed by [redacted]
	03/05/1999	Other	Reciept for sample

Remarks
Send 749(d) to [redacted] at [redacted]

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
$0.00	No Charge	Yes	No	Renee L Rice

Name of Signer

Date & Time of Signature

Meaning
ET

000002

Date: 04/05/1999

COMPLAINT/INJURY F/U DET-073
02/01-02/99 RLR Attach 10 OF

ntinuation:

oduct Label

astic bottle labeled in part (center): "Natural Herbs***Metabolife 356***Dietary Supplement Herbal formula to enhance your
ET and provide Eneryg***90 caplets"

astic bottle labeled in part (left side): "SUGGESTED USE: As a Dietary supplement, orally, adults, ONE to TWO caplets two
three times per day, or every four hours, on empty stomach one hour befor meals. DO NOT EXCEED EIGHT CAPLETS
ER DAY***CAUTION***"

lastic bottle labeled in part (right side): "Supplement Facts***Serving Size 1 caplet***Ma Huang Concentrate (aerial
art)***(12 mg naturally-occuring ephedrines)***Metabolife International Inc.***5070 Sante Fe Street San Diego, CA
2109***(619) 490-5222***5682"

Method of Collection

Twenty caplets removed by consumer and given to investigator. Sample placed in a brown glass bottle. At DET-DO. investigator placed the sample in a whirl-pak bag and then put the whirl-pak bag into the same brown glass bottle. Both the whirl-pak bag and bottle were identified "FACTS 48053 03/05/99 RLR".

000003

COMPLAINT/INJURY F/U DET-C739
02/01-02/99 RLR ATTACH 10 OF 1

Date: 04/05/1999

SUGGESTED USE: As a Dietary supplement, adult adults, ONE to TWO caplets two to three times per day, in every four hours, on an empty stomach one hour before meals. DO NOT EXCEED EIGHT CAPLETS PER DAY.

CAUTION: AS WITH ANY DIETARY SUPPLEMENT, SEEK ADVICE FROM A HEALTH CARE PRACTITIONER PRIOR TO USE IF YOU ARE PREGNANT OR NURSING, OR IF YOU HAVE HIGH BLOOD PRESSURE, HEART OR THYROID DISEASE, DIABETES, DIFFICULTY IN URINATION DUE TO PROSTATE ENLARGEMENT, OR IF TAKING A MAO INHIBITOR OR ANY OTHER PRESCRIPTION DRUG, OR INTEND ON TAKING TO REDUCE WEIGHT. REDUCE IF NERVOUSNESS, TREMOR OR NAUSEA OCCUR. NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18. KEEP OUT OF THE REACH OF CHILDREN.

*Based on multi-species clinical laboratory [illegible]

Natural Herbs

Metabolife

Dietary Supplement 356

Herbal formula to enhance your

DIET

and provide

Energy

90 Caplets

Supplement Facts

Serving Size 1 Caplet

Amount Per Serving	% Daily Value*
Vitamin E ... 5 IU	[illegible]
Magnesium (as Magnesium Chelate) ... 75 mg	[illegible]
Zinc (as Zinc Chelate) ... 5 mg	[illegible]
Chromium (as Chromium Picolinate) ... 75 mcg	[illegible]
Proprietary Blend ... 725 mg	
Guarana Concentrate (seed)	
(40 mg naturally-occurring caffeine)	
Ma Huang Concentrate (aerial parts)	
(12 mg naturally-occurring ephedrine)	
Bee Pollen	
Ginseng (root)	
Ginger (root)	
Lecithin	
Lipotrim	
Bovine Complex	
Damiana (leaf)	
Sarsaparilla (root)	
Golden Seal (aerial part)	
Nettles (leaf)	
Gotu Kola (aerial part)	
Spirulina Algae	
Royal Jelly	

* Daily Value not established

Other Ingredients: Methocel, silica, stearic acid and magnesium stearate.

Metabolife International, Inc.
5070 Santa Fe Street San Diego, CA [illegible]
(619) 490-5222

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COMPLAINT/INJURY F/U DET-0789
02/01-02/99 RLR ATTACH 5b OF 11

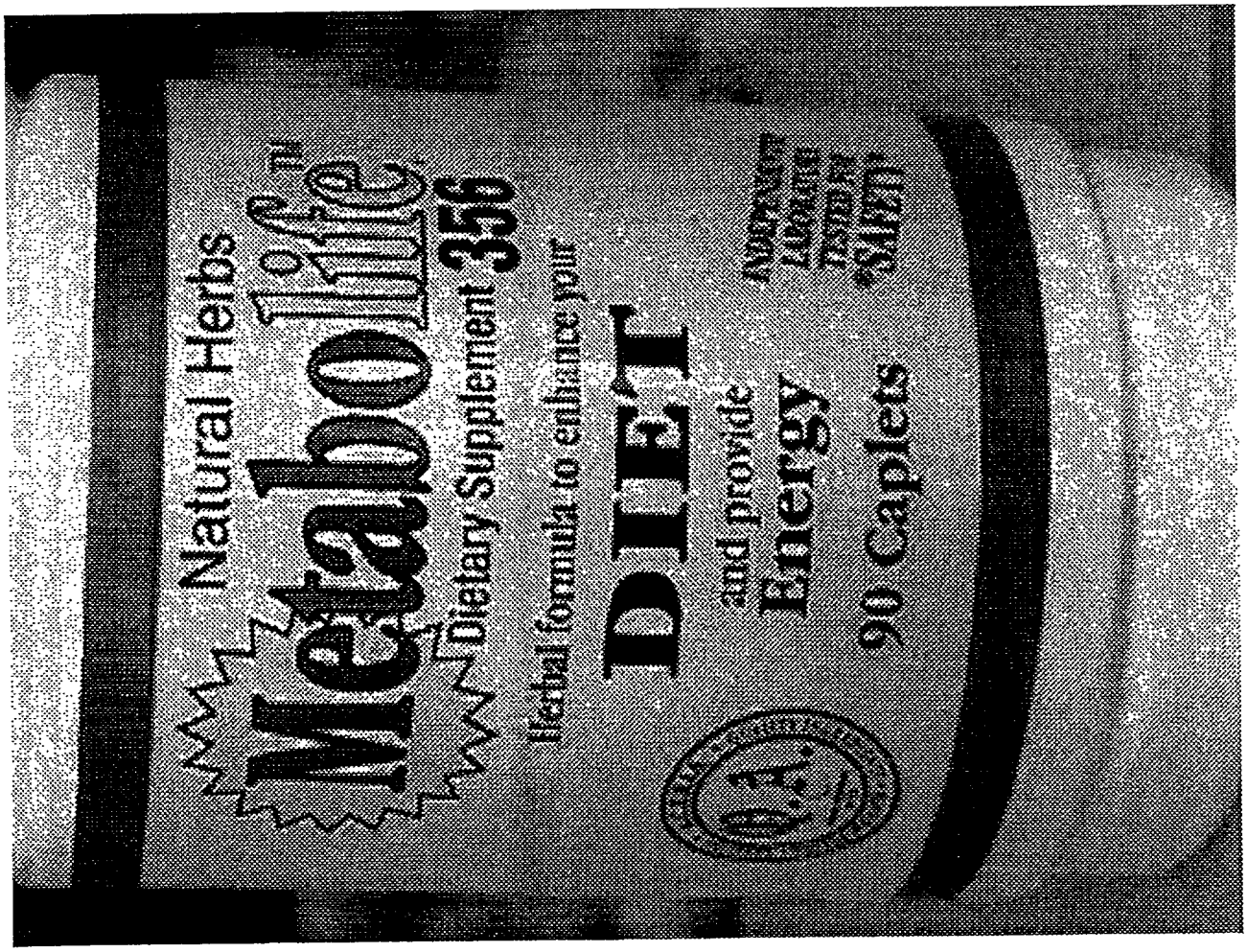
Complaint Injury/FU DET-0789

File A:MVC-018F.JPG

03/05/99 RLR

Complaint Injury/FU DET-0789

Attachment 5e of 11 03/05/99 RLR

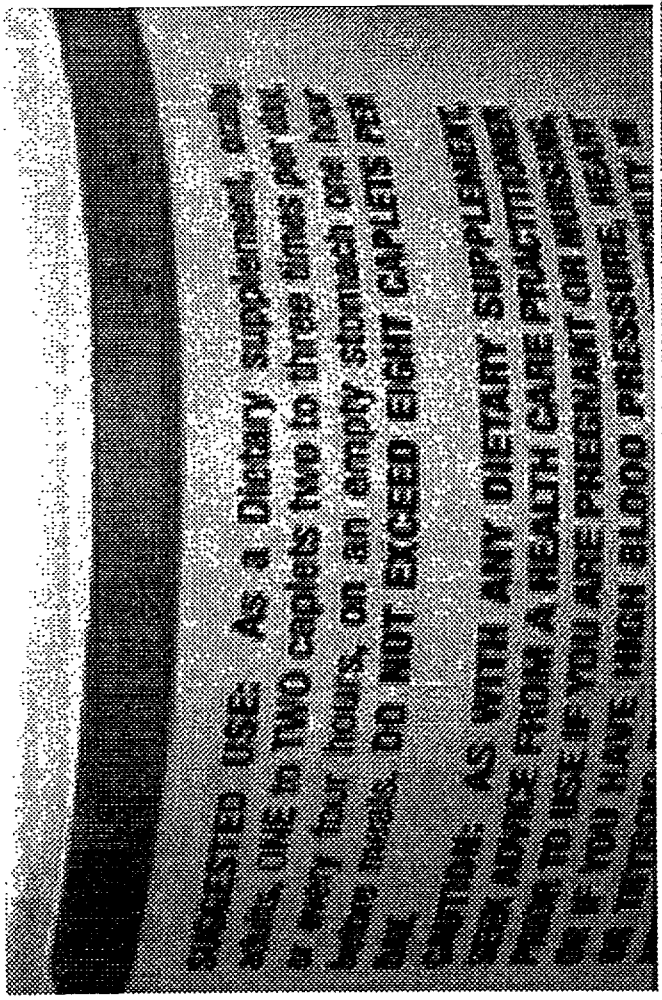


Digital photographs of the center part of the label.

Complaint Injury/FU DET-0789

File A:MVC-009F.JPG

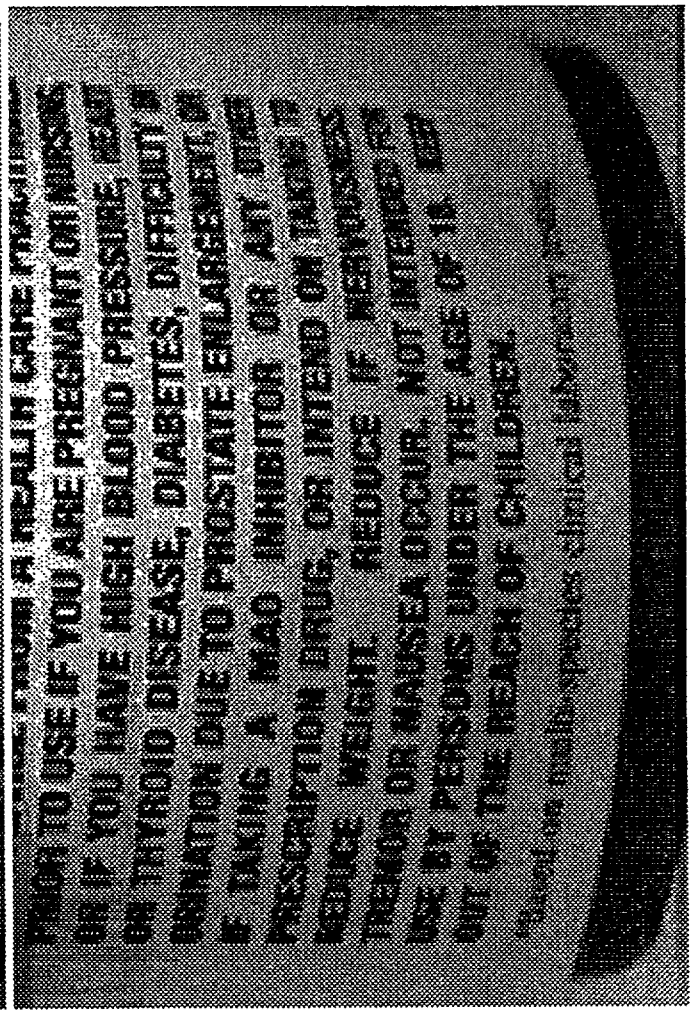
03/05/99 RLR



Complaint Injury/FU DET-0789

File A:MVC-011F..JPG

03/05/99 RLR

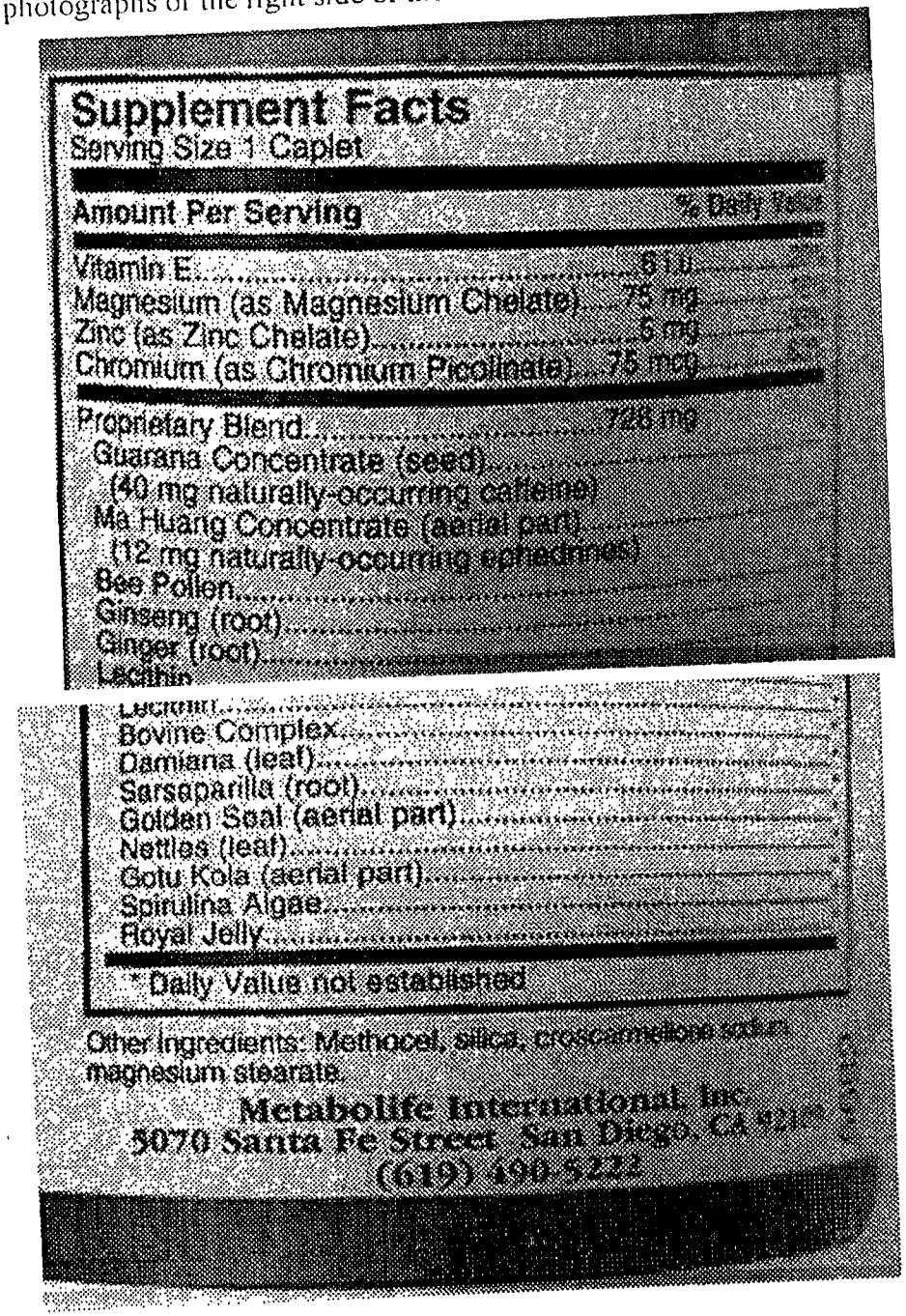


Complaint Injury/FU DET-0789 ea

Attachment 5d of 11 03/05/99 RLR

Digital photographs of the left side of the label:

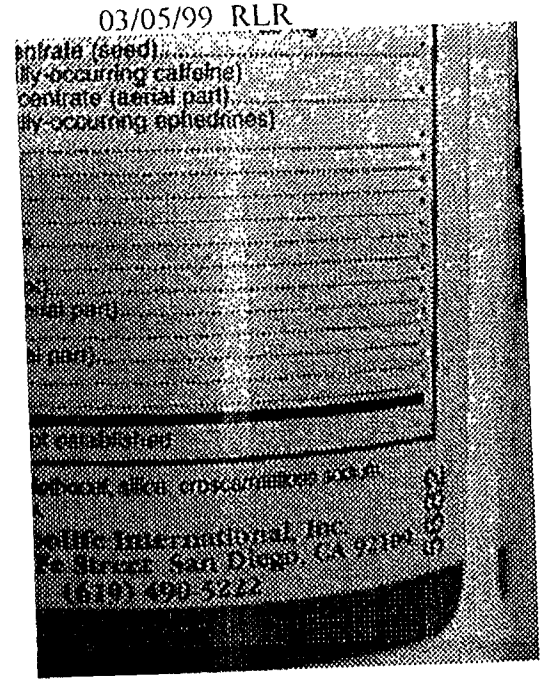
Digital photographs of the right side of the label:



Complaint Injury/FU DET-0789
File A:MVC-019F.JPG
03/05/99 RLR

Complaint Injury/FU DET-0789
File A:MVC-023F.JPG
03/05/99 RLR

Complaint Injury/FU DET-0789
File A:MVC-025F.JPG
03/05/99 RLR



Complaint Injury/FU DET-0789 RLR
Attachment 5e of 11 03/05/99 RLR

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[redacted]

SUGGESTED DOSE: As a Dietary supplement, orally, adults, ONE to TWO caplets two to three times per day, at every four hours, on an empty stomach one hour before meals. DO NOT EXCEED EIGHT CAPLETS PER DAY.
CAUTION: AS WITH ANY DIETARY SUPPLEMENT, SEEK ADVICE FROM A HEALTH CARE PRACTITIONER PRIOR TO USE IF YOU ARE PREGNANT OR NURSING, OR IF YOU HAVE HIGH BLOOD PRESSURE, HEART OR THYROID DISEASE, DIABETES, DIFFICULTY IN URINATION DUE TO PROSTATE ENLARGEMENT, OR IF TAKING A MAO INHIBITOR OR ANY OTHER PRESCRIPTION DRUG, OR INTEND ON TAKING TO REDUCE WEIGHT. REDUCE IF NERVOUSNESS, TREMOR OR NAUSEA OCCUR. NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18. KEEP OUT OF THE REACH OF CHILDREN.

** This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

*Based on multi-species clinical laboratory testing.

Natural Herbs

Metabolife

Dietary Supplement 356™

Herbal formula to enhance your

DIET

and provide

Energy**

90 Caplets

INDEPENDENTLY LABORATORY TESTED FOR SAFETY*

Supplement Facts

Serving Size 1 Caplet

Amount Per Caplet	% Daily Value
Vitamin [illegible]	[illegible]
Magnesium (as Magnesium Citrate) [illegible] mg	[illegible]
Zinc (as Zinc Citrate) [illegible] mg	[illegible]
Chromium (as Chromium Picolinate) [illegible] mcg	[illegible]
Proprietary Blend [illegible] mg	
Guarana Concentrate (seed) [illegible] mg	
40 mg caffeine (guarana extract)	
Mu Tuang Concentrate (whole plant) [illegible] mg	
7 mg caffeine (mu tuang extract)	
Sea Potato [illegible]	
Ginseng root [illegible]	
Ginger root [illegible]	
Licorice [illegible]	
Bovine Colostrum [illegible]	
Dandelion leaf [illegible]	
Schisandra root [illegible]	
Golden Seal whole plant [illegible]	
Hawthorn leaf [illegible]	
Milk thistle whole plant [illegible]	
Burdock leaves [illegible]	
Kelp [illegible]	
Daily Value not established	

Other ingredients: cellulose, silica, croscarmellose sodium, magnesium stearate.

Metabolife International, Inc.
[illegible] Santa Fe Street, San Diego, CA 92109
(619) 490-5322
For Health Questions (800) 231-4764

7-98

LOT # LOCATION

PRODUCT CODE

000008

COMPLAINT/INJURY F/U DET-0789 per
02/01-02/99 RLR ATTACH. loc OF 11

600000 Metabolife International, Inc.

5070 Santa Fe Street • San Diego • CA • 92109

COMPLAINT/INJURY F/U DET-0789
02/01-02/99 RLR ATTACH. 66 OF 11

U.S. Food and Drug Administration
1560 E. Jefferson
Detroit, MI 489207

Attn: Renee L. Rice

Envelope containing an example of Metabolife's Product Labeling from John Macaulay COMPLAINT/INJURY F/U DET-0789

COMPLAINT/INJURY F/U DET-0789
02/01-02/99 RLR ATTACH. 66 OF 11

Facsimile of label:

SUGGESTED USE: As a Dietary supplement, orally, adults, ONE to TWO caplets two to three times per day, or every four hours, on an empty stomach one hour before meals. DO NOT EXCEED EIGHT CAPLETS PER DAY.

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*Based on multi-species clinical laboratory testing.

Q.A. MANUFACTURING LABELING ACCURACY QUALITY INGREDIENTS

Natural Herbs

Metabolife™ 356

Dietary Supplement
Herbal formula to enhance your DIET and provide Energy

90 caplets

INDEPENDENTLY LABORTORY TESTED FOR SAFETY

Supplement Facts
Serving size 1 caplet

Amount Per Serving		% Daily Value
Vitamin E	6 i u	20%
Magnesium (as Magnesium Chelate)	75 mg	18%
Zinc (as Zinc Chelate)	5 mg	33%
Chromium (as Chromium Picolinate)	75 mcg	62%*
Proprietary Blend	728 mg	
Guarana Concentrate (seed) (40 mg naturally-occurring caffeine)		*
Ma Huang Concentrate (aerial part) (12 mg naturally-occurring ephedrines)		*
Bee Pollen		*
Ginseng (root)		*
Ginger (root)		*
Lecithin		*
Bovine Complex		*
Damiana (leaf)		*
Sarsaparilla (root)		*
Golden Seal (aerial part)		*
Nettles (leaf)		*
Gotu Kola (aerial part)		*
Spirulina Algae		*
Royal jelly		*

*Daily Value not established

Other Ingredients: Methocel, silica, croscamelose sodium, magnesium stearate

Metabolife International, Inc
5070 Sante Fe Street San Diego, CA 92109
(619) 490-5222

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COMPLAINT/INJURY F/U DET-0789 µK
02/01-02/99 RLR ATTACH. 5 OF 6 11