

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

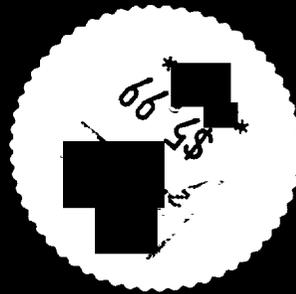
ARMS#

13099



2 - LABEL SAMPLE

**000001**



MedWatch #13099 Investigation  
Exhibit # 3  
4-5 March 1999 GM

000002



**NI** ASTHMA  
RELIEF

**TWO-WAY  
ACTION**

**ATOR EXPECTORANT**

**BREATHING  
DROWSINESS**

TABLET CONTAINS

**PHEDRINE HCL +**

**19 GUAIFENESIN**

product may be harmful or fatal

000003



60 TABLETS

**MINI**

BRANDS  
**MT-WC  
AC**

BRONCHODILATOR &

HELPS BREATHING  
WITHOUT DRUGS

EACH TABLET CONTAINS

**25 mg EPHEDRINE**

**200 mg GUAFENIN**

Caution: Excessive use of this product may lead to

000004



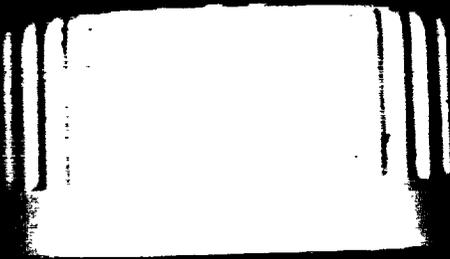


**ACTIVE INGREDIENTS:** 25mg Ephedrine Hydrochloride

**INDICATIONS:** For temporary relief of shortness of breath and wheezing due to bronchial asthma and thin bronchial secretions to rid the bronchus.

**DIRECTIONS:** Adults and children 12 years of age or older: 1 tablet every 4 hours, not to exceed 6 tablets in 24 hours. Do not exceed recommended dosage. Children under 12 years of age: Consult your doctor before using this product unless a diagnosis of asthma has been made. Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urinating. Do not use this product if you have an enlarged prostate gland unless directed by a doctor. Do not use this product if you have ever been hospitalized for asthma or if you are taking any other asthma drug for asthma unless directed by a doctor. Do not use this product, but seek medical attention if your symptoms are not relieved within 1 hour or become worse. Do not use this product if you experience nervousness, tremor, dizziness, or loss of appetite. If these symptoms persist or become worse, stop using this product. Do not take this product for persistent cough. Do not use this product with smoking, asthma, chronic bronchitis, or if your cough is accompanied by excessive phlegm. A persistent cough may be a sign of a more serious condition. If your cough persists for more than 1 week, or if you have a fever, rash, or persistent headache, consult your doctor. If you are pregnant or nursing a baby, consult your doctor before using this product. **KEEP OUT OF REACH OF CHILDREN.** In case of overdose, get medical assistance or contact a poison control center. Abuse of this product may be harmful.

000006



**ACTIVE:** 25mg Ephedrine Hydrochloride  
 For temporary relief of shortness of  
 breathing due to bronchial asthma. Helps  
 loosen secretions to rid the bronchial pas-  
 sages.  
**CAUTION:** Adults and children 12 years  
 and older: Take every 4 hours, not to exceed 6 tabs.  
 Do not exceed recommended dose.  
 Children under 12 years of age: Consult a doctor.  
 Do not use if a diagnosis of asthma has  
 not been made by a doctor. Do not use this  
 product if you have heart disease,  
 diabetes, or difficulty in urination  
 and unless directed by a doctor. Do  
 not use if you have been hospitalized for asthma or if  
 you have had asthma unless directed by a doc-  
 tor. If symptoms persist or become worse,  
 seek medical assistance immediately  
 within 1 hour or become worse.  
 If nervousness, tremor, sleepless-  
 ness symptoms persist or become  
 worse, stop using this product for persistent or  
 severe coughing, asthma, chronic bronchitis,  
 or sinusitis accompanied by excessive phlegm.  
 A persistent cough may be a sign of  
 pneumonia. If cough persists for more than 1 week, tends to  
 worsen, or persistent headache, consult  
 your doctor. If pregnant or nursing a baby, seek the  
 advice of your doctor before using this product. **KEEP THIS AND  
 ALL OTHER MEDICINES OUT OF THE REACH OF CHILDREN.** In case of accidental  
 poisoning, call your doctor or contact a poison control cen-  
 ter. This product may be harmful or fatal.

6

000007







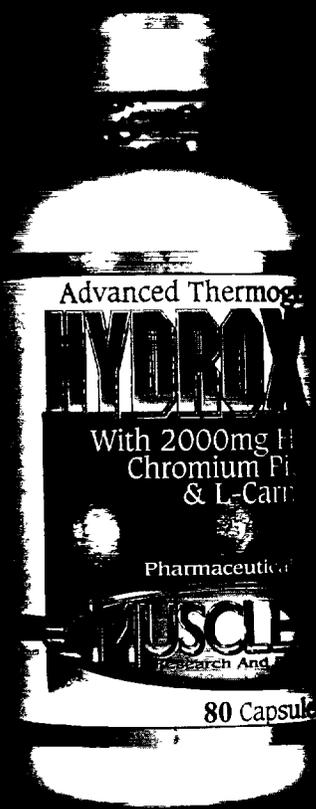
MedWatch #13099 Investigation

Exhibit # 2

4-5 March 1999

GM

000010



000011

Advanced Thermogenic Fo

**HYDROXY**

with 2000mg Hydrox  
Chromium Picolinat  
& L-Carnitine

Pharmaceutical Quality

**MUSCLE**

Research And Development

80 Capsules

000012

ed Thermogenic Formul

**MOXYGU**

2000mg Hydroxagen  
Premium Picolinate  
& L-Carnitine

Pharmaceutical Quality

**CELEC**  
And Development

80 Capsules

000013

Four Capsules provide:

Hydroxage	200
(supplying 1000mg of hydroxycitric acid)	
Shiung Extract	33
(standardized for 6% ephedra)	
Guarana Extract	9
(standardized for 22% caffeine)	
Willow Bark Extract	10
(standardized for 15% salicin)	
Carbitine	10
Chromium Picolinate	300



**MUSCLETECH**  
Research and Development  
Manufactured in the USA  
Customer Inquiries: 1-905-678

000014

Capsules provide:

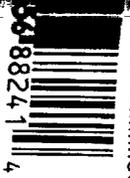
Arginine™	2000mg
Supplying 1000mg of hydroxycitric acid	
Yucca Extract	334mg
(standardized for 6% ephedra)	
Guarana Extract	910mg
(standardized for 22% caffeine)	
Yohimbin Bark Extract	100mg
(standardized for 15% salicin)	
Choline	100mg
Calcium Picolinate	300mcg



316-6188241-4  
**MUSCLETECH**  
Research and Development Inc.  
Manufactured in the USA  
Customer Inquiries: 1-905-678-3111

000015

... provide:  
..... 2000mg  
..... 30mg of hydroxyctic acid)  
..... 334mg  
[or 6% ephedra]  
..... 910mg  
[or 22% caffeine]  
..... 100mg  
..... 100mg  
[or 15% ... ]  
..... 300mcg  
..... 300mcg



**MELETECH**

Development Inc.™  
Manufactured in the USA  
Tel: 1-905-678-3114

000016

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

For Sample Number: 27459

27459 - Sample #

<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	Compliance	Official	99921857	In Progress
<b>FEI</b>	<b>Date Collected</b>	<b>Product Code</b>	<b>Responsible Firm</b>	<b>PAC</b>	<b>Hours</b>
1831179	16-APR-99	60CBH22	Manufacturer	46R801	
<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	BLT-DO			Ambient
<b>Dealer is Consumer</b>	<b>Crx/DEA Schedule</b>	<b>Recall Num</b>	<b>Consumer Compl. Num</b>	<b>Brand Name</b>	
Yes			MDR#13099	Mini Two Way Action	

**Product Description**  
Ephedra containing supplement

**Product Label**  
See continuation.

<b>Reason for Collection</b>	<b>MFG Codes</b>	<b>Expiration Date</b>
Sample collected as per [redacted] and CFSAN MedWatch #13099	98F039G	6/00

<b>Firm Legal Name</b>	<b>Address</b>	<b>Type of Firm</b>	<b>Firm FEI</b>	<b>FCE</b>
Body Dynamics, Inc.	9700 N. Michigan Rd Carmel, IN 46032 US	Manufacturer	1831179	

<b>Size of Lot</b>	<b>Est. Value</b>	<b>Rcpt Type</b>	<b>Date Shipped &amp; Doc. Ref.</b>
		FDA484	

**Description of Sample**  
Sample consists of 20 white tablets collected aseptically from consumer's container and placed in a Whirl Pack bag.

**Method of Collection**  
See continuation.

**How Prepared**  
See continuation.

<b>Collector's Identification on Package and/or Label</b>	<b>Collector's Identification on Seal</b>
"27459 3/4/99 GM"	"27459 3/4/99 Gerald Mierle"

<b>Sample Delivered To</b>	<b>Date Delivered</b>	<b>Orig C/R &amp; Records To</b>
[redacted]		BLT-DO
	<b>Lab w/Split Sample</b>	<b>Lab</b>

Document Number	Document Date	Document Type	Document Remarks
Att.#1	11/10/1998	Other	CFSAN Assignment
Att.#2	03/04/1999	Other	Authorization for Medical Records
Att.#3	03/04/1999	Other	Adverse Event Questionnaire
Att.#4	03/04/1999	Other	FDA484
Att.#5		Other	OEI Print Screen
Exh.#1		Other	Unpurged Medical Records on patient ID in MedWatch #13099
Exh.#2		Other	Copy of labeling for "Hydroxycut" lot # 36921 10/99
Exh.#3		Other	Copy of labeling for "Mini Two-Way Action" lot #98F039G

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 27459

Exh.#4

Other

Confidentiality Statement for [REDACTED]

03/08/1999

Other

to Law Firm

Memorandum to Bridgette M. Wallace, ARMS  
Monitor, HFS-636

Remarks

See continuation.

Payment Amount

Payment Method

704(d) Sample

702(b) Portion

Collector's Name

\$0.00

No Charge

No

No

Gerald Mierle

Name of Signer

Date & Time of Signature

Meaning

ET

'99 MAY 25 13:05

RECEIVED  
CLINICAL RESEARCH  
& REVIEW/OSR/CDER

**Continuation:**

**Product Label**

Product consists of 20 white tablets taken from a white plastic container labeled in part;\*\*\*"MINI TWO-WAY ACTION\*\*\*ASTHMA RELIEF\*\*\*25mg EPHEDRINE HCL+200mg GUAIFENESIN\*\*\*MARKETED BY: BDI Pharmaceuticals, a division of Body Dynamics, Inc. P.O. Box 78610, Indianapolis, IN 46278-0610\*\*\*98F039G 6/00\*\*\*"

**Method of Collection**

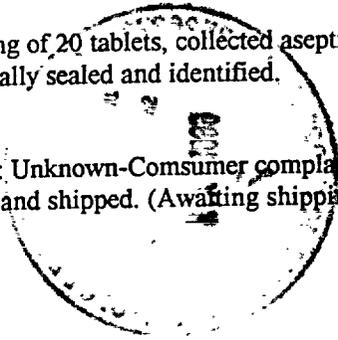
20 white tablets, which were collected from consumer's sample of 60 white tablets from a sealed hard white container which was labeled in part,\*\*\*"MINI TWO-WAY ACTION\*\*\*ASTHMA RELIEF\*\*\*25MG EPHEDRINE HCL+200MG GUAIFENESIN\*\*\*MARKETED BY: BDI Pharmaceuticals\*\*\*division of Body Dynamics, Inc., P.O. Box 78610, Indianapolis, IN 46278-0610\*\*\*98FO39G 6/00\*\*\*".

**How Prepared**

Sample consisting of 20 tablets, collected aseptically, placed in a Whirl Pack bag, closed, identified, and placed in a brown paper bag, officially sealed and identified.

**Remarks**

Estimated value: Unknown-Consumer complaint sample. Sample placed in locked storage cabinet in locked resident post until officially sealed and shipped. (Awaiting shipping instructions from CFSAN)



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER

US FOOD AND DRUG ADMINISTRATION  
900 WEST MADISON AVENUE  
BALTIMORE MARYLAND 21201-2199

2. NAME AND TITLE OF INDIVIDUAL

3. DATE

4. SAMPLE NUMBER

3/4/99

5. FIRM NAME

6. FIRM'S DEA NUMBER

7. NUMBER AND STREET

8. CITY AND STATE (Include Zip Code)

9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Drug, and Cosmetic Act [21 USC 380i(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.

(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)

- 20 Tablets "Mini Two Way Action" from container of 60 Tablets Lot # 98F039G 6/00
- Labeling for Hydroxycut 80 capsules, Muscletech Research and Development Inc. Lot # 36921 10-99
- Labeling for Mini Two Way Action 60 Tablets Marketed by BDI Pharmaceuticals a division of Body Dynamics Inc.
- All pertinent Medical Records pertaining to [redacted] patient referenced in Med Watch #13099.

MedWatch #13099 Investigation  
ATT # 4 Pg# 1 of 1  
4-5 March 1999 GM

000020

10. SAMPLES WERE

- PROVIDED AT NO CHARGE  
 PURCHASED  
 BORROWED (To be returned)

11. AMOUNT RECEIVED FOR SAMPLE

- CASH  BILLED  
 VOUCHER  CREDIT CARD

12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.)

13. COLLECTOR'S NAME (Print or Type)

14. COLLECTOR'S TITLE (Print or Type)

COLLECTOR'S SIGNATURE

Gerald Mierle, CSO

Investigator

Health Mail