

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

ARMS#

13336



1 - AFFIDAVITS

000001

AFFIDAVIT

SAMPLE NO

STATE OF

COUNTY OF

Before me, Margaret M. Annes, 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 am \_\_\_\_\_,

On February 17, 1999, I was visited by FDA Investigator Margaret M. Annes. Investigator Annes questioned me about an adverse event I experienced on January 30, 1999. I told Investigator Annes that on Thursday January 28, 1999 I experienced some restlessness in my legs in the evening and took some Ibuprofen. The following day, January 29, 1999 I went to \_\_\_\_\_ and was told to make an appointment for a complete physical. The doctor did not know for sure what was wrong and thought that it might be tendonitis. That evening I went home after an early dinner out and got into our hot tub for approximately 5 minutes. At about 1:30 a.m. on January 30, 1999 I had some difficulty with walking when I went to lay on the couch. At approximately 3 a.m., I got up to let the dog out and feed. I had trouble with the left side of my body. At approximately 7 a.m. I went to the emergency room at \_\_\_\_\_.

The doctor at \_\_\_\_\_, Dr. \_\_\_\_\_ M.D., diagnosed me as having had a stroke after reviewing the results of my CAT scan. I was then admitted into \_\_\_\_\_ for treatment and remained there until February 3, 1999 ...

Subscribed and sworn to before me at \_\_\_\_\_

this 19th day of February, 1999 (City and State)

000002

Margaret M. Annes  
(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

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... when I was transferred to [redacted] for rehabilitation therapy. I remained at [redacted] until February 13, 1999. I am currently receiving outpatient rehabilitation therapy at [redacted]

Approximately 2 1/2 years ago I was on fen-phen for weight loss. I stopped using it when the drug was pulled from the market. Then sometime between May-June, 1998 I began taking a product called Total Control from WsCa Naturals. I took 2 capsules everyday, except for a few times when I took 3. I provided Investigator Annes with an unopened bottle of Total Control, Lot # 3154 / EXP 7-01, 100 capsules. This is the same type of bottle I have been receiving. In my last shipment of the product, I am unsure of the date, I received the same Total Control Product, but with a different label. The new label lists 2 new ingredients, Chromium picolinate and spirulina. Both bottles contain (per the label) Ma Huang and other ingredients. The new bottle contains only 90 capsules. I had taken (finished) 1 bottle and had started another when I had my stroke. There are 42 capsules left from the opened bottle (Lot # 2693 EXP 2-01), 10 of which I had...

AFFIANT'S SIGNATURE AND TITLE

[redacted]

Subscribed and sworn to before me at

this 19th day of February, 19 99.

(City and State)

000003

Margaret M. Annes  
(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

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... in an old ibuprofen bottle in my purse, the other 32 are in the original container.

I have provided Investigator Annes with the original opened container of Total Control that I had been taking at the time of my stroke (I discontinued taking Total Control beginning Friday January 29, 1999) and 25 of the capsules from that container (Lot # 2693 EXP 2-01). I have also provided an unopened container of Total Control (Lot # 3154 EXP 7-01) that I had ordered before but had not taken. I have also provided copies of several sales receipts dated 7/7/98, 9/8/98 & 11/30/98 showing my purchase of Total Control from [redacted] & WesCa Naturals, San Diego, CA. I believe that the two companies are related since the phone number is the same (1-888-462-DIET) and the product was the same until the recent change. The product has always been called Total Control. I also provided copies of information and order forms that were sent to me with each shipment of Total Control.

I also released my medical records from [redacted] and ...

FIRM'S NAME AND ADDRESS (if any)

Subscribed and sworn to before me at [redacted] this 19th day of February, 1999 (City and State)

000004

Margaret M. Annes  
(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. [REDACTED]

STATE OF [REDACTED]

COUNTY OF [REDACTED]

Before me, Margaret M. Annes, 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:

... [REDACTED] to the FDA.

I believe that based on what my doctors have told me, that the Total Control product contributed to my stroke.

FIRM'S [REDACTED] AND ADDRESS (In [REDACTED] ZIP Code) [REDACTED]

Subscribed and sworn to before me at [REDACTED] (City and State) this 19th day of February, 1999.

000005

Margaret M. Annes  
(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.