

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

ARMS#

12506



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Notes on Telephone Conversation
Clinical Research and Review Staff

12506

Date	08/25/97	Phone No.	
Name	[REDACTED]	Fax No.	
Affiliation	[REDACTED]		
Address	[REDACTED]		
FDA Representatives	[REDACTED]		
Question/Subject	Death in 32yo F using D9. containing ephedra, green tea, & kola nut		

Discussion	Reported preliminary investigation into the death of a 32yo F. Had c/o severe HA; found dead. Details unclear at this time - ME case. They will get additional info to us.
Product	"Escalation" by Enzymatic Therapy (see attached info provided by [REDACTED])

Follow up	

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Signed: *LAC* 08/25/97

RECEIVED
CLINICAL RESEARCH
& REVIEW
HFS-452

Memorandum of telephone conversation

Date: 8/28/97

To: Ronald Roy, Chief, DPB, OFF, HFS-635

From: Lori A. Love, M.D., Ph.D., Director, CRRS, OSN, CFSAN, HFS-452

RE: Follow up for ARMS # 12506

Late this afternoon I had telephone discussions with the following individuals in the state of [REDACTED] concerning the death that had occurred in a young woman:

[REDACTED] M.D.

[REDACTED]

[REDACTED]

Phone: [REDACTED] Fax: [REDACTED]

[REDACTED]

The details that I currently have are sketchy. [REDACTED] was a 32 year old woman who has found unresponsive at home. She was transported to [REDACTED] where she was pronounced DOA. The local poison control called the [REDACTED] Department of Health about this case. There is an apparent history of the patient complaining of a severe headache the day before. A dietary supplement called "Escalation", made by Enzymatic Therapy was found in the vicinity of the body. According to information supplied by the [REDACTED] Department of Health, this product contains ephedra, cola nut and green tea. Judge [REDACTED] who has jurisdiction in the district where the woman died, ordered that an autopsy be performed. The body was transported, consequently, to the [REDACTED]

Dr. [REDACTED] performed the postmortem examination, and states that the only gross findings were indicative of a cardiomyopathy. Histopathology and toxicology are still pending [ephedrine and caffeine levels were specifically requested]. He will forward this information to my office as soon as it is available (hopefully by 09/01/97). Dr. [REDACTED] has possession of the product found in this person's possession. Because Judge [REDACTED] has jurisdiction, he asked that I call her for permission to collect and analyze the dietary supplement product. Judge [REDACTED] granted this and stated that she would provide written instruction to the [REDACTED] office concerning this.

Would it be possible to have the field collect this product sample for analysis? Any other investigative details that they may be able to collect would also be useful.

Lori A. Love

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