

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

ARMS#

13187



0 - FRONT

Triage unit sequence #	92318
	13187

### A. Patient information

1 Patient identifier [Redacted]	2 Age at time of event: 56 or _____ Date of birth: [Redacted]	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight 155 lbs or _____ kgs
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### B. Adverse event or product problem

1 <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2 Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other _____

3 Date of event (mo/day/yr) 9/12/98	4 Date of this report (mo/day/yr) 10/30/98
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5 Describe event or problem

Admitted to Hospital  
w Acute Pancreatitis.  
Resolved w Conservative Tx

REC'D.  
NOV 10 1998  
MEDWATCH CTU

6 Relevant tests/laboratory data, including dates

↑ amylase.  
Normal Abd. Ultrasound  
" GGT, Triglycerides.

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

None None

See no usual reason for Pancreatitis, i.e. "idiopathic"

### C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)	
#1 "Metabolite" - contains Chrom.	
#2 Picolate among other things	
2 Dose, frequency & route used	
#1 ?	
#2	
3 Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 Prior to Pancreatitis	
#2	
4 Diagnosis for use (indication)	
#1	
#2	
5 Event abated after use stopped or dose reduced	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6 Lot # (if known)	
#1	
#2	
7 Exp. date (if known)	
#1	
#2	
8 Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9 NDC # (for product problems only)	
#1	
#2	
10 Concomitant medical products and therapy dates (exclude treatment of event)	
Minocin	
Premarin	

### D. Suspect medical device

1 Brand name	
2 Type of device	
3 Manufacturer name & address	
4 Operator of device	
<input type="checkbox"/> health professional	
<input type="checkbox"/> lay user/patient	
<input type="checkbox"/> other _____	
5 Expiration date (mo/day/yr)	
6 model #	
7 If implanted, give date (mo/day/yr)	
8 If explanted, give date (mo/day/yr)	
9 Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	
10 Concomitant medical products and therapy dates (exclude treatment of event)	
000001	

### E. Reporter (see confidentiality section on back)

1 Name, address & phone #			
[Redacted]			
2 Health professional?	3 Occupation	4. Also reported to	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Family Physician	<input type="checkbox"/> manufacturer	
5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>		<input type="checkbox"/> user facility	
		<input type="checkbox"/> distributor	



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

# ADVICE ABOUT VOLUNTARY REPORTING

## Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

## Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

## Report even if:

- you're not certain the product caused the event
- you don't have all the details

## Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

## How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

## Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

## If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

**Confidentiality:** The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS  
Hubert H. Humphrey Building,  
Room 721-B  
200 Independence Avenue, S.W.  
Washington, DC 20201  
ATTN: PRA

and to:  
Office of Management and  
Budget  
Paperwork Reduction Project  
(0910-0230)  
Washington, DC 20503

Please do NOT  
return this form  
to either of these  
addresses.

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

## Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

### Official Business

Penalty for Private Use \$300

**BUSINESS REPLY MAIL**

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

**MEDWATCH**

The FDA Medical Products Reporting Program

Food and Drug Administration

5600 Fishers Lane

Rockville, MD 20852-9787

98 DIC -7 - 010 09

RECEIVED  
CLINICAL RESEARCH  
& REVIEW/OSN HFS-482



NO POSTAGE  
NECESSARY  
IF MAILED  
IN THE  
UNITED STATES  
OR APO/FPO



200002

Adverse Event Questionnaire

Complaint Number: CFSAN PROJECT # 13187

Investigator: THOMAS S. DONALDSON

District MEN-DO Phone # 612 / 334-4100

Consumer Information

Date of Report: 10/30/98 (MEDWATCH)  
MM/DD/YY

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

Name: [REDACTED] Gender: (F) M Age: 56

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

medWatch Report #13187  
Follow-Up Adverse Report #AD  
Thomas S. Donaldson 01-11-99  
Exhibit: 1 page 1 of 3

Information on Adverse Event

Date of Adverse Event: 09-12-98

Previous Adverse Effects to Product Type: Yes (No)

Give the site of consumption/ingestion (e.g. home, restaurant, office): The following information relates to the consumers' use of the product. NORMALLY TAKEN AT HOME, BUT SITE WILL VARY DUE TO TAKING PRODUCT BEFORE MEALS

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): JITTERY, SHAKY/GENERAL NERVOUSNESS, FOLLOWED BY ABDOMINAL PAIN/INGESTION AND NAUSEA. AT 2:30PM SHE WAS EXPERIENCING ABDOMINAL PAIN OF VARYING INTENSITY, AND THE HIGH LEVEL WAS MUCH STRONGER, SHE DECIDED TO GO TO THE HOSPITAL, AND SHE WAS ADMITTED AT 3:30. THE LAST DOSE OF "METABOLIFE 356" WAS TWO TABLETS @ 12:30PM

How long did the symptoms last? FROM ONSET/HOSPITALIZATION/AFTER DISCHARGE  
1 1/2 TO 2 WEEKS 4-DAYS 7-11 DAYS

Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc): USED "METABOLIFE 356" DURING A TWO AND ONE-HALF MONTH PERIOD (JULY, AUGUST AND SEPTEMBER). STARTED JULY 20, 1998 WITH 1/2 TABLET MORNING AND 1/2 TABLETS NOON (2/DAY FOR 1-WEEK), THEN 2 TABLETS BEFORE MORNING AND NOON MEAL (4/DAY FOR 1-WEEK). NONE TAKEN FROM AUGUST 04-16, RESTART AUGUST 16, 1998, 1/2 TABLET MORNING AND 1/2 TABLETS NOON (2/DAY FOR 1-WEEK), 2 TABLETS BEFORE MORNING AND NOON MEAL 4/TAT EVENING (5/DAY FOR 2 WEEKS)

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:  
PREMARIN 1.25 MG ONE TABLET/DAY SINCE 1993  
MINOCYCLINE/MINOCYCLINE 100mg ONE TABLET/DAY SINCE JANUARY 1998 - OTHER ANTIBIOTICS FOR THE SAME TREATMENT SINCE 1992.

Did event abate after use of suspected product stopped or dose reduced: Yes No (Unknown)  
MRS [REDACTED] REPEATED "METABOLIFE 356" DISEASE DURING SEPTEMBER, NOT DUE TO ANY ALLERGY REACTIONS.  
Did symptoms reoccur after reintroduction of suspected product: Yes No (Unknown) (N/A)  
MRS [REDACTED] HAS NOT USED "METABOLIFE 356" SINCE SEPTEMBER 12, 1998  
Did symptoms reoccur after using other products with the same ingredients: Yes No (Unknown) (N/A)

Medical Information

Was a health care provider seen?: (Yes) No

EMERGENCY ROOM

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

DR [REDACTED] MD - EMERGENCY ROOM DR [REDACTED] - MRS [REDACTED] DOCTOR

Occupation of Health Care Provider: (MD) Osteopath Naturopath Nurse Pharmacist

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

What medical tests were performed and what were the results?

AMYLASE 1296 WHEN PATIENT ADMITTED AND 186 DAY OF DISCHARGE

What was the medical diagnosis?

ACUTE PANCREATITIS

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

NPO STATUS, ON IV FLUID AND PAIN MEDICATION

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

DERMATOLOGIST ADULTHOLOGIC WAS TREATING A SKIN CONDITION WITH MINOXIDIL.

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

ACNE/ROSACEA TREATMENT - MINOXIDIL ELIMINATED DURING HOSPITALIZATION TO THE PRESENT.

Product Category

1. Adverse event attributed to: POSSIBLE COMBINED EFFECTS OF ANTIBIOTIC TREATMENTS AND THE USE OF "METABOLIFE 356".  
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): \_\_\_\_\_

medWatch Report #13187  
Follow-Up Adverse Report # [initials]  
Thomas S. Donaldson 01-11-99  
Exhibit: 1 page 2 of 2

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): 'METABOLIFE 356'

LABEL DOES NOT STATE MANUFACTURED OR DISTRIBUTED BY. ADDRESS ON LABEL METABOLIFE INTERNATIONAL, INC., 5070 SANTA FE STREET, SAN DIEGO, CA 920109,

DOSE: SUGGESTED USE: ONE TO TWO CAPLETS TWO TO THREE TIMES PER DAY, OR EVERY FOUR HOURS ON AN EMPTY STOMACH, ONE HOUR BEFORE MEALS. DO NOT EXCEED EIGHT CAPLETS PER DAY. MRS [REDACTED] PURCHASED THE PRODUCT FROM AN INDEPENDENT DISTRIBUTOR: [REDACTED] (PSAN)

ALL PRODUCT INFORMATION OBTAINED FROM THE INTERNET. Complaint # PROJECT #13187 Page 2 of 3

\* METABOLIFE@dayouknife.com

000004

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected): ALL ARE SUSPECT  
VITAMINE, MAGNESIUM, ZINC, CHROMIUM, GUARANA, MA HUANG,  
BEE POLLEN, GINSENG, GINGER, LECITHIN, BOVINE COMPLEX, DAMIANA, SASSAPARILLA,  
GOLDEN SEAL, NETTLES, GOTU KOLA, SPIRULINA ALGAE, ROYAL JELLY

Check here if ingredients are unknown <sup>OTHER INGREDIENTS</sup> METHOCEL, SILICA, CROSCARMELOSE,  
SODIUM, MAGNESIUM STEARATE

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below: DR [REDACTED] STATED IN MED WATCH REPORT, THAT METABOLIFE 356<sup>®</sup> CONTAINS CHROMIUM PICOLINATE AMONG OTHER THINGS.

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

-Monosodium Glutamate

-Sulfite

-Other CHROMIUM AS CHROMIUM PICOLINATE - STATED @ 75 MCG AND 62% DAILY VALUE

-Unknown

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

Product Sample Available: Yes  No  Unknown Mrs [REDACTED] GAVE ME AN EMPTY BOTTLE OF "METABOLIFE 356" ON 12-30-98 AT HER RESIDENCE.

**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) 09-12, 13, 14 & 15, 1998

Required intervention to prevent permanent impairment/damage:  Yes  No

ELEVATED AMYLASE 1296 AND AST 60

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

medWatch Report #13187  
Follow-Up Adverse Report #10  
Thomas S. Donaldson 01-11-99  
Exhibit: 1 page 3 of 3

Complaint # CFSAO PROJECT # B187  
Page 3 of 3

000005



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Reed, 1/21/99  
to DOS P

Memorandum

Date January 11, 1999  
From Thomas S. Donaldson, CSO  
Subject Follow-Up to Adverse Report [redacted]  
To Dorothy L. Olson, ASCSO

I conducted a follow-up on a medWatch adverse report filed by Dr. [redacted] MD on one of his patients. The patient, [redacted] was admitted to [redacted] due to "Acute Pancreatitis".

Mrs. [redacted] was telephoned on December 30, 1998 to establish an interview time and to obtain her approval for release of medical records. The initial interview was conducted over the telephone at the patient's request, but I stated that her signature would be required so that records could be obtained from [redacted]. Later the same morning, I visited the residence of [redacted]. I presented my credentials before continuing our discussion of the adverse condition and hospitalization. Mrs. [redacted] signed the medical records release form. Each question asked of [redacted] and her response are reported as follows:

How long and in what quantities were you taking "Metabolife 356"?

- The "Metabolife 356" purchased was shared with another individual and Mrs. [redacted] used the product during a two and one-half month period starting on July 20, 1998 as follows:
  - One-half tablet before morning meal and one and one-half tablets before noon meal (2/day for 1-week).
  - Two tablets before morning and noon meals (4/day for 1-week).
- On August 04, 1998 Mrs. [redacted] was out of "Metabolife 356" and her second order did not arrive until August 16, 1998. After receiving the second shipment, she decided to reduce the daily amount of "Metabolife 356". [redacted] decision was based on the following:
  - Weight loss was not occurring and the cost was no longer justified.
  - The amount of "Metabolife 356" on hand was low.
  - Remembering the "jittery sensation similar to drinking strong or too much coffee" that she experienced from the initial use of "Metabolife 356". [redacted] started a "weaning away" process.
- [redacted] restarted on August 16, 1998 as follows:
  - One-half tablet before morning meal, one and one-half tablets before noon meal (2/day for one week).
  - Two tablets before morning and noon meals and one tablet before evening meal (5/day for two weeks).
  - One tablet before morning meal and two tablets before noon meal (3/day for 3-days).

Supervisory Review and Follow-Up:

1-19-99 Follow-up investigation for MedWatch Project # 13187 which was made by [redacted]. Records obtained as requested in assignment and are being submitted to HHS-626 for review and evaluation of Metabolife in this case of Pancreatitis

Dorothy L. Olson, ASCSO  
Minneapolis District Office

O: HHS-626 (Dridgette Wallace)  
cc: Min (Dix) (copy of everything)  
1/20/99 cee  
Page 1 of 5

000006

Did you use "Metabolife 356" and if used how much on the day of the adverse condition?

- On September 12, 1998 "Metabolife 356" was taken one before morning meal (8:30) and two before noon meal (12:30).

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

- [REDACTED] was taking two prescription drugs before and on the day of the adverse condition (Premarin and Minocin).  
Premarin (Ayerst) one-1.25 mg tablet/day, since 1993.  
Minocin/minocycline (Barr) one-100mg tablet/day, since January 1998, but has taken two other antibiotics for the same treatment since 1992.
- Minocin/minocycline hydrochloride was prescribed by [REDACTED] dermatologist for treating a skin infection (rosacea). This medication was stopped during her hospitalization and has not been used since her discharge from the hospital to the present time.

How would you describe the onset of symptoms on the day of the adverse condition and on what date were you hospitalized?

- The onset of symptoms occurred after the noon meal on September 12, 1998. The symptoms were described as jittery, shaky, or general nervousness. These conditions were accompanied with abdominal pain/indigestion and nausea. The patient's abdominal pain was described as a "strange sensation/wave" due to a variation in the level of pain. At 2:30 PM, she was still experiencing the same conditions but the abdominal pain was more frequent and of greater intensity with each "strange sensation/wave". [REDACTED] decided to have the problem examined before her condition deteriorated further, and she might be unable to get to the hospital on her own. She was admitted to the [REDACTED] at 3:25 PM on September 12, 1998 (refer to hospital medical records Exhibit 3, page 8 of 48, lists "ADMIT TIME 15:25").

What type of medical treatments or medical drugs did you receive during hospitalization?

- Treatments during the hospitalization were for pain and bloating/gas.

What is your understanding of the basis for your discharge from the hospital?

- [REDACTED] stated that symptoms of nausea and abdominal pain of a less intensity in the upper abdominal region existed at the time of discharge. However, the laboratory test results showed that the elevated enzyme activity associated with "acute Pancreatitis" was now acceptable and she would be discharged.

Medical Records released by [REDACTED] on December 30, 1999. The records describe the treatment and testing results on patient [REDACTED] from September 12, 1998 through September 15, 1999 (Exhibit 3, 48 pages). The [REDACTED] Discharge Summary, Medical Record #: [REDACTED] DC MR #: [REDACTED] shows [REDACTED] Amylase/enzyme level was above 1200 at the time of admitting and was below 200 at the time of discharge (refer to discharge summary Exhibit 3, page 3 of 48).

Did you experience any instances of reoccurring symptoms and/or any reoccurrence of the adverse condition after discharge from the hospital?

- After returning home and for the next twelve days she experienced "withdrawal". [REDACTED] described the "withdrawal" as severe headaches and a sensory problem. The sensory problem affected her sense of smell, and was described as an uncharacteristic strong odor noted on the day of discharge at the hospital and in her home for two more days.
- The adverse condition has not reoccurred, but the blood sample laboratory results on Mrs. [REDACTED] follow-up visit with Dr. [REDACTED] in October indicated a slightly elevated enzyme activity in the liver (AST). The doctor thought that the liver enzyme activity was perhaps a "chain reaction" to the earlier problem in the pancreas.

Did you make any dietary changes during the use of "Metabolife 356"?

- [REDACTED] stated that two days before the adverse condition she had changed source foods as follows:
  1. Consumption of Milk and Cheese changed to Soy Milk and Soy Cheese
  2. Consumption of bread changed from whole grains to sprouted grains "Ezekiel Bread".

These dietary changes were the result of reading a book titled "Diet to Your Blood Type", and she has continued these dietary changes without a reoccurrence of the symptoms of the adverse condition.

How did you learn about the product and where did you purchase the product?

- "Metabolife 356" was a product [redacted] read about on the internet. The web site is operated by an independent distributor of "Metabolife 356" in [redacted] provided the original copies that she printed from the internet site (Exhibit 7, 9-pages). [redacted] purchased the product twice (1-bottle on the initial order and 2-bottles on the second order a total of 270 tablets). The cost per bottle on the second order was \$31.95 plus the shipping charges \$3.49 or a total cost per bottle of \$33.70. The quantity of "Metabolife 356" was shared with another individual and [redacted] used 135 tablets of "Metabolife 356" during the two and one-half months of use.

I initialed and dated each original copy at [redacted] residence, and stated that the originals would be returned after photocopies were made. The original documents were mailed (First Class) on January 04, 1999.

During our interview [redacted] stated that the product was available from a kiosk vendor at the [redacted]. Her response to the question of purchasing from [redacted] instead of locally, she replied that the cost was less in [redacted]. The internet information obtained from [redacted] states in part: " \*\*\* CLICK HERE to order Metabolife TM for \$34.95 + shipping \*\*\* ".

[redacted] had provided a labeled empty bottle of "Metabolife 356" to me on December 30, 1998. I called [redacted] on January 04, 1999 to ask her permission to keep the bottle and the label, because the label needed to be removed from the bottle to obtain accurate photocopies (Exhibit 6, 3-pages). She gave permission for me to keep the empty container and label.

Issues noted after reviewing documents and labeling collected are as follows:

1. Internet literature has a potential disclaimer that states, "Note: These questions and answers were developed solely by an independent Metabolife distributor" (Exhibit 7, page 17 of 18).
2. Ingredient listings differ in minor ingredients on the actual product label collected at patient's residence (Exhibit 6, page 1 of 3), the Internet literature (Exhibit 7, page 11 of 18), and pamphlet from the kiosk at the mall (Exhibit 8, page 1 of 4). The differences were as follows:
  - Bovine complex not listed on the internet literature
  - Lecithin listed tenth of eighteen on the actual label, listed fifteenth of seventeen on the internet literature and tenth of sixteen on the pamphlet from the kiosk.
  - Nettles and Gota or Gotu Kola are listed in the order reported on the actual label and on the internet literature. These two ingredients are not listed on the pamphlet from the kiosk. The same exists for the listings of "Other Ingredients".

The first nine ingredients are the same and are listed in the same order on the label, literature, and pamphlet.

I visited the [redacted] and the kiosk vendor of "Metabolife 356". I did not introduce myself or identify that I'm a Food and Drug Administration, Investigator. The product was price at \$49.95 for one bottle or \$42.95 for two bottles (each bottle contained 90 tablets). The vendor showed a sample of 6-8 tablets, which were oval, center scored, flat edged, brownish/tan in color, approximately 3/4 of an inch in length and 1/4 inch in width.

I asked the vendor for "Metabolife 356" literature, and was informed by the vendor that all the literature was on the kiosk. After briefly reading the pamphlet (Exhibit 8, one page printed on both sides and folded in half, 4-pages), I asked the vendor how to use the product/get started, and what would be the maximum I should take, his responses were as follows:

- In the morning take one tablet and then eat thirty minutes later.
- At noon take perhaps 1/2 a tablet and then eat thirty minutes later.
- Evaluate the effects of this dosage on your activity level and on your appetite.
- If results are not achieved (increased activity and/or reduced appetite) increase the dosage by 1/2 tablet until activity level and appetite effects are acceptable to you.
- Too high a dosage will be noticed initially with jitters or nervousness - similar to the experience of consuming too much coffee.
- He recommended that I do not exceed four tablets per day, and did not recommend taking before the evening meal.

On January 08, 1999, I presented my credentials to [redacted] MD and interviewed Dr. [redacted] regarding the hospitalization and use of "Metabolife 356" by his patient [redacted]. The interview was conducted at the [redacted].

Questions asked and the response by Dr. [REDACTED] are as follows:

How long has Mrs. [REDACTED] or [REDACTED] been a patient of yours?

- After examining the file, [REDACTED] stated that [REDACTED] has been a patient of the clinic since 1958, and that he first saw her as a patient in November 1987.

Did [REDACTED] consult with you prior to using "Metabolife 356"?

- No she did not, but this is not unusual for individuals using dietary products.

During the hospitalization did [REDACTED] mention the prior use of "Metabolife 356"?

- No she did not.

How or by whom were you advised of [REDACTED] use of "Metabolife 356"?

- I was advised of the use later and noted that, with a handwritten note on the patient's discharge report. The discharge report (refer to Exhibit 3, page 3 of 48) shows the date of 10/19 and the statement, "Late-found she was on an "Herbal med.". Dr. [REDACTED] recalls the mention of "Metabolife 356" was voluntary on the part of [REDACTED] and occurred during the scheduled follow-up visit in October.

Have you ever treated Mrs. [REDACTED] for the same type of problem from November 1987 to the recent hospitalization?

- No I have not.

[REDACTED] changed items in her diet just before the illness (i.e., soy milk, soy cheese, and sprouted grain bread). Would these dietary changes impact on the patient's condition at the time of hospitalization?

- No, I do not see the dietary change as causative, but rather coincidental to the hospitalization of [REDACTED]

Did you prescribe any medications to address the "acute Pancreatitis" of [REDACTED]?

- No, medication is needed for this condition.

Liver enzyme (AST) activity was observed on a follow-up visit and did you considered this a "chain reaction" as a result of the previous activity in the pancreas?

- Yes, the liver enzyme was moderately elevated in October but normal in December. The laboratory reported values as follows: October-56 and December-27.

[REDACTED] stated that she did not feel good when discharged, but laboratory results were acceptable and she was released. Was this an accurate description of her condition?

- Yes, I would not expect the patient to be free of pain or discomfort at the time of discharge, and the Amylase enzyme level was reduced from 1296 to 186.

What is a healthy individual's normal range for Amylase?

- The normal level of Amylase is 17 to 130. [REDACTED] level was 186 at the time of discharge, and 61 at the initial follow-up visit in October.

How did you determine the other medications used by [REDACTED] especially the "Minocycline/antibiotic)?"

- Mrs. [REDACTED] is being treated by a dermatologist at the [REDACTED] facility downtown. The patient's records are centrally filed and both doctors have access to her file.

How would you describe [REDACTED] health since the last visit in December, 1998.

- Her health is back to normal.

Dr. [REDACTED] reported the adverse event to medWatch on October 30, 1998. He was concerned about the drug/herbal product interaction that could produce "acute Pancreatitis in his patient. He stated that [REDACTED] had taken the antibiotic for a longer period of time than the "Metabolife 356", and that the "acute Pancreatitis" problem should have occurred earlier if the antibiotic were the causative agent.

After my visit with Dr. [REDACTED] I stopped at the clinic's administrative office and identified myself to Ms. [REDACTED] and requested the medical records on [REDACTED] (January 12, 1996 to the present). The time period was suggested by Dr. [REDACTED] as the earlier records will illustrate the patient's long time use of antibiotics without any adverse reaction.

I scheduled a second visit with [REDACTED] on January 09, 1999, to obtain her signature on the medical records release forms. I requested that Mrs. [REDACTED] sign and date both the [REDACTED] and the FDA form (Rev. 11/85), Authorization for Medical Records Disclosure-Minnesota. I picked up photocopies of these requested medical records on January 15, 1999 (Exhibit 5, 23-pages).

**Exhibits:**

1. Adverse Event Questionnaire 3-pages.
2. Medical records release form for the hospital, [REDACTED] Authorization for Medical Records Disclosure- [REDACTED] dated 12-30-98, (3-pages one a carbon copy and two photocopies of the original). The original was given to the Medical Records Department of [REDACTED]
3. Medical records released by [REDACTED] on [REDACTED] from September 12, 1998 to September 15, 1998.
4. Medical records release forms for the doctor [REDACTED] as follows:
  - Authorization for Medical Records Disclosure-Minnesota (page 1 of 3).
  - A copy of the same (page 2 of 3).
  - A copy of [REDACTED] (page 3 of 3).
5. Medical records released by the [REDACTED] on [REDACTED] from January 12, 1996 to present (23-pages).
6. "Metabolife 356" labeling from empty bottle collected from [REDACTED] residence as follows:
  - Actual label (page 1 of 3).
  - Photocopy with code dating handwritten (page 2 of 3).
  - Photocopy enlargement for ease in reading label information (page 3 of 3).
7. Internet information [REDACTED] used to select and order "Metabolife 356" (9-pages photocopied front and back so the exhibit contains 18-pages).
8. Literature collected at the "Metabolife 356" kiosk at the [REDACTED] (4-pages).

**Attachments:**

1. MedWatch Adverse event report 13187 dated 10/30/98 (2-pages).
  - MedWatch form dated 10/30/98 (page 1 of 2).
  - Notes of Telephone Conversation dated 12/17/98 (page 2 of 2).
2. Copy of memo from Chief, Domestic Programs Branch, HFS-636 to Complaint Coordinator, MIN, dated December 22, 1998, identified with CFSAN Project # 13187 (2-pages).

  
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