

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

ARMS#

13346



0 - FRONT

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

*PERSON*

Form Approved OMB No. 0910-0291 Expires 12/31/94 See OMB statement on reverse

FDA Use Only

Triage unit sequence #	96081
	13346

CFSAN

Page 1 of 1

### A. Patient information

1 Patient identifier	2 Age at time of event: or Date of birth	3 Sex	4 Weight
In confidence	29	<input checked="" type="checkbox"/> female <input type="checkbox"/> male	135 lbs or kgs

### B. Adverse event or product problem

1  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other.

3 Date of event (mo/day/yr)	4 Date of this report (mo/day/yr)
	1/12/99 postmark

5 Describe event or problem

Heart palpitations,  
panic attacks,  
anxiety,  
Restless sleep

6 Relevant tests/laboratory data, including dates

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

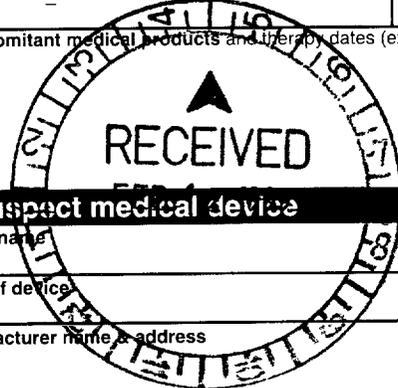
now

JAN 21 1999

MEDWATCH CTU

### C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)	3 Therapy dates (if unknown, give duration) from to (or best estimate)
#1 Enrich Power trim	4 QUARTER 1996
#2 main ingredient (ma huang)	
2 Dose, frequency & route used	5 Event abated after use stopped or dose reduced
#1 2-5 pills after meals	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
4 Diagnosis for use (indication)	8 Event reappeared after reintroduction
#1 weight loss	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6 Lot # (if known)	7 Exp. date (if known)
#1 don't know	#1
#2	#2
9 NDC # (for product problems only)	
10 Concomitant medical products and therapy dates (exclude treatment of event)	



### D. Suspect medical device

1 Brand name	4 Operator of device
2 Type of device	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
3 Manufacturer name & address	5 Expiration date (mo/day/yr)
6 model #	7 If implanted, give date (mo/day/yr)
catalog #	8 If explanted, give date (mo/day/yr)
serial #	
lot #	
other #	
9 Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)	
10 Concomitant medical products and therapy dates (exclude treatment of event)	

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### E. Reporter (see confidentiality section on back)

1 Name, address & phone #			
[Redacted]			
2 Health professional?	3 Occupation	4 Also reported to	
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	Administrative	<input checked="" type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	
5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>			



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

CTU 96081

# ADVICE ABOUT VOLUNTARY REPORTING

## Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

## Report **SERIOUS** adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

## Report even if:

- you're not certain the product caused the event
- you don't have all the details

## Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

## How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

## Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

## If your report involves a serious adverse event with a device

and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

**Confidentiality:** The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS  
Hubert H. Humphrey Building,  
Room 721-B  
200 Independence Avenue, S.W.  
Washington, DC 20201  
ATTN: PRA

and to:  
Office of Management and  
Budget  
Paperwork Reduction Project  
(0910-0230)  
Washington, DC 20503

Please do NOT  
return this form  
to either of these  
addresses.

FDA Form 3500-back

**Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

## Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

## Official Business

Penalty for Private Use \$300



NO POSTAGE  
NECESSARY  
IF MAILED  
IN THE  
UNITED STATES  
OR APO/FPO

**BUSINESS REPLY MAIL**  
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD  
POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

# MEDWATCH

The FDA Medical Products Reporting Program  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20852-9787

RECEIVED  
CLINICAL RESEARCH & REVIEW/CSRE  
FEB 22 8 58 AM '99  
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UNITED STATES FOOD AND DRUG ADMINISTRATION  
**CONSUMER COMPLAINT/INJURY REPORT**

1. COMPLAINT NUMBER  
 NYK-3832

2. DATE OF COMPLAINT  
 3/29/1999

3. FORM OF COMPLAINT	(1) <input type="checkbox"/> TELEPHONE	(4) <input checked="" type="checkbox"/> OTHER	4. SOURCE OF COMPLAINT	<input type="checkbox"/> CONSUMER	<input type="checkbox"/> TRADE SOURCE	
	(2) <input type="checkbox"/> LETTER			<input checked="" type="checkbox"/> GOVERNMENT	<input type="checkbox"/> OTHER	
	(3) <input type="checkbox"/> VISIT			<input type="checkbox"/> LOCAL	<input type="checkbox"/> STATE	<input checked="" type="checkbox"/> FEDERAL

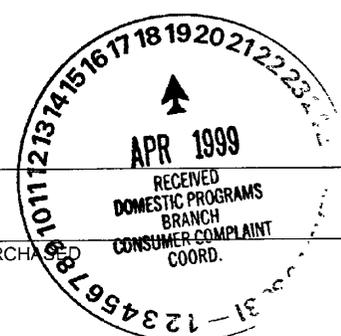
5. COMPLAINANT IDENTIFICATION	a. NAME AND ADDRESS	b. TELEPHONE NUMBER
	[REDACTED]	HOME: [REDACTED] WORK: [REDACTED]

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT/INJURY  
 MEDWATCH rec. from HFS-636, Project #13346. Reaction to Enrich Power Trim containing ma huang. Consumer returned my call today, incident happened 12/1996. Consumer purchased diet product from co-worker for weight loss as did other employees. Consumer took 10 tablets per day for approx. 5 months, during this time and prior to and 3 yrs. since, consumer stated she has suffered anxiety attacks, and dealing w/everday life. Consumer under care of physician prior to incident and following incident w/analyst because test were negative. Consumer currently diagnosed w/heart murmur. Consumer stated she did not remember the name of either her private physician nor the analyst. ER visit because she felt tightness in chest and difficulty breathing, EKG neg.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?  NO  YES (If Yes, explain in Remarks)

7. INJURY OR ILLNESS RESULTED	a. DEIO/EMOPS (HFC-130) NOTIFIED	b. TYPE SYMPTOM ONSET (HR.)	c. ATTENDING HEALTH PROFESSIONAL	d. HOSPITALIZATION REQUIRED
	(1) <input checked="" type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES  (If "yes" complete items a through d)	(1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES DATE	(1) <input type="checkbox"/> VOMITING (2) <input type="checkbox"/> NAUSEA (3) <input type="checkbox"/> DIARRHEA (4) <input type="checkbox"/> FEVER (5) <input type="checkbox"/> SKIN/EYE IRR (6) <input type="checkbox"/> HEADACHE (7) <input checked="" type="checkbox"/> OTHER 5 months chest tight & diff. breathing	(1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes", give name, address, phone, date) 12/24/1996: Er of [REDACTED]



8. PRODUCT AND LABELING	a. BRAND NAME	b. PRODUCT NAME
	c. SIZE AND PACKAGE TYPE	d. NAME AND LOCATION OF STORE WHERE PURCHASED
	e. LOT/SERIAL NUMBER	f. DATE PURCHASED
	EXP/USE BY DATE:	g. PRODUCT USED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES DATE 7/to 12/14/96
		h. AMT REMAINING none

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT	c. NAME AND LOCATION OF FIRM	d. IMPORT PRODUCT
	b. CFN	unknown	(1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES

10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD	c. DISPOSITION	11. PRODUCT CODE
	b. EVALUATION		12. INFORMATION COPIES TO:

REMARKS  
 Consumer discarded product at time of incident and has never used since. Consumer called Medwatch because she heard this on media. Consumer stated she still does not know if product caused her condition because prior history of anxiety attacks and since. Consumer stated she still may have some difficulty but minor dealing w/everday life: Consumer feels hospital gave false report of neg. EKG because she has been diag. w/ heart murmur and is filing suit. Consumer stated she went to ER because she felt the tightness in her chest and some difficulty breathing. These symptoms lasted until 2/1997. Her private physician and an analyst she visited at her phy. request did not help and she would not take any medications they prescribed.

NAME AND TITLE Marlene H.Doherty, CSI/CC	DATE 3/29/1999
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Notes on Telephone Conversation  
Clinical Research and Review Staff

Date	Feb 24, 1999	Phone No.	[REDACTED]
Name	[REDACTED]	Fax No.	[REDACTED]
Affiliation			
Address	[REDACTED]		
FDA Representatives	Richard J. Calvert, MD		
Question/Subject	Follow up on AER # 13346		

Discussion	I spoke with Mrs. [REDACTED] and identified myself as an FDA Medical Officer following up on her adverse event report. She described a period (about 4 months) of shortness of breath, palpitations, and anxiety/sleepless ness associated with use of Enrich Power Trim (5-10 caps. per day, consistent w/ directions). She had used the product ~1 mo. w/o symptoms prior to this. She visited the ER. (Dr [REDACTED] 12-25-96) They did not give a specific diagnosis, but felt her symptoms were due to the "diet pills." She took no other meds or supplements X BCPs. She discontinued the Power Trim after this, but had 3-4 months of throat tightness, shakes, and irregular breathing following this. She has been told she has mitral valve prolapse, and has seen a therapist since this time for treatment of panic attacks. She has the ER records in her home.
Follow up	I told her I would like to review her case with my supervisor. We might wish to send a Field Inspector to obtain the medical records. She no longer has the supplement.

Signed:

*Richard J. Calvert*  
Richard J. Calvert, MD

Date: 2-24-99

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## Adverse Event Questionnaire

Complaint Number: 13346

Investigator: \_\_\_\_\_

Consumer Information	
Date of Report: <u>02/24/99</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <input checked="" type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> OUSP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC
Name:	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M Age: <u>31</u>
Race: <input type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input checked="" type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other _____ <input type="checkbox"/> 9-Unknown	
Information on Adverse Event	
Date of Adverse Event: <u>12-24-96</u> Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>consumed product at home</u>
The following information relates to the consumers' use of the product.	
Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): <u>Used product a total of 5 months. After one month's use, noted insomnia, anxiety, palpitations, shortness of breath.</u>	
How long did the symptoms last? <u>4 months</u>	
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). <u>Used 5-10 capsules per day (instructions stated to use 2-3 capsules with each meal)</u>	
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>Oral contraceptives. No other medications or supplements</u>	
Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown (see note)	
Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input checked="" type="checkbox"/> Not Applicable	
Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input checked="" type="checkbox"/> Not Applicable	
Medical Information	
Was a health care provider seen?: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Give health care provider's name, address and telephone number: <u>Several visits to Emergency Room. On 12-25-96 saw Dr. [redacted] at ER</u>	
Occupation of Health Care Provider: <input checked="" type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify) _____	
What medical tests were performed and what were the results? - <u>echocardiogram</u>	
What was the medical diagnosis? - <u>No diagnosis given, symptoms attributed to "diel pills"</u>	
What treatment(s) was given (e.g., drugs, other)? - <u>Treated w/ nebulizer for "asthma" w/o improvement. Also, mitral valve prolapse was diagnosed.</u>	
Were there any preexisting condition(s)/treatment(s)? - <u>NO</u> (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input type="checkbox"/> No	

note: Symptoms of shakes, tightness of throat, palpitations & irregular breathing persisted - 3-4 months after discontinuing product.

Information obtained in phone interview w/ consumer.  
(see also notes on telephone conversation)

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*Richard J. Calvert, MD* 2-24-99  
Richard J. Calvert, MD

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Adverse Reaction Questionnaire

Complaint Number: NYK-3832

Investigator: Marlene H. Doherty, CSI/CO

Consumer Information	
Date of Report: <u>3/29/98</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input checked="" type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC
Name: <u>[REDACTED]</u>	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M Age: 32
Race: <input type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input checked="" type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <input type="checkbox"/> 9-Unknown	
Information on Adverse Reaction	
Date of Adverse Reaction: 12/1996	Give the site of consumption/ingestion (e.g. home, restaurant, office):
Previous Reaction to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Home, Office
<p>The following information relates to the consumers' use of the product. Tightness in chest; racey feeling</p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): 12/96-2/97.</p> <p>Product purchased from co-worker for weight loss 5 months prior. Complainant took a total of 10 tablets per day. Complainant having difficulty prior to taking product and three years since w/dealing w/everyday life. Seen analyst, private physician.</p> <p>How long did the symptoms last? 12/96-2/97.</p> <p>Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).</p> <p>Co-workers taking and selling product for weight loss. 5 tablets 2xday for 5 months.</p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event:</p> <p>DESOGEN rx for 4 yrs. for birth control.</p> <p>Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown</p> <p>Did symptoms reoccur after reintroduction of suspected product: Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input checked="" type="checkbox"/> Not Applicable</p> <p>Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Applicable</p>	
Medical Information	
Was a health care provider seen?: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Give health care provider's name, address and telephone number: MRS. [REDACTED] STATED SHE COULDN'T REMEMBER NAMES OF HER PRIVATE PHYS. OR ANALYST.	
Occupation of Health Care Provider: <input checked="" type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input checked="" type="checkbox"/> Other (specify) <u>psychologist</u>	
What medical tests were performed and what were the results? at ER of [REDACTED] [REDACTED] EKG - negative.	
What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)? None.	
Were there any preexisting condition(s)/treatment(s)? Panic attacks, anxiety, diff.dealing w/li (If YES, list them including allergies, and chronic diseases): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No prior and still w/less diff. now.	

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**Product Category**

1. Adverse reaction to: NOT APPLICABLE  
 Medical Food (under medical supervision)  Infant Formula  
 Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substance including botanicals such as ginseng and yohimbe, amino acids, extracts from animal glands, garlic extract; fish oils, oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para- amino-benzoic acid, and rutin, and mixtures of these ingredients)  
 Other (traditional food) \_\_\_\_\_

**Other Product Problems**

2.  Foreign Object (specify): \_\_\_\_\_  
 3.  Other (specify): \_\_\_\_\_

**Information on Suspected/Alleged Product**

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

NOT APPLICABLE

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

Check here if ingredients are unknown

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

- Aspartame  Color Additive (please specify) \_\_\_\_\_  
 Monosodium Glutamate  
 Sulfite  
 Other \_\_\_\_\_  
 Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire:  Yes  No  Unknown

Product Sample Available:  Yes  No  Unknown

**Outcome Attributed to Adverse Event:**

(If yes, include pertinent medical records)

- Death:  Yes  No  
 Life-Threatening:  Yes  No  
 Hospitalization:  Yes  No (if YES, indicate if initial or prolonged) \_\_\_\_\_  
 Required intervention to prevent permanent impairment/damage:  Yes  No  
 Did the adverse reaction result in a congenital anomaly:  Yes  No

000007

To: Bridgette Wallace@OFP@FDA.CFSAN  
From: Marlene Doherty@NYK@FDAORANER  
Certify: N  
Subject: Fwd: CFSAN Assignment 13346  
Date: Monday, March 29, 1999 at 10:49:55 am EST  
Attached: None

Comments:

FYI: Consumer finally called back - product discarded 3 yrs. ago.

Consumer was seen at ER of [REDACTED]  
[REDACTED] (our [REDACTED] No medication was prescribed, EKG because she felt tightness in her chest. Consumer was advised to follow-up w/her private physician. Consumer stated she did but could not give me physician's name. She then follow-up w/analyst per her physician's advice - she stated could not remember the name.

Consumer stated she has had/prior to taking the product for 5month in 1996 and since dealing with life in general. Anxiety attaches etc. prior to 1996 and since.

Consumer only taking birthcontrol pills for 4 yrs prior to taking product in 1996 DESOGEN.

I asked, if I sent her release for her medical records would she sign it. Consumer stated yes, but this would only be the ER visit, consumer was exp. anxiety attacks prior and continuing until today.

Marlene

- - - - - Original Message - - - - -  
- - - - -

To: Marlene Doherty@NYK@FDAORANER  
From: Bridgette Wallace@OFP@FDA.CFSAN  
Date: Friday, March 12, 1999 at 11:04:46 am EST  
Attached: None

Hi Marlene, on March 2, I faxed CFSAN Assignment 13346 for follow up on an Enrich Power Trim complaint. At this time

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the program office requested medical records, an adverse event questionnaire and labeling only. Recently they discovered their oversight and requested that I ask that the investigator collect the consumer portion of the product and expedite the process.

The sample will be analyzed for Ephedrine Alkaloids, however, at this time no analyzing district lab has been selected to perform the analysis.

Please collect the consumer sample if available and secure under official seal (no retail sample is necessary). Please hold the sample until the analyzing lab has been determined.

Please banyan me to let me know if the sample is available and to ensure that you received the message.

Thank you  
Bridgette Wallace  
Have a great day!!!

**000009**