

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

ARMS#

12906



0 - FRONT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY report by health professionals of adverse events and product problems

Page CFSAN of CFSAN/83322

Individual Safety Report

12906

A. Patient information

1 Patient identifier <small>In confidence</small>	2 Age at time of event: <u>36</u> or _____ Date of birth: _____	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight ____ 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 checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: <u>Surgery to stop bleed</u>
3 Date of event (mo/day/yr) <u>11/23/97</u>	4 Date of this report (mo/day/yr) <u>5/5/98</u>

5 Describe event or problem

Please see attached

If you have any questions regarding this event, please contact my doctor at

Dr. [REDACTED]

Fax [REDACTED]

6 Relevant tests/laboratory data, including dates

Emergency surgery was performed to stop the hemorrhaging early morning 11/24/97

REC'D

MAY 15 1998

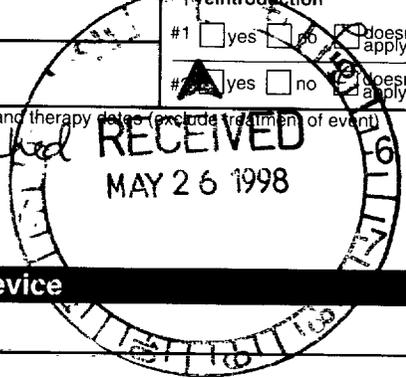
MEDWATCH CTU

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

None. In perfect health before incident

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)	<u>Manufacturer</u>	
#1 <u>AMP II Pro Drops</u>	<u>is E'OLA</u>	
#2 _____		
2 Dose, frequency & route used	3 Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 <u>Not to exceed 30</u>	#1 <u>Took for 2 1/2 months</u>	
#2 <u>Drops in a 24hr period</u>	#2 <u>did not exceed dosage</u>	
4 Diagnosis for use (indication)	5 Event abated after use stopped or dose reduced	
#1 <u>Weight Loss</u>	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 _____	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6 Lot # (if known)	7 Exp. date (if known)	
#1 <u>7100560</u>	#1 <u>11/98</u>	
#2 _____	#2 _____	
9 NDC # (for product problems only)	8. Event reappeared after reintroduction	
_____	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
10 Concomitant medical products and therapy dates (exclude treatment of event)		
<u>please see attached</u>		



D. Suspect medical device

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

E. Reporter (see confidentiality section on back)

1 Name, address & phone #			
[REDACTED]			000001
2 Health professional?	3 Occupation	4 Also reported to	
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	<u>Sales</u>	<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 checked="" type="checkbox"/>			



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 JUN -1 2:18 PM '86

5600 Fishers Lane
Rockville, MD 20852-9787

RECEIVED
CLINICAL RESEARCH
& REVIEW/DSN HFS-452

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

000002



CFM 183322

4/25/1998

DOCUMENTATION ON HEMORRHAGING INCIDENT

I bought my first bottle of AMP II PRO DROPS and LIQUA THIN in September 1997. These products are made by E'OLA, located in St George, Utah. I believe the product AMP II PRO DROPS is responsible for the hemorrhaging incident I had on November 23, 1997. The ingredients on the bottle are: Water, Ma Huang (Ephedra standardized to Ephedrine), DMAE, White Willow Extract, Guarana Extract, Licorice Root, Atractylodes Extract, Propylene Glycol, Benzoic Acid, B12.

I bought the product from a friend who was using them and had lost 10 lbs. I just wanted to lose 5 lbs. She was buying them from a multi-level distributor. There was no literature given to me on this product other than what was on the bottle. I used this product as directed for only 2 ½ months. I was also drinking coffee while taking this product; a deadly combination by the reports I have been reading. I didn't have that information when I was taking the product.

I was home alone the afternoon of November 23, 1997. I was in the bathroom washing my face. When I blew my nose, it started to bleed. I have never had a bloody nose before. I thought this was very odd. Several seconds later it started to hemorrhage out of my nose and mouth. I called 911. The paramedics came in and tried to stop the bleeding. At first they just thought it was a bloody nose. My blood pressure was normal. It became very apparent several minutes later that the bleeding wasn't decreasing. They walked me out to the ambulance, and took me to the E.R.

The doctor on call ended up packing my nose, which was excruciatingly painful. Two hours later he sent me home. When I got home, I lay down to rest. I woke up with blood running out of my nose and mouth. Again I called 911. This time they had to carry me out to the ambulance. I was taken to the E.R. again, and a specialist was called in. My nose was packed again. He told me it looked pretty bad and that I would probably need surgery. He admitted me at that time. Around 2:00 a.m. that morning I woke up to find I was hemorrhaging again. The specialist was paged and performed surgery immediately. The specialist (Dr. [REDACTED]) was confused and baffled by my hemorrhaging. He could find nothing wrong

REC'D.

MAY 15 1998

MEDWATCH CTU

000003

83322

medically with me that would cause such a massive hemorrhaging. He believes it could be contributed to the use of E'OLA's product.

After surgery, I was kept at the hospital for 3 days. The first two days I could not eat or drink anything. It was just too painful. They had to put liquids in me intravenously so that I would not dehydrate.

An appointment was made with the specialist to see him in one week to take the bandages off. After the first appointment, we had to reschedule a second appointment because the bleeding had not stopped. At the second appointment, the bandages still could not come off because the bleeding still had not stopped.

My husband and I were in the processing of relocating to [REDACTED] while all this was happening. I was not allowed to fly, so I had to drive to [REDACTED] with the bandages still on. I did not have insurance at the time, so I had to wait until January 1st to locate a specialist to assess my condition because I was still bleeding and spitting up blood in the mornings.

The bleeding finally stopped for a while in February. However, I am again experiencing the bleeding and spitting up of blood in the morning.

I am in excellent health, and was before the hemorrhaging. My medical records will indicate this. I believe the E'OLA formula of AMP II PRO DROPS' formula is dangerous. I kept the rest of the unused bottle so that it can be analyzed if necessary.

I am currently having nightmares regarding the hemorrhaging. I have made an appointment to seek counseling for this trauma.

[REDACTED]
REC'D.

MAY 15 1998

MEDWATCH CTU

000004