

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

ARMS#

13370



1 - AFFIDAVITS

000001

STATE OF

COUNTY OF

Before me, Anthony R. Petriella, 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, Sacs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Sacs. 1-9, effective April 11, 1953; and P.L. 96-98, 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 am [redacted] and I reside at [redacted] I was born on [redacted]

On or about November 6, 1998 my father purchased 1 bottle of METAFORM "METACUTS" dietary supplements (60 capsules, distributed by METAFORM of Woodland Hills CA.) from [redacted] located at the [redacted] He purchased them in hopes of having more energy after taking them. My father, [redacted] took one pill later that day and within 1/2 hour felt ancy and jittery He discontinued taking the pills as he felt that his bad reaction to taking the "METACUTS" was due to his diabetes.

Since my father could not take the pills, I began taking them. I ingested 47 pills between the end of November, 1998 through January 27, 1999. I took the pills, four at a time, per the instructions on the bottle every time I worked out at the [redacted]

Around January 7, 1999 my mother noticed that I had not been sleeping very well and that I had a lot more energy than normal.

On January 26, 1999 my co-workers noticed a change in my behavior. My work Foreman noticed that I wasn't taking directions very well and he mentioned to me that I should slow down.

On January 28, 1999, around 8:00 PM, I started having chest pains while shopping (at the time I did a lot of shopping as I felt a strong desire to spend money) and the feeling that something was blocking my windpipe (maybe from metal shavings I may have inhaled at work the day before). I started to drive home and then realized that the pain was so severe that I needed to go to the hospital but I couldn't drive. My girlfriend, [redacted] started to drive me to [redacted] and I had to call 911 enroute as the chest pains were so severe that I couldn't breathe. Before the ambulance arrived where we had stopped on the [redacted] I had started throwing up uncontrollably. After the ambulance arrived a few minutes later, I did feel as if what was in my windpipe came out, but I continued to have chest pains and my throat was still irritated. I arrived at the hospital by ambulance and was checked by the [redacted] ER physician and released.

On January 29, 1999 I went to see my family physician, [redacted] M.D. and he checked my throat. Dr. [redacted] stated that I had a throat irritation, but that I would be fine.

On February 1, 1999, my mother took me to see Dr. [redacted] again, as my family thought I was being delusional. Dr. [redacted] interviewed and then referred me to Dr. [redacted] a psychiatrist.

Also on February 1, 1999 I went to see Dr. [redacted] who interviewed me and then prescribed medications for manic/depressive behavior.

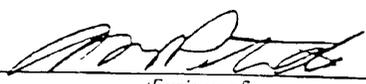
On February 3, 1999 my mother took me to see psychologist Dr. [redacted] because I had been up for three days straight.

AFFIDANT'S SIGNATURE: [redacted]

FOR [redacted]

Subscribed and sworn to before me at [redacted] this 25 day of March, 1999.

000002


(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.

STATE OF

COUNTY OF

Before me, Anthony R. Petriella, 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. 96-98, 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:

On February 3, 1999, as a result of my consultation with Dr. [redacted] I was admitted to [redacted] I was released on February 10, 1999.

On February 11, 1999 I again visited Dr. [redacted] who prescribed medication for a sore on my arm.

On February 15, 1999 I went to see [redacted] M.D. for follow-up on my hospital release. Dr. [redacted] stated that my condition was drug-induced due to the Ephedrine contained in the "METAFORM" food supplements. Dr. [redacted] prescribed medications for "Bi-polar" behavior.

On February 24, 1999 through February 27, 1999 my family started noticing my behavior becoming very irrational again.

On February 26, 1999 I visited Dr. [redacted] again and he increased my medication.

On February 28, 1999 I was re-admitted to [redacted] and was under their care until my release on March 7, 1999.

On March 15, 1999 I again saw Dr. [redacted] who lowered the amount of my medication.

On February 22, 1999, my sister, [redacted] reported my conditions by phone (as referenced above) to the U.S. Food and Drug Administration located in [redacted].

On March 24, 1999 and March 25, 1999, FDA Investigator Anthony R. Petriella visited my home and explained that my sister's complaint resulted in Complaint Number DET-0833 which generated CFSAN Medwatch assignment #13370. My sister and my mother were with me on the March 24, 1999 visit to help in my recollection of the events. My mother was also present on the March 25, 1999 visit. During these two days we discussed my recent medical history. I told Investigator Petriella that prior to taking the "METACUTS" I did not have any history of psychotic behavior.

During the March 24, 1999 visit, FDA Investigator Petriella collected 10 METAFORM tablets in the original container and provided me with a receipt for the sample. Investigator Petriella also took photographs of medications I am presently taking.

I provided Investigator Petriella with signed medical release forms for any medical records to be requested by him.

I believe the above statements to be true and accurate.

AFFIANT'S SIGNATURE AND TITLE

FIRM'S NAME AND ADDRESS

(Include ZIP Code)

Subscribed and sworn to before me at [redacted] this 25 day of March, 1999.

000003



(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