

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

ARMS#

11919



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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

ARMS # 11919

Print Approved. OMB No. 0910-0291 Expires 12/31/94 See OMB statement on reverse

FDA Use Only

Triage unit sequence #

11919. ~~011137~~

Page 1 of 1

A. Patient information

1 Patient identifier [Redacted] In confidence	2 Age at time of event: or <u>NOT reported</u> Date of birth:	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight ____ 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 - <u>potentially</u>	<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) (?) 1996

4 Date of this report (mo/day/yr) 7/29/97

5 Describe event or problem

Reporter has filed a separate AER involving herself (ARMS # 11137).

Reporter states that she is aware of an adverse event suffered by the ♀ who said she the product identified as " [Redacted] " according to the reporter, [Redacted] informed reporter by telephone that she stopped seeing and using the product because she started developing sores, for the first time in 18 years. of note, [Redacted] is currently seeing Starlight International - the company that she sold the product for. Reporter is therefore reluctant to share additional details & instead opts to provide FDA's "800" consumer advice event reporting telephone #. to [Redacted] so that [Redacted] can file report on her behalf if she desires to do so.

RELEVANT LABS - UNKNOWN

6. Relevant tests/laboratory data, including dates

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

UNKNOWN

REC'D.

AUG 05 1997

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C. Suspect medication(s)

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

#1 Nataal Jim / Straight International

#2 _____

2 Dose, frequency & route used

#1 unknown

#2 _____

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

#1 unknown

#2 _____

4 Diagnosis for use (indication)

#1 unknown (?WL)

#2 _____

5 Event abated after use stopped or dose reduced unknown

#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)

unknown

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)

000001

E. Reporter (see confidentiality section on back)

1 Name, address & phone #

[Redacted]

2 Health professional? yes no

3 Occupation

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.

my phone calls (see)

PLEASE TYPE OR USE BLACK INK



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

or FAX to:
1-800-FDA-0178

Notes on Telephone Conversation
Clinical Research and Review Staff

ARMs # 11137
see also

Date	7/25/97	Phone No.	[REDACTED]
Name	[REDACTED]	Fax No.	
Affiliation	Consumer		
Address	[REDACTED]		
FDA Representatives	Lisa Finn, RD Senior Staff Fellow		
Question/Subject	Contact [REDACTED] to see if it would be possible to get additional information on an adverse event reported by the distributor who sold her the product. [REDACTED] has filed an adverse event report involving herself - ARMs #11137		

Discussion	7/25/97 - Left message on [REDACTED]'s answering machine asking her to call me @ 202-205-4498
	7/29 - I spoke to [REDACTED] in attempt to pursue additional info on her report that the distributor from whom she had purchased her product had suffered a seizure while taking the product. She wasn't sure if the distributor would be interested in reporting her case to FDA as distributor is involved in law suit to company/product manufacturer. At my request, [REDACTED] is willing to provide FDA-mediated "800" reporting number to distributor (who is a personal acquaintance) & inform her that the reporting system is completely voluntary & confidential.

Follow up	A mediator has been completed for her to generate a separate AER/ARMs # for the report of seizure involving the distributor. The AERs # for this new report = 11919. No further HU is suggested @ this time
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Signed: *Lisa Finn*
202
CFR/AN

REC'D. 000002
AUG 05 1997
MEDWATCH CTU
Date: 7/29/97