

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

ARMS#

12980



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CIFSAN
COPY

CFSAN 9

Individual Safety Report



For VOLUNTARY
by health professionals
events and product pr

85027 # 1297709*

Page 1 of 1

A. Patient information

1. Patient Identifier [Redacted]	2. Age at time of event: 39 Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 210 lbs or _____ kgs
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B. Adverse event or product problem

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

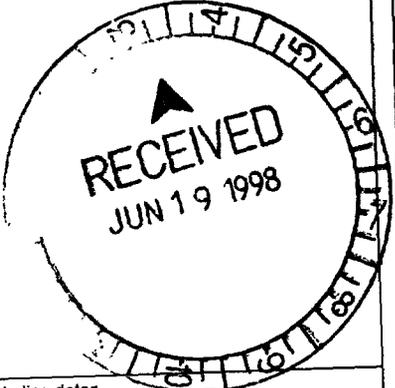
2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization	<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)

5. Describe event or problem
Intracerebral hemorrhage 17 Mar 98. Pt. was hospitalized.



6. Relevant tests/laboratory data, including dates
CT Scan & Cerebral angiography

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
Race: white. No pre-existing medical condition. NKDA

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) 12980
#1 Ultimate Orange/ Next Nutrition
#2 _____

2. Dose, frequency & route used
#1 1 scoop po before
#2 exercise

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 N/A
#2 _____

4. Diagnosis for use (indication)
#1 body building supplement
#2 _____

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 _____ #2 _____

7. Exp. date (if known) #1 _____ #2 _____

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)
vitamins (MVI) po; provate (amino acid prep)

D. Suspect medical device

1. Brand name _____

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 # _____
catalog # _____
serial # _____
lot # _____
other _____

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

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

9. Device available for evaluation? (Do not send to FDA)
 yes no 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 phone: [Redacted]

2. Health professional? yes no

3. Occupation MD

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.

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to:
1-800-FDA-0178

FDA Form 3500 (1/96)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Taken By Telephone

2wd CDS
6/18/98

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85027

Adverse Event Questionnaire

Complaint Number: 12980

Investigator: _____

Consumer Information	
Date of Report: <u>06/24/98</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury ----- <input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC
Name: [REDACTED]	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M Age: <u>39</u>
Race: <input checked="" 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 Event	
Date of Adverse Event: <u>17-MAR-98</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): [REDACTED]
<p>The following information relates to the consumers' use of the product.</p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): <u>STROKE - LEFT BRAIN BLEED - 1 1/2 hrs AFTER PRODUCT USE DURING WORKOUT AT [REDACTED].</u></p> <p>How long did the symptoms last? <u>STILL HAVE SLIGHT SYMPTOMS - LOST TOTAL SENSORY RT. SIDE.</u> Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.): <u>TOOK AS PRESCRIBED AS PRESCRIBED ON LABEL PRIOR TO WORKOUTS.</u></p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event: <u>PRILosec AS PRESCRIBED, VITAMIN-MULTI, CREATINE, VITAMIN A, E.</u></p> <p>Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/>Yes <input type="checkbox"/>No <input checked="" 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 checked="" type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" 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: <u>DR [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) <u>NEURO SURGEON.</u>	
What medical tests were performed and what were the results? <u>CAR SCAN / ANGIOGRAM - Neg. FOR TUMOR / POSITIVE FOR FURTHER BRAIN BLEED</u>	
What was the medical diagnosis? <u>STROKE - UNKNOWN REASON</u>	
What treatment(s) was given (e.g., drugs, other)? <u>NO DRUGS / TREATMENTS</u>	
Were there any preexisting condition(s)/treatment(s)? <u>NONE</u> (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input type="checkbox"/> No	

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Product Category

1. Adverse event attributed 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, 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 and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

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

Check here if ingredients are unknown

Ultimate Orange Next Nutrition

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

- Aspartame
- Monosodium Glutamate
- Sulfite
- Other MA Heme
- 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 event result in a congenital anomaly: Yes No

98 JUL -8 P12:24

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-482

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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food 7/18/98
Public Health Service

Food and Drug Administration
Los Angeles District
Pacific Region
19900 MacArthur Blvd.
Suite 300
Irvine, CA 92612-2445

Telephone: 714-798-7600
FAX: 714-798-7690

To: Bridgett Wallace
HFS-636

June 25, 1998

From: David Hernandez, CSI

Subject: Medical Record Request for:

Mr. [REDACTED]

Please find enclosed the medical records for Mr. [REDACTED]. This is all the information available from Mr. [REDACTED] and his doctors. Doctors who attended to Mr. [REDACTED] were not available.

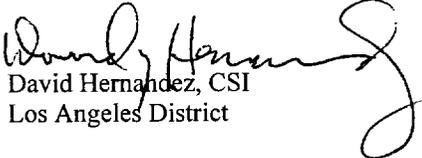
To correct the information listed on the assignment, Mr. [REDACTED] is a Navy Diver, and works on the [REDACTED]. Mr. [REDACTED] was originally seen by the ships doctor who sent him to [REDACTED] said that he was not aware of his symptoms until he noticed that he had lost his right shoe (flip-flop type) which was behind him about 15 feet. He realized that he had a numb feeling along his right side. He called the ships doctor, who immediately took him to the [REDACTED]. The attending physician at [REDACTED] was Dr. [REDACTED]. Mr. [REDACTED] said that the doctor thought it was something else, like a tumor. Further testing of the cranial region revealed bleeding. Mr. [REDACTED] said that a vessel bursted.

Mr. [REDACTED] was interviewed on 6/24/98, and appeared to be very coherent, he had no slurred speech. Mr. [REDACTED] stated that he had a slight numbness left on his face along his right side. He has regained much of his feeling along his right side. He stated that compared to the day after his stroke, he has regained much of his feelings.

At this time, both doctors who treated Mr. [REDACTED] were not available. The ship's doctor may be reached at [REDACTED]

Mr. [REDACTED] stated that the use of food supplements by Navy personnel and Marines are quite common. He estimates that approximately 60 percent of the ship's crewmen are taking some type of supplements.

A quick check of the Navy Exchange and local stores revealed that the product was available. The base exchange had 60 cans of the Ultimate Orange. The manager stated that she gets in several cases every week.


David Hernandez, CSI
Los Angeles District

98 JUL -8 P12:24

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CLINICAL RESEARCH
& REVIEW/OSN HFS-452

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