

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

ARMS#

13328



0 - FRONT

Triage unit sequence #	96390
	13328

### A. Patient information

1 Patient identifier	2 Age at time of event: <u>50</u>	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight <u>147</u> lbs or _____ kgs
In confidence	Date of birth		

### 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	<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)
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5 Describe event or problem

*This drug has affected my vision, my nose from bothing it to bleeding. It has paralyzed my right fingers for a long time my fingers were stiff and I could not move them. And pains would develop in my back, a pain in my chest, and made my head feel really weird. Like in a daze. Even serious headaches. I think these pills should be re-examined before being put on the market for sale. And all down my right side I now hurt.*

6 Relevant tests/laboratory data, including dates

*My Dr. said don't take diet pills. That stuff is junk and it does not work and you could have serious reactions to them. I think this Co. is trying to seriously damage people's health.*

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

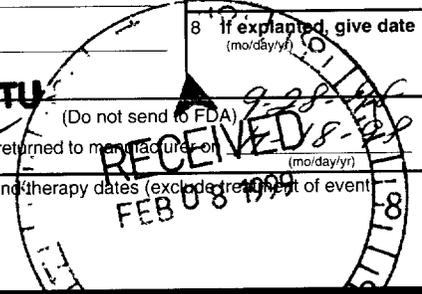
*I'm white Caucasian, and had no serious health condition. my heart kidney liver is all good - no diseases. I do not use drugs or Alcohol. I'm in good health, good condition.*

### C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)	
<i>#1 850 mg And the Co told me to take up to</i>	
<i>#2 3-3 times a day.</i>	
2 Dose, frequency & route used	3 Therapy dates (if unknown, give duration) from to (or best estimate)
<i>#1 850 mg twice</i>	<i>#1</i>
<i>#2 850 mg daily</i>	<i>#2</i>
4 Diagnosis for use (indication)	
<i>#1</i>	
<i>#2</i>	
6 Lot # (if known)	7 Exp. date (if known)
<i>#1</i>	<i>#1</i>
<i>#2</i>	<i>#2</i>
9 NDC # (for product problems only)	
<i>#1</i>	
<i>#2</i>	
10 Concomitant medical products and therapy dates (exclude treatment of event)	

### D. Suspect medical device

1 Brand name	<i>(TYROZENE)</i>
2 Type of device	<i>PILLS</i>
3 Manufacturer name & address	4 Operator of device
<i>AMERICAN WEIGHT LOSS Clinic 4060 Peachtree Rd. Suite D332 Atlanta GA 30319 (1800) 920-5819</i>	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
5 Expiration date (mo/day/yr)	6 model #
	<i>REC'D.</i>
7 If implanted, give date (mo/day/yr)	8 If explanted, give date (mo/day/yr)
	<i>JAN 27 1999</i>
9 Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> returned to manufacturer or _____ (mo/day/yr)	
10 Concomitant medical products and therapy dates (exclude treatment of event)	



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

1 Name, address & phone #		00001	
2 Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3 Occupation <i>Computer Analyst</i>	4 Reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input checked="" 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"/>			



Submit to MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787, 1-800-FDA-0178

# 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

## BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

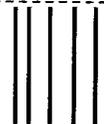
# MEDWATCH

The FDA Medical Products Reporting Program

Food and Drug Administration

5600 Fishers Lane

Rockville, MD 20852-9787



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



RECEIVED  
CLINICAL RESEARCH &  
REVIEW/SERVICES

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Notes on Telephone Conversation  
Clinical Research and Review Staff

# 13328

Date	2/24/99	Phone No.	[REDACTED]
Name	[REDACTED]	Fax No.	[REDACTED]
Affiliation	[REDACTED]		
Address	[REDACTED]		
FDA Representatives	Dr. Shah Nawaz		
Question/Subject	Call to ask the ingredients and label/labelling of the product, TYROZENE.		

Discussion	Ms. [REDACTED] told me that she had returned the product to distributor for refund. She did not have any information about ingredients of the product. She will try to find any related material about the product. She will send it to us. I gave her our office address.

Follow up	

Signed:

*Shah Nawaz*

Date: 2/24/99

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