

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

ARMS#

13032



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CFSAN Rec'd 8/3/98

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

Form Approved-OMB No 0910-0291 Expires 12/31/96
See OMB statement on reverse

FDA use only	87010
Image unit sequence #	
13032	

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A. Patient information

1. Patient Identifier [Redacted]	2. Age at time of event: 32 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 248 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 checked="" type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input 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 7/24/98 (mo/day/yr)

5 Describe event or problem
Patient found by wife unresponsive at 5:00am. EMTs found him dead. Patient was taken to ER, tried to resuscitate with epinephrine, etc., but was not successful.

6 Relevant tests/laboratory data, including dates
Normal amount of ephedrine, Pre-morbid tox. screen did not show anything but opiate and ephedrine

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
white, 2 years prior- Malignant melanoma (no trace of at time of autopsy), surgery for torn rotator cuff.

C. Suspect medication(s)

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

#1 St Johns Wort 50mg

#2 Ephedrine

2 Dose, frequency & route used

#1 as directed by

#2 label

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

#1 several months

#2

4 Diagnosis for use (indication)

#1 purchased OTC

#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)
Vicodin for pain

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 # REC'D.

catalog #

serial # JUL 27 1998

lot #

other # MEDWATCH CTU

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 physician

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

000001

87010

To: mlj@nicks, k6c@nicks
From: Bridgette Wallace@OFP@FDA.CFSAN
Certify: Y
Subject: Fwd: CFSAN Assign.
Date: Saturday, November 7, 1998 at 8:05:30 am EST
Attached: None

Comments:

I think we should close this one out. Please let me know if you have any objections.

----- Original Message -----

To: Bridgette Wallace@OFP@FDA.CFSAN
Cc: Jean Brewer@SEA@FDAORAPAR, Robert Williams@SEA@FDAORAPAR
From: Janice Carter@SEA@FDAORAPAR
Date: Thursday, November 5, 1998 at 11:53:58 am PST
Attached: None

Hi Bridgette--

Re CFSAN Assign. #13032--St. John's Wort. The Investigator assigned to follow up on this one reported that the physician tried to get the information requested from the consumer's family several weeks ago but said it was difficult because they were still grieving. When the Investigator tried her again recently, she was a bit short. The doctor told the Investigator that she didn't have any data to confirm nor does she even speculate that the St. John's Wort was associated with the patient's death. We would like to close this one out from our end--any objections? Thanks much.

Jan