

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

ARMS#

13265



0 - FRONT

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER
DET-0789 **13265**

2. DATE OF COMPLAINT (Month/Day/Year)
11/17/98

3. FORM OF COMPLAINT	(1) <input checked="" type="checkbox"/> TELEPHONE (2) <input type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT	4. SOURCE OF COMPLAINT	(1) <input checked="" type="checkbox"/> CONSUMER (2) <input type="checkbox"/> GOVERNMENT (3) <input type="checkbox"/> TRADE SOURCE (4) <input type="checkbox"/> OTHER (Indicate in Remarks)
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5. COMPLAINANT IDENTIFICATION	a. NAME AND ADDRESS (Include ZIP Code) [REDACTED]	b. AREA CODE AND TELEPHONE NUMBER HOME [REDACTED] WORK ()
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6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT/INJURY Complainants wife started taking Metabolife on September 7th, 1998 and was hospitalized on October 7th, 1998 with a mass on her left ovary with another mass starting on her right ovary. Complainant and wife believe Metabolife responsible for tumor on ovary. Wife hospitalized and right oophorectomy performed.
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7. INJURY OR ILLNESS RESULTED	a. BB (HFC-161) NOTIFIED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" complete items a through d)	b. TYPE SYMPTOMS ONSET (HR.) 1. <input checked="" type="checkbox"/> VOMITING _____ 2. <input type="checkbox"/> NAUSEA _____ 3. <input type="checkbox"/> DIARRHEA _____ 4. <input type="checkbox"/> FEVER _____ 5. <input type="checkbox"/> SKIN/EYE IRR. _____ 6. <input type="checkbox"/> HEADACHE _____ 7. <input type="checkbox"/> OTHER _____	c. ATTENDING HEALTH PROFESSIONAL (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" give name, address, and phone number) [REDACTED]	d. HOSPITALIZATION REQUIRED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" give name, address, phone number and dates) Same as [REDACTED] hospitalized 10/19-21/98
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8. PRODUCT AND LABELING	a. BRAND NAME Metabolife	b. PRODUCT NAME Dietary Supplement 356	d. NAME AND LOCATION OF STORE WHERE PURCHASED [REDACTED]
	c. SIZE AND PACKAGE TYPE 90 caplet plastic btll		
	e. PACKAGE CODE/SERIAL NUMBER/ETC. 5682		
	f. DATE PURCHASED 09/07/98	g. PRODUCT USED (If "yes" enter date) (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES	h. AMT REMAINING 40 caplets

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT LOS-DO	c. NAME AND LOCATION OF FIRM (Include ZIP Code) Metabolife International Inc. 5070 Sante Fe Street San Diego, CA 92109 619-490-5222	d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES
	b. C.F. NO.		

10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE: RX (2) DESCRIPTION: TUMOR	c. DISPOSITION (1) <input type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT EI (3) <input type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (Closes File) (5) <input type="checkbox"/> REFERRED TO STATE/LOCAL AGENCY (Closes file) (6) <input type="checkbox"/> REFERRED TO OTHER FDA DISTRICT (7) <input type="checkbox"/> REFERRED TO OCI	11. PRODUCT CODE 58YCY99
	b. EVALUATION (1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input checked="" type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		12. INFORMATION COPIES TO: <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFD-730 <input checked="" type="checkbox"/> HFC-161 <input type="checkbox"/> HFV-236

REMARKS
 Per instruction 1-2 caplets 3x a day. Ingredients: Vitamin E, Magnesium Chelate, Zinc Chelate, Chromium Picolinate, Guarana Concentrate, MA-Hueng concentrate, bee pollen, ginseng root, lechitin, bovine complex, damiana, sarsaparilla, golden seal, nettles, Gotucola, spirulina algae, royal jelly. Other ingred: menthocol silica and corscamellose sodium and magnesium sterate.

Send MedWatch form to complainant - copy of complaint to DEIO & CFSAN.

NAME AND TITLE Linda R. Smith, Paralegal Specialist, DET-DO	DATE 11/17/98
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INDEXED
 DET-DO
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COMPLAINT / INJURY FOLLOW-UP *Progs B265* 1. COMPLAINT NUMBER
DET-0789

2.a. ACTION REQUESTED
 (1) INVESTIGATION
 (2) COLLECT SAMPLE
 (3) INSPECTION
 (4) OTHER:

2.b. REMARKS (Additional details) *F/U to a serious adverse reaction from individual using product containing Ephedra. Obtain labeling; historical medical records from complainant to show any preexisting medical conditions; medical records specifically related to the adverse event; and if possible, an autopsy report including any lab reports*

2.c. REQUESTING OFFICIAL'S NAME AND TITLE **2.d. DATE REQUESTED** **2.e. PRODUCT NAME**
Sally S. Eberhard; Food Team Co-Leader *1/26/99* *METABOLIFE*

3.a. ASSIGNED TO: **3.b. DUE BY:** **4.a. ACTION TAKEN** **4.b. SAMPLE NUMBER(s)**
Renee Rice, Investigator *ASAP* (1) INVESTIGATION
 (2) SAMPLE COLLECTED *48053*
 (3) INSPECTION
 (4) NONE

4.c. DESCRIPTION OF ACTION TAKEN *See continuation sheet for details*

APR 1999
 RECEIVED
 DOMESTIC PROGRAMS
 BRANCH
 CONSUMER COMPLAINT
 COORD.

4.d. ACTION OFFICIAL'S NAME AND TITLE **4.e. ACTION DISTRICT** **4.f. DATE COMPLETED**

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE **6. PROGRAM DATA**

5.a. HOME DIST. <i>New Jersey</i>	5.c. NAME AND ADDRESS (Manufacturer) <i>Garden State Nutritional Nutritionals</i>	6.a. OPERATION <i>13</i>	6.b. PAC <i>21R801</i>	6.c. PRODUCT CODE <i>54YCY99</i>
5.b. CF NO. <i>2244049</i>	<i>100 Lehigh Drive Fairfield, NJ 07004 (973)575-9200</i>	6.d. EMP. HOME DIST. <i>9</i>	6.e. EMP. NO. <i>511</i>	6.f. POS CL. <i>2</i>
				6.g. HOURS <i>68</i>

7. EVALUATION	8. FINAL DISPOSITION	9. INFO.
(0) <input type="checkbox"/> PENDING (1) <input type="checkbox"/> NO ACTION INDICATED (NAI) (2) <input type="checkbox"/> VOLUNTARY ACTION INDICATED (VAI) (3) <input type="checkbox"/> OFFICIAL ACTION INDICATED (OAI) (4) <input type="checkbox"/> NOT AN FDA OBLIGATION (5) <input checked="" type="checkbox"/> REFERRED TO HOME DISTRICT (6) <input type="checkbox"/> INSUFFICIENT INFO. UNABLE TO EVAL. (7) <input type="checkbox"/> REFERRED TO OCI	(1) <input type="checkbox"/> FOLLOW-UP NEXT E1 (2) <input type="checkbox"/> WARNING LETTER (3) <input type="checkbox"/> CITATION (4) <input type="checkbox"/> SEIZURE (5) <input type="checkbox"/> INJUNCTION / PROSECUTION (6) <input type="checkbox"/> REFERRED TO OTHER AGENCY (7) <input type="checkbox"/> RECALL (8) <input type="checkbox"/> NO ACTION (Indicate Agency in Remarks)	COPIES TO: <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFV-236 <input type="checkbox"/> HFZ-343 <input checked="" type="checkbox"/> HFC-161 <input checked="" type="checkbox"/> HFS-636 <input checked="" type="checkbox"/> <i>NWJ-DD</i> <input checked="" type="checkbox"/> <i>LOS-DD</i> <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____

REMARKS *To: NWJ-DD for any required followup at the manufacturer.
 To: HFS-636 (Bridgett Wallace).
 Det-Da plans no further follow-up. 000002*

NAME AND TITLE OF DISPOSITION OFFICIAL **DISPOSITION** **DISPOSITION DATE**
Melvin C. Robinson, SE *Retreat* *April 5, 1999*

Adverse Event Questionnaire

Complaint Number: DET-0789

Investigator: Renee L Rice

Consumer Information	
Date of Report: <u>02-01-99</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: [REDACTED]	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M Age: <u>40</u>
Race: <input checked="" 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>10/19/98 (surgery)</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>After approximately three weeks of taking the product, the consumer noticed a small lump in her abdomen. She felt bloated but was not in pain.</u> How long did the symptoms last? <u>The lump continued to increase in size until it was removed by surgery.</u> Give the circumstances of exposure (i.e. how much was taken, how often was it taken, etc.): <u>The consumer took 49 tablets during an approximate three week period, with an average of 2-3 tablets of product taken per day. The product was taken as directed on the product label. The consumer also ate a lot of fruits while taking the product.</u> List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>None</u></p> <p>Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/>Yes <input type="checkbox"/>No <input checked="" type="checkbox"/>Unknown 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 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 Phone [REDACTED]	
Give health care provider's name, address and telephone number [REDACTED]	
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>Blood work (CBC) = normal, chest X-ray = normal, pap smear = normal, ultrasound = 10x16mm smooth mass arising from left adrenal, pregnancy test = negative</u>	
What was the medical diagnosis? <u>Ovary (left) Benign Cystic Brenner Tumor and Mucinous Cystadenoma</u>	
What treatment(s) was given (e.g., drugs, other)? <u>Exploratory laparotomy Left salpingo-oophorectomy</u>	
Were there any preexisting condition(s)/treatment(s)? <u>None</u> (If YES, list them including allergies, and chronic diseases): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <u>penicillin</u>	

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COMPLAINT/INJURY F/U DET-0789
02/01-02/99 RLR ATTACH. 4a OF 6 11

Product Category

1. Adverse event attributed to:

Medical Food (under medical supervision) Infant Formula

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): N/A

3. Other (specify):

N/A

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):

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

Check here if ingredients are unknown

Vitamin E, Magnesium (as Magnesium Chelate), Zinc (as Zinc Chelate), Chromium (as Chromium Picolinate)

Guarana (naturally-occurring caffeine), Ma Huang (naturally-occurring ephedrines), Bee pollen, Ginseng,

Ginger, Lecithin, Bovine Complex, Damiana, Sarsaparilla, Gold Seal, Nettles, Gata Kola, Spirulina Algae,

Royal jelly, methocel, silica, croscarmellose sodium, magnesium stearate.

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

Aspartame

Monosodium Glutamate

Sulfite

Other _____

Unknown

Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: Yes No

Unknown Product Sample Available: Yes No Unknown

patient Consumer has 40 caplets on hand as of 02/10/99.

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) Emergency Room visit on 10/7/98
Hospitalized on 10/19-10/21/98

Required intervention to prevent permanent impairment/damage: Yes No Exploratory laparotomy and

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

Left salpingo-oophorectomy
on 10/19/98

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date March 6, 1999
From Renee L. Rice, Investigator (Detroit District)
Subject Continuation sheet to a Complaint/Injury Follow-up – DET-0789

This was a complaint/injury follow-up investigation conducted in response to a complaint injury report (DET-0789) which generated a CFSAN Medwatch #13265 assignment, dated 01/20/99. The complainant believed that the consumption of a dietary supplement was responsible for the presence of a tumor on her left ovary. The investigation was performed on 2/1-2/2/99 by Detroit District's Investigator Rice.

Product: Metabolife Dietary Supplement 356

Manufacturer: Garden State Nutritionals
100 Lehigh Drive
Fairfield, NJ 07004
Ph. (973) 575-9200

Distributor: Metabolife International, Inc.
5070 Sante Fe Street
San Diego, CA 92109
Ph. (619) 490-5222

Complainant: Mr. [REDACTED] for Mrs. [REDACTED]
[REDACTED]

Physician: [REDACTED]

SUMMARY OF FINDINGS

A visit was made to [REDACTED] home and the history surrounding the incident was discussed. Mrs. [REDACTED] noticed the presence of a lump in her abdomen about two weeks after ingesting the product. The lump was diagnosed as a tumor on her left ovary. Mrs. [REDACTED] was later hospitalized and the tumor and her left ovary were removed. All pertinent medical history records were obtained. The attending physician was out-of-town for the following months so no interview was conducted. The [REDACTED] also have hired a lawyer to represent them for medical compensation.

Mrs. [REDACTED] had only one bottle of product. Digital photographs and a facsimile of the label were obtained and a sample (#48053) was collected from the consumer. This label had a product code number but did not contain a lot number or expiration date. According to the distributor, the firm has never

approved anyone to sell their product at the specific location at which the consumer purchased the product.

INTERVIEW WITH COMPLAINANT

During the visit on 02/01/99, the consumer (Mrs. [REDACTED]) stated that she purchased the Metabolife Dietary Supplement 356 to lose weight. She bought the product at a nearby shopping mall [REDACTED] on 9/7/98. At that time, Mrs. [REDACTED] stated she was feeling well. She further stated that she does not have a physician that she sees regularly. Mrs. [REDACTED] stated that she did visit Dr. [REDACTED] a few years ago for a routine check-up but believes that the physician has retired or is not practicing since his office had been recently vacated (i.e., located somewhere between [REDACTED] and [REDACTED]). The consumer could not remember the physician's first name and phone number. No previous medical history records were obtained since the physician (mentioned above) could not be located.

On 9/7/98, Mrs. [REDACTED] stated that she began taking the product. She initially began consuming a half of a caplet for the first couple of days and then increased her dosage to 2-3 caplets/day for approximately three weeks. Mrs. [REDACTED] stated she had ingested a total of 49 caplets during this period and also gave one caplet to her husband [REDACTED]. While taking the product, both Mr. and Mrs. [REDACTED] stated that they felt very hyperactive.

After approximately two weeks of taking the product, the consumer noticed a small lump in her abdomen, which was about the size of a tennis ball. Around the third week, the lump had reached a size of a large cantaloupe and the consumer felt she looked as if she were 1-2 months pregnant. At this time, Mrs. [REDACTED] stated she stopped taking the product.

On 10/7/98, the consumer felt the lump was continuing to grow in size. She initially went to the [REDACTED] at the [REDACTED] and a core assessment was performed (Exh. A-1/3). A urine analysis was conducted and indicated that Mrs. [REDACTED] was not pregnant (Exh. A-4/6). The consumer was then referred to go to [REDACTED] for her medical condition (Exh. A-7). On the same day, Mrs. [REDACTED] went to [REDACTED] and the report indicates the consumer's condition and medical history (Exh. B -1/3).

The consumer was in the ER between 1:18 p.m. -7:00 p.m.

Chief Complaint:	Abdominal bloating
Initial Assessment:	An enlarged pelvic abdominal mass
Past history:	Cervical conization
Allergies:	Penicillin
Present Medication:	None
Ultrasound:	10 x 16 cm smooth mass arising from left adnexal
Pregnancy Test:	Negative
Progress Note:	Schedule follow-up visit with Dr. [REDACTED]

On 10/9/98, the consumer visited Dr. [REDACTED] at the [REDACTED] which is part of [REDACTED]. During this visit, a Pap smear was performed on Mrs. [REDACTED] and found to be satisfactory (Exh. C-1), as well as a core assessment (Exh. C-2/6). Mrs. [REDACTED] stated she was given her options by Dr. [REDACTED] which

included: removal of pelvic mass (adnexal-left), exploratory laparotomy, oophorectomy, possible hysterectomy, possible cancer staging, possible removal of ovaries and tubes. Mrs. [REDACTED] stated that she signed consent forms for the operation, anesthetics, and related procedures. Her surgery was then scheduled for 10/19/98.

On 10/14/98, the consumer visited Dr. [REDACTED] at the [REDACTED] for a complete blood count (CBC) and chest x-ray and these tests were noted to be normal (Exh. D-1/2).

The consumer was admitted at [REDACTED] for her surgery. Mrs. [REDACTED] stated that she was never hospitalized before except for the birth of her two children. The reports indicate Mrs. [REDACTED] condition and procedures performed while she was hospitalized (Exh.E-1/22).

The consumer was hospitalized at [REDACTED] from 10/19/98 (9:06 a.m.) through 10/21/98 (9:40 a.m.).

Pre-Operative Diagnosis:	Left adnexal mass measuring 16 x 9 x 9 cm Mucinous cystadenoma based on frozen section.
Post-Operative Diagnosis:	Left adnexal mass measuring 16 x 9 x 9 cm Mucinous cystadenoma based on frozen section.
Operation:	Exploratory laparotomy Left salpingo-oophorectomy
Anesthesia:	Epidural
Operative Findings:	Approximate 20 cm x 9 cm left ovarian mass Ruptured cyst (0.5-1mm) on right ovary Liver, diaphragm, pelvis, and appendix were noted to be within normal limits.
Pathology of left adnexal mass:	Benign cystic Brenner tumor and mucinous cystadenoma (left ovary)
Cytology of fluid (blood):	Negative for malignant cells
Surgeons:	[REDACTED] M.D. and [REDACTED] M.D.

On 10/22/98, Mr. [REDACTED] stated that he called Dr. [REDACTED] office ([REDACTED]) and requested medication for his wife's nausea and support was provided (Exh. F).

On 10/23/98, the consumer had her staples removed by Dr. [REDACTED] at the [REDACTED]. Medical reports indicate that patient was doing well and pain was controlled (Exh. G).

On 11/2/98, Mrs. [REDACTED] stated that she called Dr. [REDACTED] office ([REDACTED]) and requested medication for her pain and coughing. Medical records indicate she was given a prescription for pain medication (Motrin) and instructed to take cough syrup for her cough (Exh. H).

On 11/13/98, the consumer visited her husband's doctor, Dr. [REDACTED] to treat her for the cold she had developed. Mrs. [REDACTED] stated that this doctor gave her sinus and pain management medication. Mrs. [REDACTED] stated that the medication alleviated most of her cold symptoms within a few days.

On 11/20/98, the consumer had her follow-up visit at the [REDACTED] Mrs. [REDACTED] stated that her most of her cold had went away by this time but was still taking cough syrup for

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her coughing. The medical records from Dr. [REDACTED] indicate that Mrs. [REDACTED] wound-scar was healing well and another follow-up visit was recommended for one year later (Exh. I).

On 03/05/99, another visit was made to the [REDACTED] home. Digital photographs were taken of the label since the previous photographs taken on 02/01/99 were out of focus and unreadable. A sample (# 48053) of the product, which consisted of 25 caplets, was collected and a receipt was given to the consumer. Mrs. [REDACTED] has 15 caplets remaining in her possession. Mrs. [REDACTED] gave me copies of her medical records pertaining to this event and signed an affidavit in my presence.

CONSUMER COMPLAINT TO METABOLIFE

Mr. [REDACTED] stated that he contacted Metabolife International, Inc. and informed the firm of his wife's reaction to product. On 12/31/98, Mr. [REDACTED] (husband) stated that he received a call from a person named Dr. [REDACTED] from Metabolife International, Inc. Mr. [REDACTED] stated that Dr. [REDACTED] wanted them to sign release papers and made offers to pay some of their medical expenses. Mr. [REDACTED] stated that he refused Dr. [REDACTED] offer and directed this matter to his attorney. Mr. [REDACTED] stated that Metabolife International, Inc. sent him the papers in the mail a few days later, in which he in turn gave them to his lawyer.

PHYSICIAN RECORDS

On 02/02/99, Mrs. [REDACTED] medical history records were obtained from Dr. [REDACTED] office [REDACTED] and the [REDACTED]. On the same day, an attempt was made to talk Dr. [REDACTED] Ms. [REDACTED] (Manager of [REDACTED] stated that Dr. [REDACTED] was currently in [REDACTED]

DISCUSSION WITH THE MANUFACTURER

On 2/16/99, a phone conversation was held with Mr. [REDACTED] to discuss the "5682" number that appeared on the lower right hand corner of the consumer's label (Attach. 5). Mr. [REDACTED] is an [REDACTED] for Metabolife International Inc.'s corporate office (San Diego, CA; Ph. 619 490-5222 x731). Mr. [REDACTED] stated this number (i.e., 5682) relates to the firm's product code number used for manufacturing. The manufacturer usually uses either a 3 or 4-digit number to identify what type of product was manufactured for each of its customers. Mr. [REDACTED] stated that this product was most likely manufactured by Garden State Nutritionals (Fairfield, NJ) (Attach. 6a).

Mr. [REDACTED] stated that the firm's lot number is located on the lower left side of the label within the red border/band and consists of black lettering (Attach. 6b/c). The firm uses the one of the following two lot numbering systems as shown below (Attach. 6d):

- 1) @### MM/YY (e.g., L808 12/01)
- 2) ##### @## MM/YY (e.g., 811411A12 11/00)

Where @ = letter
= number
M = month
Y = year

The consumer's product label did not contain either of the lot numbering systems mentioned above (Attach. 5). Mr. [REDACTED] also stated that his firm has never approved a bona fide distributor to sell their product at [REDACTED] although the firm is currently in the process of selecting a distributor for this location.

PRODUCT LABELING

The consumer purchased only one bottle of product. Pictures were taken of the label but the photographs were not used since they were out of focus and were unreadable. The product itself consists of an oblong, uncoated, brown and white speckled caplet that was scored with a line through the center on one side.

The product was contained in a white plastic bottle (approximately 10.5-cm in height x 5 cm in width) with white plastic screw on cap. The consumer stated the bottle was sealed at the time of purchase and there was no evidence of tampering. The bottle had a yellow self-adhesive label with a red line bordering the top and bottom part of the label. All print on label was in black ink except for the word Metabolife (i.e., "Metabo" in red ink and "life" in dark yellow). See Attachment 5 for a facsimile of the labeling.

Attachments

- 1 a/e Follow-up to Adverse Event Report, Project #13265
- 2 Complaint Injury Report, Complaint No. DET-0789, dated 11/17/98
- 3 Authorization for Medical Records Disclosure signed by Complainant dated 02-01-99
- 4 a/b Adverse Event Questionnaire
- 5 a Facsimile of the label on the product which was purchased by the consumer
- b/e Digital photographs of the label on the product which was purchased by the consumer
- 6 a E-mail message from [REDACTED] of Metabolife International, Inc., dated 2/16/99
- b/c Facsimile transmittal sheet from [REDACTED] of Metabolife International, Inc., dated 2/17/99
- d E-mail message from [REDACTED] of Metabolife International, Inc., dated 2/17/99
- e/g An example of product labeling received from [REDACTED] of Metabolife International, Inc.
- 7 a E-mail message from Ronald Roy of CFSAN, dated 02/26/99
- b E-mail message from Ronald Roy of CFSAN, dated 03/01/99
- 8 FDA 484 - Receipt for sample, dated 03/05/99
- 9 FDA 463a - Affidavit signed by Mrs. [REDACTED] dated 03/05/99
- 10 Copy of C/R # 48053 (in progress, pending decision of which lab will perform analysis)
- 11 Floppy disk containing digital photographs obtained on 03/05/99

Exhibits

- A-1/7 Report of the emergency visit made at the [REDACTED] on 10/7/98
- B-1/3 Report of the emergency visit made at [REDACTED] on 10/7/98
- C-1/5 Medical reports obtained from the [REDACTED] of visit on 10/09/98
- 6 Cytology report of cervical (Pap) smear
- D-1 Clinical laboratory report of blood work taken during visit of 10/14/98
- 2 Operative report indicating chest x-ray results
- E Medical records obtained from [REDACTED] for the complainant's hospitalization inpatient stay from 10/19-21/98
- 1/4 Admission and discharge orders
- 5/12 Interdisciplinary progress notes and post anesthetic notes
- 13/17 Laboratory analysis report

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- 18/19 Operative report
- 20 Clinical laboratory report of the surgical pathology results for the complainant's left adnexal mass
- 21 Clinical laboratory report of the non-gyn cytology for the complainant's body fluid
- 22 Inpatient's clinical summary
- F Phone record from obtained from the [REDACTED] dated 10/22/98
- G Medical records obtained from the [REDACTED] of visit on 10/23/98
- H Phone record from obtained from the [REDACTED] dated 11/2/98
- I Medical records obtained from the [REDACTED] of visit on 11/20/98

Renee L. Rice

Renee L. Rice, Ph.D.
Investigator

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