

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

ARMS#

13127



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# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

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

FDA Use Only

Trace unit  
sequence #

13127

Page \_\_\_\_\_ of \_\_\_\_\_

## A. Patient information

1 Patient identifier	2 Age at time of event: or Date of birth:	3 Sex	4 Weight
In confidence	49 yr.	<input checked="" type="checkbox"/> female <input type="checkbox"/> male	____ 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 checked="" type="checkbox"/> death 9/4/98 (mo/day/yr)	<input type="checkbox"/> disability
<input 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) 9/4/98	4. Date of this report (mo/day/yr) 10/8/98

5. Describe event or problem

Reporter is the husband of the deceased.

Consumer was in good health and suddenly died. Cause remains unknown. Autopsy results are still pending.

Husband went through their medicine cabinet. Consumer had purchased Microhydria - a nutritional supplement said to be a "super antioxidant". Husband doesn't know how frequently his wife took the product. His wife was also taking a prescription medication - Imitrex - for migraines. Doesn't know when last dose was. Concerned about possible interaction.

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.)

## 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	Microhydria - silica, potash	#1	?
#2	manufacturer - Royal Bodycare	#2	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1	?	#1	<input 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
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1		#1	<input 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)	9. NDC # (for product problems only)	
#1			
#2			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
Imitrex - sumatriptan (oral)			

## 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)			
Report taken by telephone by: N. Sifman CRS - Medical Officer			

Report taken by telephone by: N. Sifman  
CRS - Medical Officer

## 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		<input checked="" 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"/>			



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

or FAX to:  
1-800-FDA-0178



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

**NEW ENGLAND DISTRICT  
MEMORANDUM**

DATE: December 30, 1998  
FROM: Atricia L. Irons  
SUBJECT: CFSAN Project No. 13127  
TO: Bridgette Wallace, DOEP, HFS-636

Here is a chronology of what has been done on this so far. I called the Medical Examiners office this morning and they still have not completed the toxicology report.

11/9/98 - spoke with [REDACTED]. He said that autopsy report came in and nothing was found. He said that the toxicology report was due to come out sometime this week. He stated that the toxicologist told him that microhydrin is not easily detected in the system so nothing may be found.

Mr [REDACTED] also told me that his wife had been taken several other OTCs such as Sea Silver brand Collodiol Silver. He said that she had a tendency of taken more than the recommended dosage to compensate for her height (she was 6'2").

I told him that we needed to see all the prescriptions and OTC that she had taken over the year. He said he would gather them up and call me.

11/25/98 - Received call from Mr. [REDACTED] and set up time to pick up drugs from his office.

12/2/98 - Visited Mr. [REDACTED] office to pick up all the prescriptions. He said that a friend of his wife wanted to go through the drugs and see what she wanted so he wanted the bottles back intact. The bottles were brought to the office and copies of all labels were made and mounted on paper.

12/15/98 - Medical Examiner's office was called to see if the results were in and they had not yet been completed.

Atricia L. Irons  
CSI  
NWE-DO

*Recd 1/5/99  
for DOEP*

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