

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

ARMS#

12733



0 - FRONT

FDA Use Only	76278
Triage unit sequence #	12733

A. Patient information

1 Patient identifier	2 Age at time of event: 47 or Date of birth	3 Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4 Weight 273 lbs or kgs
----------------------	---	--	-------------------------------

B. Adverse event or product problem

1 <input checked="" type="checkbox"/> Adverse event and/or	<input type="checkbox"/> 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) 12-13-97	4 Date of this report (mo/day/yr) 12-23-97
--------------------------------------	--

5 Describe event or problem
Patient had History of Hypertension. He was currently not taking any Hypertension meds. He stated he was taking purple Blast 1/2 po Twice Daily. Pt was admitted to ICU w difficulty speaking and weakness and confusion. CT scan showed Hypertensive Bleed in the Right lenticular nucleus.

6 Relevant tests/laboratory data, including dates
CT scan showed Rt. Basal ganglia hemorrhage.

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

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 Purple Blast		#1 Appx. 3-4 weeks	
2 Dose, frequency & route used		4 Diagnosis for use (indication)	
#1 1/2 po B.I.D		#1 obesity	
6 Lot # (if known)		7 Exp. date (if known)	
#1 unknown		#1 unknown	
9 NDC # (for product problems only)		5 Event abated after use stopped or dose reduced	
N/A		#1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	
10 Concomitant medical products and therapy dates (exclude treatment of event)		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
None.		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	

D. Suspect medical device

1 Brand name	RECEIVED JAN 27 1998	4 Operator of device
2 Type of device		<input checked="" type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
3 Manufacturer name & address		5 Expiration date (mo/day/yr)
		7 If implanted, give date (mo/day/yr)
6 model #	JAN 23 1998	8 If explanted, give date (mo/day/yr)
catalog #		
serial #	MEDWATCH CTU	
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)		
000001		

E. Reporter (see confidentiality section on back)

1 Name, address & phone #		
[Redacted]		
2 Health professional?	3 Occupation	4 Also reported to
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Pharmacy	<input 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 type="checkbox"/>		

PLEASE TYPE OR USE BLACK INK

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

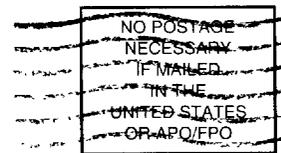
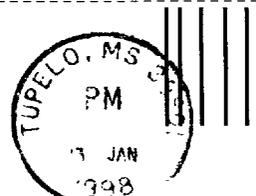
FDA Form 3500-back

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

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN/HFS-452
JAN 27 1998

000002



Adverse Event Questionnaire

Complaint Number: 12733

Investigator: JAMES BLAKELY

Consumer Information		
Date of Report: <u>03/16/98</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	12-23-97 <u>MEDWATCH</u>
Name: [REDACTED]	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M	Age: <u>47</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>12-12-97</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>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>WIFE FOUND NONRESPONSIVE IN BED, LEFT SIDE PARALYZED</u> <u>LAST CAPSULE 6:30 PM FOUND AT 8:30 AM</u> How long did the symptoms last? <u>CONTINUING</u> Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.): <u>2 CAPSULES PER DAY, ONE AT BREAKFAST & ONE AT LUNCH</u> <u>FOR 3 WEEKS PRIOR TO INCIDENT</u>		
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event. <u>PURPLE BLAST</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 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 <u>SEE MEDICAL RECORDS</u>		
Give health care provider's name, address and telephone number: [REDACTED]		
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>HOSPITAL STAFF</u>		
What medical tests were performed and what were the results? <u>SEE MED RECORDS</u>		
What was the medical diagnosis? <u>INTRACRANIAL HEMORRHAGE</u> What treatment(s) was given (e.g., drugs, other)? <u>DRUGS, REHAB</u>		
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 <u>OTHER THAN OBESITY</u>		

000003

#12733
3-16-98
DWA

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):

PURPLE BLAST (EPHEDRA, KOLA NUT, GUARANA, PASSION FLOWER, GINSENG, DANICIN)
3 CAP PER DAY AFTER MEALS MFG: NVE PHARMACEUTICALS, NEWTON, NJ
FOR ENERGY & CURBS APPETITE

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

Check here if ingredients are unknown

SEE ABOVE

If a particular ingredient is suspected of contributing to the adverse event, 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) PROLONGED

Required intervention to prevent permanent impairment/damage: Yes No

Did the adverse event result in a congenital anomaly: Yes No

000004

Labeler/Retailer:

[REDACTED]

Manufacturer:

NVE Pharmaceuticals
Newton, NJ

Victim:

[REDACTED]

MedWatch Reporter:

[REDACTED]

This investigation was precipitated as a follow-up to CFSAN's Adverse Reaction Monitoring System Project #12733 which resulted from a MedWatch report dated 12-23-97. This report alleged that one male's ingestion of a product called "Purple Blast" might be implicated in an ensuing intracranial hemorrhage accident.

On 3-16-98 per prior arrangement with the reporting pharmacist, [REDACTED] I visited [REDACTED] to follow-up on subject MedWatch injury complaint. Ms. [REDACTED] during an earlier telephone call, had refused to furnish me the name of the complaint. She stated that this would have to be accomplished in person through their Risk Manager. The initial information furnished by Ms. [REDACTED] was essentially the same as that reported via the MedWatch format. She did at this point inform me that the suspect product contained ephedra, kola nut, guarana, passion flower, and ginseng.

Upon my arrival at the hospital I introduced myself to and exhibited my credentials for Ms. [REDACTED]. After a brief conversation with her, she escorted me to the offices of the facility's Risk Manager, [REDACTED] to whom I also exhibited my credentials. Ms. [REDACTED] also on the advise of hospital counsel refused to furnish me with the victim's identity. After some general conversation, I was able to persuade her to telephone the victim so that I might explain the purpose of my investigation to him and solicit his approval. She did so and I was able to talk briefly with the victim and schedule an immediate interview. Before my departure I explained to Ms. [REDACTED] that I would be obtaining a

000005

consent from him for his medical records. She stated she would have someone begin accumulating them immediately.

I then proceeded to the victim's residence where I introduced myself and displayed my credentials for Mr. [REDACTED] and his wife, [REDACTED]. I explained to both that I was following up on a report filed by [REDACTED] wherein they surmised that his illness might have been attributable to his intake of Purple Blast.

The victim is a 47 year old white male (DOB [REDACTED] who is approximately 5'6" and now weighs 230 lbs. Before this incident he espoused to be in good health, although overweight (290 lbs) with no intake of tobacco, drugs, and only moderate alcohol. He stated he had been on blood pressure medicine approximately nineteen years ago but none since. He stated he had not been ill in the recent past and suffered from no long term problems other than seasonal allergies. He has been a 30 year employee (machine operator) of [REDACTED]. They professed no immediate stress in their lives prior to this incident. His father did die with a heart attack at age 69. There is no other evidence of heart disease in his family.

He stated he purchased suspect product at [REDACTED] as he had been told by others and then store personnel that it was ideal for losing weight. He admitted to have been taking this product twice daily, once at breakfast and once at dinner, for approximately three weeks. He stated he noted no particular ill effects from consuming same. He was not on any other medication during this time frame.

He then showed me the remaining portion of suspect product. These soft gelatin capsules are bright purple and appear to be approximately 1 1/2 cm in length by 1/2 cm in diameter. They are packaged in a clear plastic bottle with a purple and white label. Each capsule was identified "PAO 224/3850".

Ms. [REDACTED] stated that she had been extremely tired and gone to bed very early on 12-12-97. She stated she awoke around 8:30 pm that evening to find her husband's legs over her lower body. She tried to arouse him and have him move and could not. She then struggled out from under him, turned on the light, and found him more or less incoherent. She stated he was lying on his stomach, salivating, unable to move, and with slurred speech. He stated he was conscious the whole time, but could not respond or move. She awoke her children and called 911.

000006

He was transported to [REDACTED] where he was received in the emergency room and immediately treated for a cardiovascular accident. It was at this point they advised Ms. [REDACTED] that her husband had suffered a severe stroke. This small hospital then decided to immediately transfer him to the larger regional hospital, [REDACTED]. Within two hours he was received at the new facility and again diagnosed with an intracranial hemorrhage - right basal ganglia.

They stated that he was hospitalized from 12-12-97 through 1-21-98. During the time frame 12-22-97 through 1-21-98 he was housed in the facility's [REDACTED].

At the present time Mr. [REDACTED] is mobile with the aid of a walker. He still has only limited use of his left side particularly his arm. No other bodily functions seemed impaired. He is presently on blood pressure medicants only. He stated that he has lost approximately 60 lbs as a result of this episode.

I explained that I would need to get a copy of his medical records for review by our experts. Ms. [REDACTED] signed several copies of Authorization for Medical Records Disclosure due to his incapacity. I thanked them for their assistance and departed.

I then proceeded to [REDACTED] where I met and exhibited my credentials for [REDACTED]. I explained the purpose of my visit and gave her a signed Authorization for Medical Records Disclosure. She promptly complied and furnished a copy of Mr. [REDACTED] file. This is attached as Exhibit #3.

Due to the late hour I was not able to return to [REDACTED] and pick up the additional medical records on this date.

This assignment dictated that I attempt to identify the manufacturer of the suspect product. The witnessed product labeling bore only the name [REDACTED] as the manufacturer with no address. Therefore I made a visit to [REDACTED] in an attempt to identify the manufacturer.

Upon my arrival I identified myself to and exhibited my credentials for [REDACTED]. I explained that I was following up on a complaint on suspect product and needed to identify the manufacturer of same. Mr. [REDACTED] stated that this product was in fact manufactured for them by [REDACTED]. He stated that his firm labeled the product after receipt. He stated that [REDACTED] was in fact short for [REDACTED].

000007

This corporation is owned by [REDACTED] his mother and father, and encompasses this health food store, a gym, this product, and other enterprises. He stated they intentionally left any address off the product to preclude their competition from determining the source of this lucrative product and ordering it themselves. He added that this product is sold in-house only and not distributed to outside accounts. He professed that it is sold as an energy supplement and as an appetite depressant. He furnished me a copy of a product label which is attached as Exhibit #1.

He added that this product is marketed by [REDACTED] under the name "Purple Passion". He stated his product label is a direct copy of [REDACTED] label with his new names substituted in the appropriate places. He implied that [REDACTED] markets this product as a sexual arousal aid and not as an energy boost and diet aid.

He then queried me as to the nature of the complaint. I informed him that this product had been implicated as a potential causative or adjunct agent in a stroke. Upon hearing this he stated that this was impossible since this product contained only natural ingredients and not enough to hurt anyone. He stated for example it contained only 25 mg ephedra per capsule, not as much ephedrine as a children's antihistamine.

He went on to state that he routinely gives new customers a flier which cautions them not to take this product if they have heart disease, high blood pressure, or any other condition. He stated he did this because of the recent warnings FDA has given relative to ephedrine compounds. He furnished me a copy of this flier. See Exhibit #2.

I informed him that this product was presently mislabeled in that it fails to bear the address of the manufacturer or distributor. He promised to correct same immediately. I also informed him that it appeared to me that his promotion and product labeling are making drug claims for this supplement and as such this product is an unapproved new drug. I informed him that further FDA review would determine if this product were in fact being marketed as an unapproved drug. He insisted this product is labeled and sold as a food supplement only.

On the morning of 3-17-97 I returned to [REDACTED] [REDACTED] presented Ms. [REDACTED] an Authorization for Medical Records Disclosure, and picked up a copy of Mr. [REDACTED] file. This is attached as Exhibits #4 & 5. Exhibit #4 is his hospital file while Exhibit #5 is his rehab file.

000008

- Exhibit #2 - Suspect product promotional flier
- Exhibit #3 - Victim's Medical Records from [REDACTED]
- Exhibit #4 - Victim's Medical Records for confinement in [REDACTED]
- Exhibit #5 - Victim's Medical Records for confinement in [REDACTED]


James W. Blakely
Investigator - NOL-DO
[REDACTED]

The following are attached as exhibits:

- Exhibit #1 - Suspect product labeling
- Exhibit #2 - Suspect product promotional flier
- Exhibit #3 - Victim's Medical Records from [REDACTED]
- Exhibit #4 - Victim's Medical Records for confinement in [REDACTED]
- Exhibit #5 - Victim's Medical Records for confinement in [REDACTED]


James W. Blakely
Investigator - NOL-DO
[REDACTED]