

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

ARMS#

12460



0 - FRONT

# MEDWATCH

**Voluntary reporting**  
by health professionals of adverse  
events and product problems

Form Approved: OMB No. 0910-0001 Expires: 4/30/98  
 Page 1 of 1 Attachment on Reverse

FDA Use Only  
 FD-1089 (Rev. 11/95)  
 Sequence # 65337  
12460

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

*CESAN*

Page \_\_\_ of \_\_\_

### A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: or <u>64Y/O</u> Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight <u>143</u> lbs or _____ kgs
-------------------------------------	--	---	--

In confidence

### 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 checked="" 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) <u>11/10/96</u>	4. Date of this report (mo/day/yr) <u>06/05/97</u>
---	---

5. Describe event or problem  
**64 Y/O FEMALE NORMOTENSIVE, WITH NO IDENTIFIED RISKS OR FAMILY HX OF CVA. EXPERIENCED LEFT SIDED CVA.**



### 6. Relevant tests/laboratory data, including dates

[Redacted area]

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

**NO RISK FACTORS, NON-SMOKER, NON-DRINKER  
 NO KNOWN DRUG ALLERGIES. ALL LABS WNL EXCEPT  
 GLUCOSE 125, SR. CREATININE 1.0**

### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 <u>SHAPE-FAST</u> #2 _____	
2. Dose, frequency & route used #1 <u>2 BID</u> #2 _____	3. Therapy dates (if unknown, give duration) (from/to or best estimate) #1 _____ #2 _____
4. Diagnosis for use (indication) #1 _____ #2 _____	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known) #1 _____ #2 _____	7. Exp. date (if known) #1 _____ #2 _____
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # (for product problems only) #1 _____ #2 _____	
10. Concomitant medical products and therapy dates (exclude treatment of event) <b>NOT ON ANY MEDICATIONS</b>	

### D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other: _____
5. Expiration date (mo/day/yr)	6. If implanted, give date (mo/day/yr)
7. If explanted, give date (mo/day/yr)	8. If explanted, give date (mo/day/yr)
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)	

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

1. Name & address [redacted] [redacted] [redacted] M.D.	phone # [redacted]
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation <b>PHARMACIST</b>
4. Also 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"/>	



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

or FAX to:  
 1-800-FDA-0178

**COMPLAINT/INJURY REPORT**

1. COMPLAINT NUMBER  
SEA 5675

2. DATE OF COMPLAINT (Month/Day/Year)  
8/12/97

3. FORM OF COMPLAINT (1)  TELEPHONE (3)  VISIT (2)  LETTER FAX from CFSAN

4. SOURCE OF COMPLAINT (1)  CONSUMER (3)  TRADE SOURCE (2)  GOVERNMENT (4)  OTHER (Indicate in Remarks) Pharmacist

5. COMPLAINANT IDENTIFICATION

a. NAME AND ADDRESS (Include Zip Code) [Redacted], MD

b. AREA CODE AND TELEPHONE NO. HOME ( ) WORK [Redacted]

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT/INJURY  
64 y/o female normotensive, with no identified risks or family history of CVA. Experienced left sided CVA.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1)  NO (2)  YES (Explain in Remarks)

7. INJURY OR ILLNESS RESULTED (1)  NO (2)  YES (If "YES" complete Items a through d)

a. EIB (HFC-161) NOTIFIED (1)  NO (2)  YES DATE

b. TYPE SYMPTOMS ONSET (HR.)  
1  VOMITING \_\_\_\_\_  
2  NAUSEA \_\_\_\_\_  
3  DIARRHEA \_\_\_\_\_  
4  FEVER \_\_\_\_\_  
5  SKIN/EYE IRR. \_\_\_\_\_  
6  HEADACHE \_\_\_\_\_  
7  OTHER \_\_\_\_\_  
left sided CVA

c. ATTENDING HEALTH PROFESSIONAL (1)  NO (2)  YES (if "yes" give name, address, and phone no.)

d. HOSPITALIZATION REQUIRED (1)  NO (2)  YES (If "yes" give name, address, phone no. and date)



8. PRODUCT AND LABELING

a. BRAND NAME

b. PRODUCT NAME  
Shape-Fast

c. SIZE AND PACKAGE TYPE

d. NAME AND LOCATION OF STORE WHERE PURCHASED

e. PACKAGE CODE/SERIAL NUMBER/ETC.

f. DATE PURCHASED

g. PRODUCT USED (If "yes" enter date) (1)  NO (2)  YES

h. AMT REMAINING

EXP/USE BY DATE:

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT

b. C.F. NO.

c. NAME AND ADDRESS OF FIRM (Include Zip Code)

d. IMPORT PRODUCT (1)  NO (2)  YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEYWORD (1) CODE OR (2) DESCRIPTION  
CVA

b. EVALUATION (1)  NOT AN FDA OBLIGATION (2)  OBLIGATION, NO VIOLATION (3)  FDA ACTION INDICATED (4)  INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION (1)  IMMEDIATE FOLLOW-UP (2)  F/U NEXT EI (3)  CLOSED WITHOUT FURTHER INVESTIGATION (4)  REFERRED TO OTHER FEDERAL AGENCY (Closes file) (5)  REFERRED TO STATE/LOCAL AGENCY (Closes file) (6)  REFERRED TO OTHER FDA \_\_\_\_\_ DISTRICT

11. PRODUCT CODE

12. INFORMATION COPIES TO:  
 HFN - 355  HFZ - 343 (Biologics)  HFZ - 400  
 HFN - 730  HFC - 161  
 HFN - 333  HFS - 635  
 HFV - 236

REMARKS

NAME AND TITLE: Janice D. Carter, CCC

DATE: 8/12/97

000002

**COMPLAINT / INJURY FOLLOW-UP**

**1. COMPLAINT NUMBER**  
SEA 5675

**2.a. ACTION REQUESTED**

- (1)  INVESTIGATION
- (2)  COLLECT SAMPLE
- (3)  INSPECTION
- (4)  OTHER:

**2.b. REMARKS (Additional details)**

Per request from CFSAN: Collect medical records and product labeling. Complete Adverse Event Questionnaire form (attached).

**2.c. REQUESTING OFFICIAL'S NAME AND TITLE**

Janice D. Carter, CCC

**2.d. DATE REQUESTED**

8/12/97

**2.e. PRODUCT NAME**

Shape-Fast

**3.a. ASSIGNED TO:**

James I. Vik,

**3.b. DUE BY:**

9/12/97

**4.a. ACTION TAKEN**

- (1)  INVESTIGATION
- (2)  SAMPLE COLLECTED
- (3)  INSPECTION
- (4)  NONE

**4.b. SAMPLE NUMBER(s)**

**4.c. DESCRIPTION OF ACTION TAKEN**

Contacted [redacted] in [redacted] and spoke with Dr. [redacted]. Dr. [redacted] was the attending physician during the complainant's stay at the hospital. She was very much aware of the complainant and appeared to know her personally. Dr. [redacted] volunteered to talk with the complainant who had requested her name not be released and gained permission for the FDA to gather medical records. The complainant was not interviewed and her request for privacy in this matter has been honored.

97 OCT 10 A 7:11

RECEIVED  
CLINICAL RESEARCH  
& REVIEW/OSN HFS-452

**4.d. ACTION OFFICIAL'S NAME AND TITLE**

James I. Vik, Investigator

**4.e. ACTION DISTRICT**

SEA

**4.f. DATE COMPLETED**

9/18/97

**5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE**

**6. PROGRAM DATA**

**5.a. HOME DIST.**

**5.c. NAME AND ADDRESS**

**6.a. OPERATION**

13

**6.b. PAC**

03R801

**6.c. PRODUCT CODE**

54DCC99

**5.b. CF NO.**

**6.d. EMP. HOME DIST.**

SEA

**6.e. EMP. NO.**

154

**6.f. POS CL.**

- 2

**6.g. HOURS**

8

**7. EVALUATION**

- (0)  PENDING
- (1)  NO ACTION INDICATED (NAI)
- (2)  VOLUNTARY ACTION INDICATED (VAI)
- (3)  OFFICIAL ACTION INDICATED (OAI)
- (4)  NOT AN FDA OBLIGATION
- (5)  REFERRED TO HOME DISTRICT
- (6)  INSUFFICIENT INFO. UNABLE TO EVAL.
- (7)  REFERRED TO OCI

**8. FINAL DISPOSITION**

- (1)  FOLLOW-UP NEXT E1
- (2)  WARNING LETTER
- (3)  CITATION
- (4)  SEIZURE
- (5)  INJUNCTION / PROSECUTION
- (6)  REFERRED TO OTHER AGENCY  
*(Indicate Agency in Remarks)*
- (7)  RECALL
- (8)  NO ACTION

**9. INFO.**

- COPIES TO:**
- HFB-100
  - HFD-730
  - HFV-236
  - HFZ-343
  - HFC-161
  - HFS-635
  - SCB/M*

**REMARKS**

(copy sent 10/2/97) JDC

**NAME AND TITLE OF DISPOSITION OFFICIAL**

*R Williams, MPT*

**DISPOSITION**

*SEA*

**DISPOSITION DATE**

*09/23/97*

Adverse Reaction Questionnaire

Complaint Number: SEA 5675  
CFSAN #12460

Investigator: Jim Vik

Consumer Information	
Date of Report: <u>06/05/97</u> MM/DD/YY	Initial Report Source: <input checked="" 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>Ms. [REDACTED]</u>	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M Age: <u>64</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 type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <input type="checkbox"/> 9-Unknown	
Information on Adverse Reaction	
Date of Adverse Reaction: <u>11/10/96</u> Previous Reaction to Product Type: <input type="checkbox"/> Yes <input type="checkbox"/> No	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>Home</u>
The following information relates to the consumers' use of the product. <u>See Medical records.</u>	
Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):	
How long did the symptoms last? Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).	
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event:	
Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown 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>[REDACTED] MD, [REDACTED]</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>see medical records</u>	
What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)?	
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Product Category

SEA 5675

CFSAN #12460

1. Adverse reaction to:

Medical Food (under medical supervision)  Infant Formula

Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances 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, cozymes, 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): *Shape-Fast 100 mg capsules*

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

Check here if ingredients are unknown

*Mahuang (standardized to 8% total alkaloids; calculated to 10mg ephedrine willow bark (30 mg aspirin); Kelp (standardized to 1% organic iodine) Kola Nut (standardized to 20 mg caffeine.*

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

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

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