

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

ARMS#

11915



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AZMS.
11915

DATE: 7/9/97 TIME: 1735

Call Type (T)	Patient (P)	Exposure Duration (D)	REASON EXPOSURE OCCURRED (R)	
			Unintentional	Intentional
0. Exposure Information Requests. 1. Drug Info 2. Drug Identification 3. Environmental 4. Medical 5. Occupational 6. Poison 7. Prevention/safety 8. Teratogenicity 9. Other	1. Human 2. Animal If more than one patient involved, list as M.	1. Acute 2. Acute-on-chronic 3. Chronic If 2 or 3 code duration. 4. Unknown	1. General 2. Environmental 3. Occupational 4. Therapeutic error 5. Misuse 6. Bite/sting 7. Food poisoning 8. Unknown	9. Suspected suicidal 10. Misuse 11. Abuse 12. Unknown
Adverse Reaction (During normal or recommended use.)				
15. Drug 16. Food 17. Other				
18. Unknown reason				

PATIENT DATA
Name: [REDACTED]
Telephone no: () [REDACTED]
Address: [REDACTED]
Zip: [REDACTED]

CALLER DATA
Name: [REDACTED] RN DVM
 MD RPh
Relationship to patient: OHP
 Self Mother Grandparent
 Spouse Father Other relative Babysitter
 Other NEPHROLOGY

Age: 47 years Months Days Unknown age
Gender/Pregnancy: Male Female Unknown
 Pregnant - weeks of pregnancy: _____

Telephone no: [REDACTED]
Address: [REDACTED]
Zip: [REDACTED]
County/Other code: [REDACTED]

Weight: 275 lbs. _____ kg.
Prior medical history: PMH: 0
M. Q Antacids; K⁺ Supplement;
A: 0 Amoxicillin;
MD name & phone no. _____

Site of Caller	Site of Exposure
<input type="checkbox"/> Own Residence	<input type="checkbox"/>
<input type="checkbox"/> Other Residence	<input type="checkbox"/>
<input type="checkbox"/> Workplace	<input type="checkbox"/>
<input type="checkbox"/> (code) Health Care Facility	<input type="checkbox"/>
<input type="checkbox"/> School	<input type="checkbox"/>
<input type="checkbox"/> Restaurant/Food Service	<input type="checkbox"/>
<input type="checkbox"/> Public Area	<input type="checkbox"/>
<input type="checkbox"/> (code) Other	<input type="checkbox"/>
<input type="checkbox"/> Unknown	<input type="checkbox"/>

SUBSTANCE DATA
Substance: Chinese Tea Herbal
Amount: Root
Ingredients: Clearance=300
BUN=5 SGOT 7100's
Cr=1.2 SGPT
Time of duration of exposure: Since Feb-95
Route of exposure: Ingestion Inhalation/nasal Aspiration (with ingestion) Ocular Dermal Bite/sting Parenteral Other Unknown

STORY, SYMPTOMS, EVALUATIONS & ASSESSMENT
- proteinuria
- K⁺ 4.1 (4.5 = normal)
- microalbuminuria
- muscle weakness
- diarrhea x 6mo
- muscle weakness
- Admitted [REDACTED]
- muscle biopsy
pt on a leave from Dec-90
S/S x Feb/March/April - at which time pt stated she stopped meds but unclear if all meds were stopped. Her S/S cont. + medicine work-up has been @. ? if

1000001

Treatment Facility

Code

MANAGEMENT PLAN, FOLLOW-UP NOTES AND OUTCOME: (Time & date each entry)

DATE/TIME

A: Pot. for adverse $\frac{1}{2}$ s from chronic use of meds.

P: Obtain complete list of meds + $\frac{1}{2}$ s Will then consult ϵ TOXICOLOGY ϵ ped.

1745 - $\frac{1}{2}$ list of meds; PT has also been given STEROIDS ϵ Δ ; Creatinine Clearance = 300. Cr = .2; BUN = 5; Nephrology consulted; WORK-UP: EMGs; Auto Immune Work-up; Urine protein electrophoresis; Vit levels. PCC to forward chart to C.C.

7/11/97 1000 Call from Dr. [redacted] she has seen pt. Dr. [redacted] = hx of using herbal products to diet since Dec. In Feb developed diarrhea ϵ leg muscle weakness, arthritis. Had low K+, hypokalemia, treated ϵ NSAIDs, steroids, other meds will r/o lipid storage myopathy. Chinese products "Dieters Natural Tea, regular strength" made by FFC Co. USA Distribution 1-2 Year ago, no ingredients listed. P) will try to contact store where purchased to find USA distributor [redacted]

7/11/97 1235 call to [redacted] unaware of product. will try to obtain info [redacted]

7/14/97 1000 Call to FDA [redacted]

CONSULTANTS/RESOURCES USED:

- Medical director [redacted]
- Other consultant _____
- Texts _____
- Other _____

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PATIENT NAME

HOSPITAL NAME

CHART NUMBER

PHONE NUMBER

7/14/97

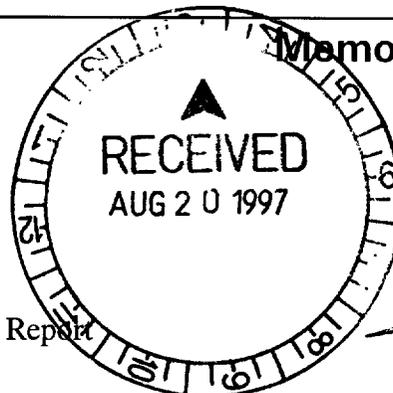
Call from Dr. [redacted]
 Further history - Patient has been changing herbs taken
 Detox tea was used x 1 mo in January. Sx started in
 February. Most recent products were Root-to-Health
 (as laxative) and papaya (last 2 mo). Admitted to
 hospital on 5/20 with hyponatremia, proteinuria,
 pulmonary edema. Course has been progressing downhill
 despite discontinuation of herbs. CPK was 13,000 in ^{May} June,
 9000 in June, and now 5000. All antibody studies
 have been negative. Muscle biopsy shows lipid
 infiltration. Current tx includes feldam, potassium,
 Nistalil, Imodium, Darvocet, endapamide, cyclosporine,
 Casopide, Tagamet, steroids, NSAIDs.

- a) suspect immunologic medical problem.
 Still trying to identify Chinese products.
- b) Dr. [redacted] will call Dr. [redacted] and let him know we
 are evaluating herbs. She will bring in products to
 PCC on 7/16.



Memorandum

Date August 12, 1997
From Michael V. Owens, Investigator, DET-DO
Subject Expedited Request for Follow-up to Adverse Event Report
To Bridgette M. Wallace, CFSAN ARMS Monitor
Consumer: [REDACTED]



11915

This memo is in regards to CFSAN Project #11915, Request for Follow-up on Adverse Event Report, dated 7/23/97, (attachment A). This assignment involved following-up on an adverse event allegedly involving a product containing ephedrine which had been filed by [REDACTED] address same as above.

On 7/29/97, I met with Dr. [REDACTED] the consumer identified on the assignment request. At that time she briefly explained why she had filed the Med Alert form regarding the patient named [REDACTED]. She said this person has remained hospitalized at [REDACTED] since May 1997. The admitting physician Dr. [REDACTED] had contacted the Poison Control Center and stated that he thought they should take a look at the herbal products Ms. [REDACTED] had been taking. Dr. [REDACTED] then arranged for a member of her staff, Dr. [REDACTED] a consultant for the Center and also a member of the [REDACTED] staff to interview Ms. [REDACTED]. At the time of the interview Dr. [REDACTED] collected all 12 sample containers of various herbal supplements from Ms. [REDACTED] and brought them to Dr. [REDACTED]. Dr. [REDACTED] provided me with a photocopy of the consultation record of that visit, (exhibit 1). At that time Dr. [REDACTED] also provided a photocopy of "Formula for Arthritis - Components" which listed various names of herbal ingredients, (exhibit 2).

Dr. [REDACTED] and I examined each container and determined that most of them had been previously opened. At that time I observed that there was one container labeled as containing ephedrine. This small white plastic bottle had a blue and gold/silver colored metallic type label which appeared worn and had no lot number or expiration date, (photo exhibits 3-6). This product was labeled "PER FORM". I removed the lid from this container, which had been previously opened, and observed four brown gel type capsules, three light brown colored caplets, and five white tablets inside. Dr. [REDACTED]

stated that she believed that the white tablets were prescription muscle relaxers which had been prescribed by a doctor for Ms. [REDACTED]. She was unable to identify exactly which of the remaining few capsules actually belonged to the original bottle.

As per the assignment I collected all 12 products from Dr. [REDACTED]. At that time I also obtained a signed affidavit from Dr. [REDACTED] which stated her involvement with this particular case, (exhibit 7).

On 7/30/97, as per our telephone conversation, it was decided that you would check with Dr. Lori Love and ask for a decision as to whether or not an analysis should be conducted on the one ephedrine product which was collected. On 8/1/97, I received your banyan message stating that an analysis would not be needed, however, label and medical records collection would be needed for completion of the assignment, (exhibit 8).

Photographs were taken of all of the remaining herbal products which Ms. [REDACTED] had allegedly been taking. These photographs are attached as exhibits to this memorandum, (exhibits 9-31). All of these products can be observed grouped into one photograph in exhibit 32. Although the photographs are clearly in focus, the lettering on most of labels is very small and the assistance of a magnifying glass would be most helpful. A complete list of these products can be observed in the exhibit section of this memo.

On 8/8/97, I attempted to set up an interview with Ms. [REDACTED]. I telephoned the [REDACTED] and asked to speak with the patient, [REDACTED]. I was eventually connected to [REDACTED] R.N., who is currently MS. [REDACTED] attending nurse. I asked to speak to [REDACTED] and at that time she explained that it would not be possible because Ms. [REDACTED] is now on a mechanical respirator and cannot speak. Therefore, Ms. [REDACTED] was not interviewed as part of this assignment.

I am forwarding the photographs of the labeling of the herbal products along with this memo. During the interview with Dr. [REDACTED] I was informed that obtaining copies of the medical records could take a few weeks, especially since Ms. [REDACTED] is currently hospitalized. When I receive the medical records I will forward them immediately to your attention. As per your banyan message the herbal products were returned to Dr. [REDACTED]. Please note that a notation and signature by Dr. [REDACTED] was made on the original FDA 484, Receipt for Samples when the items were returned on 8/12/97.

Exhibits

- 1 Photocopy of consultation, 2 pgs.
- 2 Photocopy of Formula for Arthritis - Components, 2 pgs.
- 3-6 Photo's of "PERFORM" herbal product labeling.

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- 7 Signed affidavit FDA form 463a, by [REDACTED] dated 7/25/97.
- 8 Photocopy of banyan message.
- 9-11 Photographs of Juice Plus labeling.
- 12-15 Photographs of labeling for "NOW" vitamin B-12, and "GNC" vitamin B-2 both in same photo.
- 16-18 Photographs of labeling for "Multi-Fiber Formula" and "Multi-Herb Formula" both in same photo.
- 19-22 Photographs two bottles of "CHEWABLE PAPAYA ENZYME" with labeling.
- 23-29 Photographs of labeling for Natural Tea with labeling of inside packaging included.
- 30 Photograph of all herbal products grouped into one picture.
- 31 Photo negatives.
- 32 Copy of receipt for samples, also indicating signature of [REDACTED] indicating return of products.
- 33 Photocopy of original assignment dated 7/23/33, from HFS-636.


Michael V. Owens,
Investigator, DET-DO

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Herbal Products taken by [REDACTED]

1. Dieter's Natural tea, regular strength. Manufactured by FFC, USA, "Made in China", Wuzhou, 28 Fuman Road, Wuzhou, Quangxi, China, distributed by New Prosperity, Australia. No ingredients listed. Took 1-2 teabags/day for one month in January.
2. Perfect Herbal Formula. Label states chromium picolinate
3. Chewable Papaya Enzyme. Chandle Nut Co, Pittsburg
4. Triozyme Enzyme. Vital Foods, Livonia MI, contains pepsin, papain, aspergillus, malt diastase, pancreatic enzymes
5. Vitamin B2. General Nutrition Co., contains riboflavin 15 mg.
6. Vitamin B12 Sublingual. Now Foods, Glendale, IL.
7. Multifiber formula. No information available
8. Juice Plus-Kosher form. NSA, Memphis TN, contains natural fruit powder, enzymes
9. Root-To-Health. Hsu Ginseng, Wausau, WI, contains Radix salviae, Multiorrhizae, Radix paeoniae rubra, Semen persicae, licorice, lignum dalbergiae odorifera. Has been taking most recently during last 2 months prior to hospitalization.
10. MultiHerb formula (internal cleansing system). Contains alfalfa leaf, fenugreek, ginger root, dandelion root, fennel seed, yarrow flower, cat's claw bark, hawthorne berries, Australian herb, licorice root, marshmallow root, red clover tops, red raspberry root, safflower oil, skullcap, burdock root, chickweed, mullein root, papaya leaf, black cohosh root, cayenne fruit, Irish moss, Pacific kelp, slipper elm bark, yellow dock root, milk thistle extract, Echinacea augustifolia leaf, Ginkgo biloba extract.

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