

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

ARMS#

13345



0 - FRONT



CFSAN

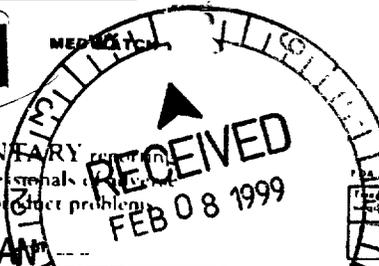
MEDWATCH

APPENDIX

Appendix

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems



Form Approved OMB No. 0910-0201 Expires 12/31/96

96916  
13345

A. Patient information

1 Patient identifier  
2 Age at time of event: 29  
3 Sex: female  
4 Weight: 150 lbs

B. Adverse event or product problem

1 Adverse event and/or Product problem  
2 Outcomes attributed to adverse event: death, spontaneous AC  
3 Date of event: 3 3 99  
4 Date of this report: 2 2 99

Describe event or problem  
Pt's last miscarriages began on Nov 3 - took the hormonal preparations until December. ultrasound showed total demise at 9 weeks gestational age.

6 Relevant tests/laboratory data, including dates  
⊕ HCG ~~at~~ December

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
2 previous normal pregnancies, normal births  
No tobacco, No EtOH. Very healthy

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler if known)  
#1 Magic Herb... Plus Formulation Prostate  
#2...  
2 Dose, frequency & route used  
#1 oral  
#2 oral  
3 Therapy dates (if unknown give duration)  
#1 Nov - Dec '98  
#2 Nov - Dec '98  
4 Diagnosis for use (indication)  
#1 Retardation  
#2  
5 Event abated after use stopped or dose reduced  
#1 yes no doesn't apply  
#2 yes no doesn't apply  
6 Lot # (if known)  
7 Exp date (if known)  
8 Event reappeared after reintroduction  
#1 yes no doesn't apply  
#2 yes no doesn't apply  
9 NDC # (for product problems only)  
10 Concomitant medical products and therapy dates (exclude treatment of event)  
none

D. Suspect medical device

1 Brand name  
2 Type of device  
3 Manufacturer name & address  
4 Operator of device  
5 Expiration date  
6 model #  
7 If implanted, give date  
8 If explanted, give date  
9 Device available for evaluation?  
10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1 Name, address & phone #  
2 Health professional?  
3 Occupation: MD  
4 Also reported to  
5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box



Mail to: MEDWATCH, 5500 Fishers Lane, Rockville, MD 20852-0787  
or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FEB 3 '99 10:10

MEDWATCH THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

ADFS DRUG INFORMATION # 98

3129

000001

HF-2

CTU 96916

ARMS\* Adverse Event Questionnaire

Complaint Number: 13345

Investigator: \_\_\_\_\_

Consumer Information	
Date of Report: <u>02/02/99</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <input checked="" type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC
Name:	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M Age: <u>22</u>
Race: <input 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>2 Feb 99</u> Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>home</u>
<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): <u>Fetal death at approx. 13 wks gestation</u></p> <p>How long did the symptoms last? <u>N/A</u></p> <p>Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). <u>Took 2-3 capsules per day of "Magic Herb" for about 3 months. Last menstrual period 3/Nov. Stopped Magic Herb when home pregnancy test was positive in early Dec. 98.</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: <u>Also using a Contraceptive tablet, discontinued at same time.</u></p> <p>Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <u>N/A</u></p> <p>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</p> <p>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 Give health care provider's name, address and telephone number: <u>See MedWatch form</u>	
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? - <u>on 2nd OB visit, no fetal heart beat detected on Doppler - Ultrasound exam confirmed fetal death, perhaps several weeks earlier.</u> What was the medical diagnosis? <u>Fetal Death</u> What treatment(s) was given (e.g., drugs, other)? - <u>D&amp;C procedure done on next day.</u>	
Were there any preexisting condition(s)/treatment(s)? - <u>No</u> (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input type="checkbox"/> No	

Information obtained in a telephone interview with consumer  
3-2-99

[Redacted Signature] MD

**Adverse Event Questionnaire**

Complaint Number: 13345

Investigator: THOMAS S. DONALDSON

District MIN Phone # 612 / 334-4100 EXT 182

**Consumer Information**

Date of Report: 04-08-99  
MM/DD/YY

Initial Report Source:  ORA  Consumer Injury  Telephone  Correspondence  MedWatch  
 USP  PQRS  Poison Control  CDC  Other (specify):

Name: [REDACTED] Gender:  M Age: 22

Race:  1-White  2-Black  3-Asian/Pacific Islander  4-Native American  5-Hispanic  
 8-Other  9-Unknown

**Information on Adverse Event**

Date of Adverse Event: 02-02-99 - DR [REDACTED] DIAGNOSIS OF  
[REDACTED] PREGNANCY WAS CONFIRMED BY ULTRASOUND AT [REDACTED]

Previous Adverse Effects to Product Type: Yes No

NOT APPLICABLE, [REDACTED] INITIAL USE OF HERBAL PRODUCTS.

Give the site of consumption/ingestion (e.g. home, restaurant, office): The following information relates to the consumers' use of the product. MRS [REDACTED] IS A HOUSEWIFE WITH TWO YOUNG CHILDREN, A WORKS AT HOME (OCTOBER-DECEMBER) MANUFACTURING HOLIDAY WRATHS.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): [REDACTED] HAD TWO SYMPTOMS: 1) LACK OF ENERGY CONSTANTLY TIRED, 2) CONSTANT FEELING OF NAUSEA WITHOUT GETTING SICK. THESE SYMPTOMS WERE PRESENT WITH HER SECOND PREGNANCY.

EMBRYONIC DEMISE AT APPROXIMATELY 9 MENSTRUAL WEEKS, AS REPORTED ON RADIOLOGICAL CONSULTATION BY [REDACTED] MD (EXHIBIT 6, PAGE 4 OF 22).  
"MAGIC HERB" USED 10-01-99-12-02 OR 04-99 (60 DAYS ESTIMATED USAGE) + 60 DAYS LAPSED 10-02-99.

How long did the symptoms last?  
NAUSEA IS GONE, BUT LACK OF ENERGY/TIRED FEELINGS REMAIN, WHICH CAN BE ATTRIBUTED TO RAISING TWO YOUNG CHILDREN.

Give the circumstances of exposure (i.e. how much was taken, how often was it taken, etc.). "MAGIC HERB" 3 CAPSULES PER DAY (2/BREAKFAST & 1/LUNCH). PRODUCT WAS TAKEN DAILY FROM 10-01-99 TO 12-02 OR 04-99 (CONSUMED 143 CAPSULES). THE USAGE IS ILLUSTRATED IN ATTACHMENT 6. 1ST OF 2 BOTTLES OF "MAGIC HERB" PURCHASED JULY 98 AND USED OCCASIONALLY UNTIL OCTOBER 1.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:

"PRENATAL VITAMINS" - 1 TABLET/DAY 12-14-98 TO 02-01-99

"MAGIC HERB" - 3 CAPSULES/DAY 10-01-99 - 12-02 OR 04-98

"GENGENG" - 4-6 CAPSULES/DAY 11-22-98 TO 12-02 OR 04-98 (ILLUSTRATED IN ATTACHMENT 6)

Did event abate after use of suspected product stopped or dose reduced: Yes No Unknown

N/A

Did symptoms reoccur after reintroduction of suspected product: Yes No Unknown N/A

Did symptoms reoccur after using other products with the same ingredients: Yes No Unknown N/A

[REDACTED] GAVE [REDACTED] THE REMAINDER OF BOTH HERBAL PRODUCTS, AND HAS NOT CONSUMED THESE PRODUCTS SINCE 12-02 OR 04-98.

Complaint # 13345

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**Medical Information**

Was a health care provider seen? Yes No

Give health care provider's name, address and telephone number: [REDACTED]

DR. [REDACTED]  
Occupation of Health Care Provider MD Osteopath Naturopath Nurse Pharmacist

Other (specify) \_\_\_\_\_

What medical tests were performed and what were the results?

URINE SPECIMEN 12-22-98 HCG POSITIVE  
ULTRA SOUND -

What was the medical diagnosis?

EMBRYONIC DEMISE AT APPROXIMATELY 9 MENSTRUAL WEEKS. (02-02-99)

What treatment(s) was given (e.g., drugs, other)?

MEDICATIONS TO CONDUCT DILATION AND CURETTAGE ON 02-03-99

WEEKLY EVALUATION OF HCG LEVEL (02-11-99/823 - 02-21-99/51)

Were there any preexisting condition(s) or treatment(s)?

YES

(If YES, list them including allergies, and chronic diseases): Yes No

ASTHMA DURING ELEMENTARY SCHOOL YEARS NOT PROBLEMS SINCE

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**Product Category**

1. Adverse event attributed to:

\_\_\_ Medical Food (under medical supervision)

\_\_\_ Infant Formula

X 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-benzoic acid, and rutin; and mixtures of these ingredients.)

\_\_\_ Other (traditional food) \_\_\_\_\_

Other Product Problems

2. Foreign Object

(specify): \_\_\_\_\_

3. Other (specify): \_\_\_\_\_

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**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):

MAGIC HERB DIET PLUS FORMULA WITH CHROMIUM PICOLINATE

MAGIC HERB, P.O. BOX 23504, OKLA. CITY, OK 73123

DIRECTIONS FOR USE: TAKE UP TO 3 CAPSULES DAILY. TWO IN THE MORNING ONE AT LUNCH TIME

→ WARNING: THIS PRODUCT CONTAINS NATURAL STIMULANTS.  
IF PREGNANT OR NURSING OR HAVE ANY OTHER MEDICAL PROBLEMS, SEEK THE ADVICE OF A HEALTH PRACTITIONER BEFORE USING THIS PRODUCT.

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

EACH CAPSULE CONTAINS:  
MA HAUNG (EPHEDRA SINENSIS) 300mg  
STANDARD EXTRACT 8% EPHEDRA ALKALOIDS  
COLA NUT EXTRACT (COLA NUT FDA) 200mg (CONTAINS 5mg AFFEINE)  
Check here if ingredients are unknown

(EXHIBITS, PAGES 8-9)  
FROM LABEL AS STATED -  
NO ANALYSIS DATA TO VERIFY

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

-Aspartame Color Additive (please specify) \_\_\_\_\_

-Monosodium Glutamate

-Sulfite

-Other MA HAUNG (STANDARD EXTRACT 8% EPHEDRA ALKALOIDS) 300 mg  
CHROMIUM PICOLINATE 200 mcg

-Unknown

Is the product label available? If yes submit a quality copy along with this questionnaire? (Yes) No

Unknown PHOTOCOPY INCLUDED OF "MAGIC HERB" (EXHIBIT 8) AND "GINSENG" (EXHIBIT 9)

Product Sample Available (Yes) No Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records) ULTRA SOUND CLINIC & HOSPITAL (EXHIBIT 6, PAGES 14-15 OF 22)  
HOSPITAL RECORDS D&C / PATHOLOGY (EXHIBIT 3).

Death: Yes (No) PATIENT'S DIAGNOSIS EMBRYONIC DEMISE / PATIENT VS PREGNANCY

Life-Threatening: Yes (No) PATIENT'S IS HEALTHY

Hospitalization: Yes (No) (if YES, indicate if initial or prolonged) OUT PATIENT / DILATION / CURETTAGE  
ON 02-03-99

Required intervention to prevent permanent impairment/damage: Yes (No)

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

→ CAMELLIA SINENSIS 50mg  
GUARANA 100mg  
CHROMIUM PICOLINATE 200mcg  
Kelp 20mg  
WHITE WILLOW 20mg  
SPERULINA 20mg  
LICORICE 20mg  
SIBERIAN GINSENG 100mg  
Fo-Ti 20mg  
ASTRAGALUS 20mg  
ASHWAGANDHA 30mg



U.S. Dept. of Health and Human Services  
Food & Drug Administration

Thomas S. Donaldson  
Investigator

Minneapolis District Office  
240 Hennepin Avenue  
Minneapolis, MN 55401

Phone: (612) 334-4100 ext. 182  
Fax: (612) 334-4134

Notes on Telephone Conversation  
Clinical Research and Review Staff

Date	March 1, 1999	Phone No.	[REDACTED]
Name	Dr. [REDACTED], M.D.	Fax No.	[REDACTED]
Affiliation	[REDACTED]		
Address	[REDACTED]		
FDA Representatives	Richard J. Calvert, MD		
Question/Subject	f/u of ARMS 13345		

Discussion	I spoke w/ Dr [REDACTED] re f/u of the MedWatch report she filed on 2 Feb 99 (Fetal demise @ 9 wks assoc Magic Herb Diet Plus Formula) [Ma Huang, Guarana, other ingredients]. She agreed to contact the patient to see if further f/u by me would be okay regarding the supplement use. She stated she had the supplement bottle in her medical office, given to her by the patient. She would call me back today or tomorrow in followup.

Follow up	

Signed:

*[Handwritten Signature]*

Date: 3-1-99

000006

Notes on Telephone Conversation  
Clinical Research and Review Staff

Date	2 Mar 99	Phone No.	[REDACTED]
Name	[REDACTED]	Fax No.	[REDACTED]
Affiliation	Consumer		
Address	[REDACTED]		
FDA Representatives	Richard J. Calvert, MD		
Question/Subject	Product use information re ARMS # 13345		

Discussion	<p>After Dr. [REDACTED] Mrs. [REDACTED] physician checked to see that it would be okay, I phoned Mrs. [REDACTED] to obtain further information on the adverse event associated with use of "Magic Herb." Mrs. [REDACTED] began using Magic Herb tablets (2-3 per day, as per instructions on label) and a Consery tablet for weight loss and energy in <del>the</del> Sept. of 1998. Approx. Dec. 1, 1998 she learned she was pregnant by a home pregnancy test, and discontinued product use. Her first OB visit (Jan 4) was uneventful and confirmed a pregnancy. At her next visit <sup>(Feb. 2, 1999)</sup>, no fetal heart beat could be detected by Doppler, and an ultrasound exam the same day confirmed that the fetus had died, probably several weeks earlier. A D+C procedure was done the next day. Mrs. [REDACTED] desired a copy of my "report" when it was completed. Mrs. [REDACTED] confirmed it would be okay for FDA inspectors to obtain the pills from Dr [REDACTED]</p>
Follow up	<p>I will need to speak to Dr. Lori Love about whether we can release clinical summaries or other reports to consumers.</p> <p>[REDACTED] The consumer reports she is 22 years old, not 29 as noted on the Med Watch form.</p>

Signed:

*Richard J. Calvert*

Date: 2 Mar 99

000007



I picked-up the patient's medical records at the [REDACTED] en route to the medical clinic in [REDACTED]. Dr. [REDACTED] MD had the [REDACTED] send a "Consent for Release of Information" to the [REDACTED] regarding the treatment of [REDACTED] (Exhibit 1, including the FAX transmittal sheet). I met [REDACTED] of the Medical Records department (hospital policy does not permit the release of an employees last name). I presented my credentials and she handed me an envelope containing [REDACTED] records. I informed [REDACTED] that my interview with [REDACTED] would include her signature on the FDA release form for the same hospital records, and that a copy of the FDA release form would be mailed to the hospital Medical Records department (Exhibit 2). The copy was mailed to the hospital on March 22. The records were for the treatment of [REDACTED] on February 03, 1999 (Exhibit 3, 3-pages). The each page from the envelope was identified on the reverse side as follows: FDA 03-18-99 TSD 01 of 03 - 03 of 03. The original hospital copies were not available for identification

I presented my credentials and business card to the receptionist/medical assistant of the [REDACTED]. She handed me an envelope. The envelope contained a copy of the [REDACTED] release form dated March 16, 1999 (Exhibit 4) and twelve pages of medical records for [REDACTED]. Each page was identified on the reverse side as follows: FDA 03-18-99 TSD 01 of 12A - 12 of 12A. At the completion of the interview, Dr. [REDACTED] identified twelve pages from [REDACTED] file that should be copied for the investigation. The additional records were identified on the reverse side as follows: FDA 03-18-99 TSD 01 of 12B - 12 of 12B. Upon further review, the twenty-four (24) pages did not include a laboratory report confirming the pregnancy. The laboratory report was in [REDACTED] file and a copy was included and identified on the reverse side as follows: FDA 03-18-99 TSD 01 of 01C. The original records were identified in the same manner. Upon completion of the identification procedure, I realized that the date was wrong.

All records identification was done with the wrong date. The actual date was 03-19-99. My records identification dating error was noted before leaving the [REDACTED]. The error was reported to [REDACTED] an employee that assisted with the records collection. [REDACTED] stated that she would place a note in the file regarding the dating error. I did not correct and initial the original records in the patient's clinic file for the reasons as follows:

- Record collections were completed in one day March 19, 1999.
- A member of the clinic staff was advised of the error.

[REDACTED] signed the FDA AUTHORIZATION FOR MEDICAL RECORDS DISCLOSURE-MINNESOTA issued to the [REDACTED] dated 03-19-99 (Exhibit 5).

The Investigator copy of each record was corrected and initialed. The records are included with this memorandum except for three (3) records as follows: 07 of 12A, 08 of 12 B and 12 of 12B (Exhibit 6, 22-pages).

On Friday March 19, credentials were shown to Dr. [REDACTED] MD for the purpose of discussing the medWatch report filed February 02, 1999 regarding the clinic's patient [REDACTED]. The interview was conducted at the [REDACTED]

Dr. [REDACTED] is a graduate of the [REDACTED]. She has maintained a full time practice at the [REDACTED] from September 1996 to the present.

In response to how long [REDACTED] has been a patient of the clinic, Dr. [REDACTED] examined the file and stated that [REDACTED] (maiden name [REDACTED]) first visited the clinic in July of 1991. The visit was for abdominal pain and upper respiratory cough.

How would you describe [REDACTED] past and present health? Dr. [REDACTED] stated that [REDACTED] health is normal, and that the file indicates only minor medical issues. The patient is not on any prescription medications. Her past medical history includes an asthmatic condition when she was in sixth grade with no problems since.

When was the pregnancy listed in the medWatch report confirmed by the [REDACTED]? A specimen was collected and tested hCG positive on December 22, 1999 and [REDACTED] was informed the same day (Exhibit 6, page 13 of 22)..

[REDACTED] initial OB examination and assessment was conducted by Dr. [REDACTED] MD on January 04, 1999 (Exhibit 6, page 06 of 22-Dr. [REDACTED] notes and Exhibit 6, page 18 of 22-assessment form date 01-04-99).

Dr. [REDACTED] MD conducted the second OB examination on February 02, 1999, and during this examination the [REDACTED] mention the use of two herbal products (Exhibit 6, page 05 of 22-Dr. [REDACTED] notes). A 1998/1999 calendar notes the specific sequence of events as reported on the documents collected (Attachment 4).

Have you ever treated Mrs. [REDACTED] for the same type of problem? No I have not, and her clinic file documents two normal deliveries as follows: Dr. [REDACTED] a baby boy [REDACTED] and Dr. [REDACTED] a baby boy [REDACTED]. A copy of the pregnancy assessment form for each birth is included as follows: [REDACTED] (Exhibit 6, page 16 of 22), and [REDACTED] (Exhibit 6, page 17 of 22).

Was the most recent pregnancy planned? The clinic records indicate that [REDACTED] received her last shot of Depo Provera on November 01, 1996, and Dr. [REDACTED] stated that each shot gives the patient three (3) months protection. [REDACTED] did express the desire to have another child during her clinic visit for a physical exam and pap smear on February 13, 1998. Dr. [REDACTED] notes and the office staff tabs on the same record are dated 2-13-97 (Exhibit 6, page 08 of 22). The date will be corrected in the clinic's file.

A member of the clinic medical staff advised [REDACTED] of the positive pregnancy test and that prenatal vitamins left from previous pregnancy could be used on December 22, 1998 (Exhibit 6, page 07 of 22). Dr. [REDACTED] did not consider the prenatal vitamins as clinically significant.

I telephoned Dr. [REDACTED] MD on April 05, 1999 to verify observations listed in the two previous paragraphs. We reviewed and agreed that the year was 98 not 97, and that the prenatal vitamins were from the February prescription written by Dr. [REDACTED] MD and not from the previous pregnancy.

A description of the events from February 02 to the present were as follows:

- Dr. [REDACTED] MD stated that on February 02, 1999 she conducted an examination of the patient and that she requested an Ultra-Sound be done to confirm the findings of her examination. The clinic conducted the Ultra-Sound and the findings indicated an embryonic demise at approximately nine (9) menstrual weeks (refer to clinic records Exhibit 6, page 14 of 22).
- The doctor, at the patient's request scheduled a Dilation and Curettage (D and C) procedure for the next day.
- Dr. [REDACTED] reported the adverse event to medWatch on February 02, 1999. The patient's use of herbal products (October/November 1998) could be a contributing factor in the fetal demise.
- On February 03, 1999, [REDACTED] was treated and released from the [REDACTED].
- A handwritten note on the Surgical Pathology report NO [REDACTED] states "needs quantitative HCG's weekly until '0' " (Exhibit 6, page 09 of 22). The same laboratory report states Beta hCG 823. Dr. [REDACTED] stated that the result of a specimen drawn on February 21 was Beta hCG 51. I did not request a copy of this laboratory report.
- Dr. [REDACTED] noted a telephone conversation with Dr. Calvert of the Food and Drug Administration on March 01, 1999 (Exhibit 6, page 04 of 22).

[REDACTED] was scheduled for a 3:00 PM interview at the [REDACTED]. This time was convenient for Mrs. [REDACTED] due to day care responsibilities for an additional child. She brought her youngest son [REDACTED] (age 2) to the interview. The clinic staff watched [REDACTED] during our interview.

How did you learn about the products?

- [REDACTED] stated that she was looking for a natural product to increase her energy level and that she had felt lacking in energy since the birth of her second child. In July 1998, a food supplement store named [REDACTED] was visited by Mrs. [REDACTED]. "Magic Herb" was one product in the store that the owner stated had worked for her, and that it may work for [REDACTED].
- [REDACTED] stated that "Ginseng" was recommended by a friend and that the owner of the store thought that "Ginseng" could be taken along with "Magic Herb".

[REDACTED] stated that she purchased both products from the [REDACTED] store in [REDACTED]. The store was located in a mini mall area with several other businesses. I observed the [REDACTED] store while waiting for my lunch at the [REDACTED]. The products purchased were as follows:

**Magic Herb Diet Plus Formula with Chromium Picolinate** / two (2) bottles of 90 capsules each. The first bottle was purchased in July 1998 and the second bottle in October or November 1998. Mrs. [REDACTED] does not remember the specific date of each purchase.

Nature's Way, Wild Siberian **Ginseng** Root / one (1) bottle of 100 capsules. Mrs. [REDACTED] was not sure but thought she purchased the "Ginseng" in November 1998. The capsules were taken during the last week of November and the first week of December. [REDACTED] was sure of these weeks because it was the last two weeks that she manufactured Holiday wreaths (**Attachment 5** for manufacturing time period).

[REDACTED] stated that the two products were used according to label directions and at the time of day as follows:

- "Magic Herb" two (2) capsules with breakfast usually one hour after awakening, and one (1) capsule with lunch sometime between noon and 3:00 PM.
- "Ginseng" was usually taken at the same time as the "Magic Herb" and normally 2 capsules twice each day. [REDACTED] stated that on a few days she would take a third dose of "Ginseng", but she could not recall specific dates.

A majority of the "Magic Herb" product was used from October 01, 1998 through December 02 or 04, 1998 on a daily basis. During the stated time period the product was not used or the number of capsules taken were reduced by [REDACTED] but she could not recall specific days (i.e., expected usage 189 -195 capsules and the actual usage 143 capsules). The actual consumption does not account for those capsules taken in July, August and/or September 1998. The label exhibit contains a photocopy of the remaining capsules (**Exhibit 8**, page 08 of 08).

We discussed the use of "Ginseng" since only thirty-one (31) capsules were used. The "Ginseng" label exhibit includes a photocopy of the remaining capsules (**Exhibit 9**, page 06 of 06). I asked Mrs. [REDACTED] to recall how the product was used so that her daily consumption could be accurately assessed. She stated that it was a very busy time of the year, and the determining factor was her energy level or how tired she was on a particular day. [REDACTED] stated that the last week in November and the first week in December 1998 was the time period of taking an occasional third dose of "Ginseng". The third dose was taken due to working lots of long hour days those two weeks (i.e., a long hour day included child care and wreath manufacturing from 10:00 AM to 10:00 PM or 12:00 Midnight).

Were you taking other medications or prescription drugs at the time of the adverse condition?

- Prenatal vitamins from a prescription dated February 13, 1998 were taken one per day starting on December 14.
- Aspirin or Tylenol was taken on some days for backache.

A copy of a 1998/1999 calendar shows the specific time periods that the products were used by Shannon L. Gilbert, but the daily usage was could not be accurately determined (**Attachment 6**).

Did you make any dietary changes during the use of "Magic Herb" and "Ginseng"?

Regular eating habits were maintained without changes.

[REDACTED] had the "Prenatal Vitamin" prescription filled and the prescription was available when I telephoned her at home on April 02. Mrs. [REDACTED] read the label as follows: Prenatal Vitamins, bottle of one-hundred (100) tablets, a substitute for Prenatal 1+1, dated 2-13-98 and to take one (1) per day. [REDACTED] stated that she started taking one vitamin tablet a day on December 14, 1998 and continued until her clinic examination on February 02, 1999.

The Adverse Event Questionnaire is included with this memorandum (**Exhibit 7**)

Expiration dates / Lot numbers were as follows:

- Magic Herb no "open" expiration date, but separate print or hand stamp of a number 070989 immediately to the right of the firm's address (**Exhibit 8**, page 04 of 08).
- Ginseng has a lot number 806455 and "open" expiration date JUNE 2001 on the bottom of the bottle (**Exhibit 9**, page 05 of 06).

The retail price of each product appeared printed on a sticker on the bottle cap as follows:

- Magic Herb - 20.00 (**Exhibit 8**, page 07 of 08).
- Ginseng - \$ 8.34 (**Exhibit 9**, page 05 of 06).

The "Magic Herb" product contains Ginseng. "Magic Herb" contains 100 mg of Siberian Ginseng per capsule (**Exhibit 6**, page 5 of 8). [REDACTED] on a busy day could consume 2, 760 mg of Ginseng using both products (i.e., "Magic Herb" @ three (3) capsules per day or 3 X 100 = 300 mg and "Ginseng" @ six (6) capsules or 6 X 410 = 2460 mg). This level of consumption was possible on some days during the last two weeks of manufacturing wreaths.

**Exhibits:**

1. A copy of the CONSENT FOR RELEASE OF INFORMATION issued by the [REDACTED] to the [REDACTED] for recent treatment of [REDACTED] dated March 16, 1999 and a copy of the FAX TRANSMITTAL SHEET (2-pages).
2. A copy of FDA AUTHORIZATION FOR MEDICAL RECORDS DISCLOSURE - MINNESOTA to the [REDACTED] dated March 19, 1999 and signed by [REDACTED] (1-page).
3. Medical records collected from the hospital Medical Records Department on March 19, 1999 three (3) pages as follows:
  - Operative Report for [REDACTED] dated February 03, 1999 and sign by [REDACTED] (page 1 of 3).
  - Documentation for LIMITED PELVIC ULTRASOUND performed on [REDACTED] February 03, 1999 with Dr. [REDACTED] in attendance (page 2 of 3).
  - Documentation for Surgical Pathology report identified as No. [REDACTED] on [REDACTED] dated February 03, 1999 (page 3 of 3).
4. A copy of the CONSENT FOR RELEASE OF INFORMATION issued by the [REDACTED] for the clinic's records on [REDACTED] dated March 16, 1999 (1-page).
5. A copy of the FDA AUTHORIZATION FOR MEDICAL RECORDS DISCLOSURE - MINNESOTA to the [REDACTED] dated March 19, 1999 and signed by [REDACTED] (1-page).
6. Medical records collected from the [REDACTED] used in the report are as follows:
  - History and Physical record identified by MR NUMBER [REDACTED] / Preop on [REDACTED] prepared by Dr. [REDACTED] MD dated February 02, 1999 (pages 1 and 2 of 22).
  - Operative Report dated February 03, 1999 signed by [REDACTED] stamped as received by the clinic on February 08, 1999 (page 3 of 22).
  - Doctor and Staff notes:
    - Dr. [REDACTED] notes on the call from Dr. Calvert at FDA dated March 01, 1999 (page 4 of 22).
    - Dr. [REDACTED] notes on the OB examination, dated February 02, 1999 (page 5 of 22).
    - Dr. [REDACTED] notes on the initial OB examination, dated January 04, 1999 (page 6 of 22).
    - Nurse Practitioner advised patient that pregnancy test was positive on December 22, 1998 (page 7 of 22).
    - Dr. [REDACTED] notes physical examination and pap smear, dated February 13, 1997 (page 8 of 22).
  - Laboratory Reports:
    - Report dated February 11, 1999 for sample ID [REDACTED] with BETA HCG 823 H mIU/ml (page 9 of 22).
    - Report of Surgical Pathology identified as No. [REDACTED] dated February 03, 1999 on [REDACTED] specimen labeled uterine contents (page 10 of 22).
    - Report of specimen collected on February 02, 1999 indicating WBC-high / Creatinine-low (page 11 of 22).
    - Report pap smear drawn on January 04, 1999 note at additional comments regarding wbc (page 12 of 22).
    - Report specimen collected December 22, 1998 to confirm pregnancy/Urine hCG positive (page 13 of 22).
  - Ultrasound Reports:
    - Results of Radiological Consultation at the clinic on February 02, 1999 (page 14 of 22).
    - Results of Limited Pelvic Ultrasound at the [REDACTED] on February 03, 1999 (page 15 of 22).
  - Pregnancy assessment forms:
    - Dated [REDACTED] first child a boy [REDACTED] 16 of 22)
    - Dated [REDACTED] second child a boy [REDACTED] (page 17 of 22).
    - Dated January 04, 1999 fetal demise (page 18 of 22).
  - A copy of the flowcharts from [REDACTED] clinic file (pages 19, 20, 21 and 22 of 22).
7. Adverse Event Questionnaire (3-pages).

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8. Photocopy of the label on Mrs. [REDACTED] partial bottle of "Magic Herb" retained at the [REDACTED] with a photocopy of the capsules remaining in the bottle and of the top-cap / bottom-rigid white plastic bottle (8-pages).
9. Photocopy of the label on Mrs. [REDACTED] partial bottle of "Ginseng" retained at the [REDACTED] with a photocopy of the capsules remaining in the bottle and of the top-cap / bottom-rigid white plastic bottle 6-pages).

**Attachments:**

1. Assignment Control Form for Assignment Number 91953 dated March 09, 1999 (1-page).
2. medWatch Adverse event report 13345 dated 2-2-99 (1-page).
3. Copy of facsimile TRANSMITTAL from Center for Food Safety and Applied Nutrition to Dirk Mouw, MIN-DO, Consumer Complaint Coordinator dated March 04, 1999 (page 1 of 3). Attached memorandum from Chief, Domestic Programs Branch, HFS-636 to District Director, Director, Investigations Branch, and Complaint Coordinator, MIN, dated March 04, 1999, CFSAN Project # 13345 (page 2 of 3 and page 3 of 3).
4. 1998/1999 calendar noting the medical events that occurred with [REDACTED] pregnancy (1-page).
5. 1998 calendar noting the weeks of manufacturing wreaths for the 1998 Holiday Season (1-page).
6. 1998/1999 calendar noting the time periods of taking "Magic Herb" and Ginseng" and "Prenatal Vitamins" (1-page).

  
Thomas S. Donaldson, CSO  
Minneapolis District Office

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