

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

ARMS#

12887



0 - FRONT

CF-AN

Triage unit sequence #	82534
	12887

### A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: 32 or Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 187 lbs or [redacted] kgs
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### 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 checked="" type="checkbox"/> other: <i>adverse event to supplement</i>	

3. Date of event (mo/day/yr) *3/5/98-3/12/98*

4. Date of this report (mo/day/yr) *4/14/98*

5. Describe event or problem

*Severe stomach cramps & diarrhea for 1 day following 1st dose; resolved within 24 hrs. Reoccurred after 2nd & 3rd dose. Stomach cramps & diarrhea continued for 1 week following the 3rd dose.*

*Also increased heart rate & anxiety for approximately 6-8 hrs after each dose.*

*Note: Thermadrine by Sportpharma contains 300mg ephedra, 150mg guarana, 75mg willow bark extract, 80mg caffeine, 60mg cayenne & 40mg ginger root.*

6. Relevant tests/laboratory data, including dates:

*NI*                      **REC'D.**

**MAY 06 1998**

**MEDWATCH CTU**

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

*NONE - SUBJECT IS A HEALTHY ACTIVE MALE W/NO UNDERLYING MEDICAL CONDITIONS*

### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 *Thermadrine dietary supplement (purchased @ GNC)*  
*manufacturer: Sportpharma*

2. Dose, frequency & route used

#1 *1 capsule 1x daily PO*

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 *3/4, 3/9, & 3/11/98*

4. Diagnosis for use (indication)

#1 *dietary energy supplement*

5. Event abated after use stopped or dose reduced

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

6. Lot # (if known)

#1 *~~34573~~*

7. Exp. date (if known)

#1 *~~1/2000~~*

8. Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

*NONE*

### D. Suspect medical device

1. Brand name *NA*

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other.

5. Expiration date (mo/day/yr)

6. model #

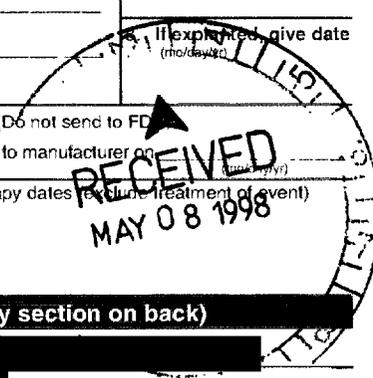
7. If implanted, give date (mo/day/yr)

8. If expired, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA if returned to manufacturer or destroyed)

yes  no  returned to manufacturer or destroyed

10. Concomitant medical products and therapy dates (exclude treatment of event)



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

1. Name & address                      phone: [redacted]

2. Health professional?  yes  no

3. Occupation *Epidemiologist*

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



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

or FAX to:  
1-800-FDA-0178