

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

ARMS#

13202



1 - AFFIDAVITS

000001

AFFIDAVIT

MedWatch #1
2/4,5/99

JAN

SAMPLE NO.

STATE OF

COUNTY OF

Before me, JOHN A HOLLINGS, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared _____ in _____ State aforesaid, who, being duly sworn, deposes and says:

Jan _____ and live at _____

On 2/1/99 I provided FDA Investigators John A. Hollings and Edward J. Janik information regarding my adverse experience with the diet supplement called PHENSAFE.

In early October, 1998 I purchased 1 bottle of a diet supplement called PHENSAFE which I used as a weight loss product. I began taking this product in October and continued for 3-4 weeks. I took this product 3 times daily, 3 capsules each time with a glass of water, before meals as instructed by the product directions.

I immediately began to experience extreme thirst and increased frequency of urination. I continued to take this product as the labeling instructed until I began to experience stomach and back pain. During the first week of November

AFFIANT'S SIGNATURE AND TITLE

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Subscribed and sworn to before me at _____ (City and State)

this 1ST day of FEB., 19 99

[Signature]
(Employee's Signature)

000002

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF

COUNTY OF

Before me, JOHN A. HOLLINGS, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared _____ in the county and State aforesaid, who, being duly sworn, deposes and says:

I went to the _____ Emergency Room and was told I had food poisoning and an elevated white cell count. This was my first medical treatment concerning this event. Approximately 1 week later I visited Dr. _____ office in _____ and informed them of my symptoms of stomach/back pain, increased frequency of urination, extreme thirst. Laboratory tests were performed and I was contacted by Dr. _____ from Dr. _____ office, and told to go to _____ for an Ultra Sound examination. I visited Dr. _____ on 11/16/98, a few days after the Ultra Sound exam, and was admitted to _____ on 11/17/98. I was released from the hospital the next day. I continued to visit Dr. _____ office during December and was _____ from _____ until the 1st week of January when I was informed of my recovery.

AFFIANT'S

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Subscribed and sworn to before me at _____ (City and State)

this 1ST day of FEB, 19 99

000003

[Handwritten Signature]
(Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF

COUNTY OF

Before me, JOHN A. HOLLINGS, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared [redacted] in the county and State aforesaid, who, being duly sworn, deposes and says:

I also provided the Investigators with the product carton and insert, which will be copied and returned to me. The product bottle and remaining capsules were brought to the hospital when [redacted] I was admitted on 11/17/98. Dr. [redacted] had the product tested. I do not know of the results and Dr. [redacted] has possession of the product bottle and capsules. The product carton is labeled in part: "*** PHENSAFE Diet Supplement #90 Fast Absorption CAPSULES * Lose Weight * Feel good * Energize * Supplement Facts * Serving Size: Three (3) Capsules * St. John's Wort 300mg * L-Glutamic Acid HCL 100mg * Chromellate 125mg * Sida Cordifolia * BIOPERINE * Directions: Take 2 or 3 capsules.... * Warnings: * Do not use if... high blood pressure,.... * These statements have not been evaluated by the FDA. This product is not intended to diagnose treat, cure or prevent any disease. * Distributed by: Applied Nutrition P.O. Box 66490 Los Angeles, CA 90066 USA ***".

AFFIANT'S SIGNATURE AND TITLE

FIRM'S NAME AND ADDRESS

000004

Subscribed and sworn to before me at [redacted] (City and State)

this 1ST day of FEB, 19 99

John A. Hollings
(Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF

COUNTY OF

Before me, JOHN A. HOWINGS, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508), effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared [redacted] in the county and State aforesaid, who, being duly sworn, deposes and says:

The product insert is labeled in part: "*** PHENSAFE DIET & EXERCISE PROGRAM Safe Effective Natural & Three Easy Steps PhenSafe Dietary Formula * a) Fresh Vegetables & Fruits * b) High Quality Protein * c) Starches & Carbohydrates * d) Fats * e) The Importance of Water * Ten Important Diet Tips ***"

I have also given the Investigators my permission to access my medical records concerning this adverse event for treatment received from [redacted] Dr. [redacted] and [redacted]

[redacted] admission. I have signed and provided to the Investigators form Authorization For Medical Records Disclosure.

The above is true and correct to the best of my knowledge and belief.

AFFIDANT'S SIGNATURE AND TITLE

[redacted signature and title]

Code

000005

Subscribed and sworn to before me at [redacted] (City and State) this 1ST day of FEB, 19 99.

[Handwritten signature]

(Employee's Signature)

Employee of the Department of Health and Human services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88 effective May 4, 1980.