

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

ARMS#

13085



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CFSAN

CFSAN

28752
88752

FDA Report

Received Date: 7/27/98

13085

Accno: 025446

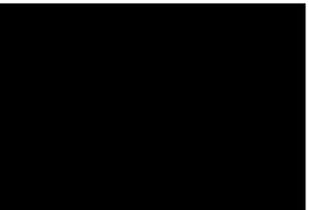
Product: H.E.L.P.

Generic: Dietary Supplement

os Form: Capsule

Adm Route: Oral

Reporter: MD



Lot Number: 9834108

Expiration Date: 6/30/00

NDC Number:

Container Size: 30 Caps

Strength:

Manufacturer: Dakotah Intl

XManufacturer:

Labeler:

Sample Available:

Sample Submitted:

Reported Manufacturer:

Reported FDA:

Reported Other:

Remarks - Problems:

A 31-year-old female, who was not taking any other medications except for H.E.L.P. two capsules daily for a period of two to three months, experienced muscle cramps in her legs for ten days followed by two days of severe muscle weakness. She was hospitalized with severe hypokalemia (1.6), elevated transaminase levels, proteinuria, and metabolic acidosis. See file for copy of the label.

for information further...

REC'D.

SEP 02 1998

MEDWATCH CTU

Adverse Event Questionnaire

Complaint Number: CFSAN Project #13085

Investigator: Paula J Perry

Consumer Information		
Date of Report: <u>12/17/98</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury	
	<input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Polson Control <input type="checkbox"/> CDC	
Name: [REDACTED]	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M	Age: 31
Race: <input checked="" type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other _____ <input type="checkbox"/> 9-Unknown		
Information on Adverse Event		
Date of Adverse Event: <u>7-20-98</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office):	
Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No N/A	Home	
<p>The following information relates to the consumers' use of the product.</p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): Experienced leg cramping, difficulty walking, and extreme body weakness after taking How long did the symptoms last? <u>4 weeks</u> product for approximately 3 months Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). <u>2 capsules daily consumed by mouth, 1 in morning and 1 in evening</u></p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event: N/A</p> <p>Did event abate after use of suspected product stopped or dose reduced: <input checked="" type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" type="checkbox"/>Not Applicable Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" type="checkbox"/>Not Applicable</p>		
Medical Information		
Was a health care provider seen? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Hospitalization <u>7/20-25/98</u>		
Give health care provider's name, address and telephone number: [REDACTED] Doctor's on staff		
Occupation of Health Care Provider: <input checked="" type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify) _____		
What medical tests were performed and what were the results?		
What was the medical diagnosis? Medical records attached		
What treatment(s) was given (e.g., drugs, other)?		
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		

000002

Product Category

1. Adverse event attributed to:

Medical Food (under medical supervision) Infant Formula

Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzolic acid, and rutin; and mixtures of these ingredients.)

Other (traditional food) _____

Other Product Problems

2. Foreign Object

(specify): _____

3. Other (specify): _____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

Label not available, product identified as "HELP" (weight loss product)

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

Check here if ingredients are unknown Reportedly a natural ingredient product

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

Aspartame

Monosodium Glutamate

Sulfite

Other _____

Unknown

Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: Yes No

Unknown Product Sample Available: Yes No Unknown

Outcome Attributed to Adverse Event:
(if yes, include pertinent medical records)

Death: Yes No

Life-Threatening: Yes No

Hospitalization: Yes No (if YES, indicate if initial or prolonged) prolonged 7/20-25/98

Required intervention to prevent permanent impairment/damage: Yes No

Did the adverse event result in a congenital anomaly: Yes No

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Bridgette M. Wallace
HFS-636, ARMS Monitor

THRU: Lillie Jihson, SCSO, HOU-RP
M. Joe Uribe, CCC, DAL-DO

FROM : [REDACTED] Resident Post

DATE: December 29, 1998

*Rec'd 1/11/99
JDCRP*

SUBJECT CFSAN Project #13085, Lora Lea Moore - Medical Records

Attached are medical records pertaining to the hospitalization and subsequent medical care of Mrs. [REDACTED] in response to an assignment memo of 9-29-98 from HFS-636 which requested medical records and Adverse Event Questionnaire (IOM Exh 910-D) be collected and submitted for evaluation and review.

Mrs. [REDACTED] stated she had consumed 2 capsules daily of a weight loss product called "HELP" for approximately 3 months when she experienced leg cramping, difficulty walking, and extreme body weakness. She was admitted to [REDACTED] in [REDACTED] on 7-20-98 and discharged 7-25-98, with subsequent follow-up care. Mrs. [REDACTED] stated the product was sold to her by an individual (stating she could not remember the person's name) and not purchased through a retail outlet.

Medical records were collected from [REDACTED] (Attachment 1); Dr. [REDACTED] (Attachment 2); Dr. [REDACTED] (Attachment 3); and [REDACTED] (Attachment 4).

Attachments
as stated

Paula J Perry
PAULA J PERRY
CSO, Ltr-RP

000004