

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

ARMS#

12669



0 - FRONT

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER
DAL 89001
2. DATE OF COMPLAINT (MONTH/YEAR)
07-16-97

12669

3. FORM OF COMPLAINT (1) <input type="checkbox"/> TELEPHONE (2) <input type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT	4. SOURCE OF COMPLAINT (1) <input type="checkbox"/> RETAILER (2) <input type="checkbox"/> TRADE SOURCE (3) <input type="checkbox"/> GOVERNMENT (4) <input type="checkbox"/> OTHER <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 (Indicate in Remarks)	5. NAME AND ADDRESS (Include Zip Code)		6. ARPA COMP AND TELEPHONE NUMBER	
		[REDACTED]		HOME [REDACTED] WORK [REDACTED]	

6. COMPLAINT OR INJURY	7. DESCRIPTION OF COMPLAINT/INJURY		8. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (Explain in Remarks)
	Complainant's daughter had gone to clinic and was given capsules which he feels contained ephedra. She experience heart palpitations, nervousness and somnia. She signed up with the [REDACTED] She ate food specified by program and took pills which contained ephedra. Two capsules were taken 3 times a day. SEE ATTACH BANYAN FOR DETAILS.		

7. INJURY OR ILLNESS RESULTED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" complete items a through d)	8. IIB (IFC-161) NOTIFIED (1) NO (2) <input checked="" type="checkbox"/> YES DATE:	9. TYPE SYMPTOMS 1. <input type="checkbox"/> VOMITING - 2. <input type="checkbox"/> NAUSEA - 3. <input type="checkbox"/> DIARRHEA - 4. <input type="checkbox"/> FEVER - 5. <input type="checkbox"/> SKIN/WRITER - 6. <input type="checkbox"/> HEADACHE - 7. <input checked="" type="checkbox"/> OTHER -	10. ONSET (HR)	11. ATTENDING HEALTH PROFESSIONAL (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes" give name and address, and phone number)	12. HOSPITALIZATION REQUIRED (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes" give name and address, and phone number)
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8. PRODUCT AND LABELING	a. BRAND NAME QUICK WEIGHT LOSS	b. PRODUCT NAME DIETARY SUPPLEMENT
	c. SIZE AND PACKAGE TYPE	d. NAME AND LOCATION OF STORE WHERE PURCHASED
e. PACKAGE CODE/SERIAL NUMBER/ETC.		[REDACTED]
EXP/USE BY DATE: n/s		f. AMT REMAINING n/s

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT DALLAS	c. NAME AND LOCATION OF FIRM (Include Zip Code)	d. IMPORT PRODUCT (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES
	b. C.F. NO. NOCFN		

10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE RX	(2) DESCRIPTION REACTION	c. DISPOSITION (1) <input checked="" type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT RI (3) <input type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (Close File) (5) <input type="checkbox"/> REFERRED TO STATE/LOCAL AGENCY (Close File) (6) <input type="checkbox"/> REFERRED TO OTHER FDA DISTRICT	11. PRODUCT CODE 54----
	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"/> HFD-100 <input type="checkbox"/> HFD-343 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFD-161 <input type="checkbox"/> HFD-236 <input type="checkbox"/>

REMARKS

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DEC 1 1997

NAME AND TITLE: **RONDA LOYD, CCC**

10-08-97

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CLINICAL RESEARCH & REVIEW/OSN IFS-452

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COMPLAINT / INJURY FOLLOW-UP			1. COMPLAINT NUMBER DAL 89001		
2.a. ACTION REQUESTED (1) <input checked="" type="checkbox"/> INVESTIGATION (2) <input type="checkbox"/> COLLECT SAMPLE (3) <input type="checkbox"/> INSPECTION (4) <input type="checkbox"/> OTHER:		2.b. REMARKS (Additional details) Conduct appropriate assignment group 3 Type/Reason Cons. Compl. Comp. By 11-20-97			
2.c. REQUESTING OFFICIAL'S NAME AND TITLE DAVE AKEN, Supervisor, CSO		2.d. DATE REQUESTED 10-9-97 Initials: [redacted] 10/20/97 Product Name Dietary Supplement			
3.a. ASSIGNED TO: Austin - RP Team 3		3.b. DUE BY: ASAP	4.a. ACTION TAKEN (1) <input type="checkbox"/> INVESTIGATION (2) <input checked="" type="checkbox"/> SAMPLE COLLECTED (3) <input type="checkbox"/> INSPECTION (4) <input type="checkbox"/> NONE	4.b. SAMPLE NUMBER(s) 98-755-227	
4.c. DESCRIPTION OF ACTION TAKEN an interview was conducted on 10/29/97 with the daughter. A statement was taken and a sample of the dietary supplement was collected. See attached memo.					
4.d. ACTION OFFICIAL'S NAME AND TITLE Iris MacInnes, Investigator			4.e. ACTION DISTRICT Dal-Do	4.f. DATE COMPLETED 11/7/97	
5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE		6. PROGRAM DATA			
5.a. HOME DIST. FIA-DO	5.b. NAME AND ADDRESS SLIM FOR LIFE, Inc. 4350 W. Sunrise Blvd., #22 Plantation, FL 33313	6.a. OPERATION 13	6.b. PAC 21R801	6.c. PRODUCT CODE 54PHG09	
5.b. CF NO.	6.d. EMP. HOME DIST. 7	6.e. EMP. NO. 140	6.f. POS CL. 2	6.g. HOURS 24	
7. EVALUATION (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 type="checkbox"/> REFERRED TO HOME DISTRICT (6) <input type="checkbox"/> INSUFFICIENT INFO. UNABLE TO EVAL. (7) <input type="checkbox"/> REFERRED TO OCI		8. FINAL DISPOSITION (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 (Indicate Agency in Remarks)		7. <input type="checkbox"/> RECALL (8) <input type="checkbox"/> NO ACTION	
9. INFO. COPIES TO: <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFV-238 <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFC-161 <input type="checkbox"/> HFS-636 <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____					
REMARKS					
NAME AND TITLE OF DISPOSITION OFFICIAL		DISPOSITION	DISPOSITION DATE		

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 & REVIEW/OSN HFS-452
 '97 DEC -5 A8:41

Adverse Reaction Questionnaire

Complaint Number: DAL 89001

Investigator: Iris MacInnes

Consumer Information	
Date of Report: <u>7/16/97</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 type="checkbox"/> F <input type="checkbox"/> M Age: 21
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"/> 6-Other <input type="checkbox"/> 9-Unknown	
Information on Adverse Reaction	
Date of Adverse Reaction: <u>11/22-12/12/96</u> Previous Reaction to Product Type: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Give the site of consumption/ingestion (e.g. home, restaurant, office): Home
The following information relates to the consumer's use of the product.	
Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): First symptom occurred first week 11/22/96 with more energy. By second week symptoms included heart palpitations, shaking, insomnia, difficulty breathing, hot flashes, sweating, and increased heart rate.	
How long did the symptoms last? After intake of product was discontinued.	
Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.): Product was taken orally, three times a day. First week dosage was 1 cap. three times a day. Second week dosage was 2 caps. three times a day. Then decreased dosage (on her own) to 1 cap. three times a day. Continued this dosage until 12/12/96, when dosage was discontinued.	
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: No medications other than Tylenol, the dietary supplement, a multivitamin. Complainant was on a diet program that consisted of various food supplements, i.e., protein drinks soups, complainant is vegetarian. Copy of food diary attached.	
Did event abate after use of suspected product stopped or dose reduced: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input 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 type="checkbox"/> Not Applicable	
Medical Information	
Was a health care provider seen? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Give health care provider's name, address and telephone number:	
Occupation of Health Care Provider: <input type="checkbox"/> MD <input type="checkbox"/> Chiroprath <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?	
What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)?	
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Product Category

1. Adverse reaction to:

Medical Food (under medical supervision) Infant Formula

Dietary Supplement (e vitamins; an essential mineral; a protein; a herb or similar natural substance including botanicals such as ginseng and yohimbin; animal cells; 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 hydroflavonols, cyanoglucosides, glycosides, saponins, and other substances of these ingredients.)

Other (traditional food) _____

Other Product Problems

2. Foreign Object (specify): _____

3. Other (specify): _____

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label): Herbal Balance. Herbal approach to weight loss.

Days 1-2: 1 cap. 1 hour before lunch. 1 cap. Days 3-4: 1 cap. 1 hour before lunch, 1 cap. 1 hour before dinner. Days 5-6: 1 caps. 1 hour before lunch. 1 cap. 1 hour before dinner. If optimum level not reached add second cap. to dose before dinner after Day 6. Do not exceed four (4) capsules per day.

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

Check here if ingredients are unknown

Each capsule contains 480 mg of proprietary blend of: Ephedra sinica (Ma Huang, stem extract 1:4), Llex paraguariensis (Mate leaf), Arctostaphylos uva-ursi (Bearberry; Uva ursi, leaves), astragalus membranaceus (Bai chi, root), Polygonum multiflorum (fo ti, root), Valeriana officinalis (Valerian, root), B-carotene, Crataegus oxyacanthoides (Hawthorne berry), Lawsonia inermis (Henna, leaf), Rhamnus purshiana (Cascara sagrada, bark), Glycyrrhiza glabra (Licorice, root)

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

- Aspartame
- Monosodium Glutamate
- Sulfite
- Other, Ephedra (Ma Huang, stem)
- 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

Outcome Attributed to Adverse Events
(if yes, include pertinent medical records)

Death: Yes No

Life-Threatening: Yes No

Hospitalization: Yes No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: Yes No

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

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CLINICAL RECORDS & REVIEW

To: Konda Loyd@DALDO.IB@FDAORASWR
Cc: Dave Akon@DALDO.IB@FDAORASWR
Bcc:
From: Robert Deininger@DALDO.IB@FDAORASWR
Subject: Fwd: Diet. Suplmt Complaint
Date: Thursday, October 2, 1997 18:48:45 CDT
Attach: [REDACTED]
Certify: N
Priority: Normal
Defer until:
Expires:
Forwarded by:

Comments:
Complete Consumer Complaint form for this and recommend action per outstanding instructions for ephedra products. Send through the DIB office for assignment. Thanks.

----- Original Message -----
To: Robert Deininger@DALDO.IB@FDAORASWR
From: Elaine Crosby@DALDO.Comp@FDAORASWR
Date: Thursday, October 2, 1997 at 1:05:14 pm CDT
Attached: [REDACTED]

Bob, compliance received a call from [REDACTED] Director for [REDACTED] [REDACTED] Mr. [REDACTED] had apparently been referred to [REDACTED] and [REDACTED] asked me to oversee that a follow-up call occurred.

I believe the complaint should be followed up by the Austin RP collecting medical releases, samples, copies of records and any supplemental information (see below). We might even want to discuss the matter with [REDACTED] to determine if they are interested in performing a joint RI of the clinic in [REDACTED]. I know [REDACTED] worked with [REDACTED] on the Formula One death a couple years ago. Mr. [REDACTED] is apparently this matter and has access to resources to achieve that end. Therefore, I tried to obtain considerable background information to expediate the implementation of a comprehensive investigation. A consumer complaint form can be filled out extracting the pertinent information from the attached memo. We should also alert DEIO and the home district (as soon as we find out where Slim For Life is located) regarding additional adverse reactions.

I spoke with Mr. [REDACTED] on 9/29. He informed me that he wanted to file a complaint against [REDACTED] in [REDACTED]. He said his 20 yr. old daughter, [REDACTED] had gone there to lose some weight and paid \$1400 in advance for their program. The program included the intake of capsules which turned out to contain ephedra. His daughter experienced heart palpitations, nervousness, and insomnia and returned to relay her reactions with the clinic but was told these symptoms received some counseling from an aunt who distributes vitamins. The aunt inquired as to the ingredients and informed the daughter that ephedra was essentially equivalent to amphetamines and suggested she discontinue their useage. He said he took the clinic to small claims court and was successful in being reimbursed. He stated the clinic conceded in court that the product contains ephedra. His concern is that the clinic promoted the use of the product as being safe and effective for weight loss when in fact it can be dangerous. He indicated that at his daughter is a student at [REDACTED] and is willing to provide any information ne

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cessary. She does not have classes on Mon., Wed. or Fri. and her phone # [REDACTED]

On 10/1/97 I placed a call to [REDACTED] to obtain some additional info. [REDACTED] explained that she signed up for the program last Oct/Nov.; that the program consists of identified foods which can be consumed at specified quantities along with a remembers the capsules as being labeled as containing ephedra but does not remember if they are labeled for weight loss or any other useage. According to the program, two capsules were to be consumed 3 times a day. [REDACTED] said she initially followed the program but began experiencing insomnia. She tried to take the last two capsules before dinner hoping this would alleviate the insomnia but it continue as did the heart palpitations. After two weeks, she returned to the clinic to relay her adverse reactions but was told these were not side effects and that she should continue the program. In spite, of their suggestion to increase the dosage she decided to cut the daily consumption to 1 capsules 3 times a day. When the reactions continued she spoke with Dr. [REDACTED] at the [REDACTED]. He advised against continued useage especially if there was a family history of heart problems.

[REDACTED] indicated that they inquired during the screening process if SHE had heart untaried the family history information anyway. She was told that it only was pertinent if SHE had heart problems. She stated they noted her side effects in her chart and she will try to get the clinic to provide her with a copy. She has 4/6 bottles of the vitamins and Slim For Life at home in [REDACTED] and will bring them back when she goes home the weekend of 10/11. [REDACTED] stated that she did not visit either a physician or hospital when she experienced the side effects. She is willing to sign a medical release and to provide us with samples. She also knows of others who are experiencing health problems as a result of having been through the program. She indicated that the clinic guarantees safe weight loss and that was not only an economic deception it was potentially harmful as she had serious side effects without any pre-existing conditions.

Additional specifics:

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MEMORANDUM

Date: November 7, 1997

To: CFSAN, Adverse Reaction Monitor

From: Iris C. MacInnes, CSO

Subject: Complaint DAL-89001 Follow up

4.c. DESCRIPTION OF ACTION TAKEN:

A telephone call was made to the complainant's daughter, Ms. [REDACTED], who resides at

[REDACTED]

I set a time to meet with Ms. [REDACTED] on Wednesday, October 29, 1997 @ 2:00 p.m. Upon arrival to Ms. [REDACTED] residence I showed her my credentials. I asked Ms. [REDACTED] to explain the circumstances that lead her to start using the dietary supplements. A statement was taken of Ms. [REDACTED] account of the events leading to the complaint on the dietary supplement called "Herbal Balance" distributed by

Slim For Life, Inc.
4350 W. Sunrise Boulevard
Suite 122
Plantation, FL 33313

Ms. [REDACTED] stated that she could not remember specific dates but all the information was included in her court documents. I asked her about the court documents. Ms. [REDACTED] stated that she took the [REDACTED] to Small Claims court for deceptive practices, under the [REDACTED]. She settled with the firm on 9/19/97 for an undisclosed amount. She stated that she would have her court documents sent to me by mail for my information.

The affidavit was signed on 10/31/97. To summarize, Ms. [REDACTED] joined a diet program at the firm below, after she saw a friend, who had lost a lot of weight, in a commercial for the firm.

[REDACTED]

She began taking the dietary supplements which were described by a technician at

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the [REDACTED] as a natural way to increase her metabolism and help her to lose weight. The first week she took 1 capsule, three times a day for one week. The second week, she was instructed to increase her dosage to 2 capsules, three times a day.

During the second week on the program, she began having the following side-effects, insomnia, heart palpitations, difficulty breathing, hot flashes, sweating and increased heart rate. She told a technician, during one of her visits to the [REDACTED] that she was having these side effects. The technician told her that she must be under a lot of stress. The technician told her that the dietary supplements were natural and safe. The technician then told her that she should increase her dosage to three capsules, three times a day to acclimate her body to the dietary supplement faster. Ms. [REDACTED] did not believe that increasing the dosage would make her feel better. She stated that she decreased her dosage back to one capsule, three times a day.

She continued having the side-effects, but believed the technician when she was told that the dietary supplements were safe. She then spoke to a relative who sold vitamins and was told that if the product had Ephedra (Ma Huang) to stop taking the dietary supplement. She discontinued taking the supplement on 12/12/98.

I asked Ms. [REDACTED] if she sought medical attention when she began having the side-effects. She stated that she did not. She did state that records maintained by the [REDACTED] would include information about her health during the time she was on the program. She then provided a medical release for her records. Attached are the medical releases (3).

Currently, Ms. [REDACTED] is not suffering from any side-effects, however she does not know the long-term side-effects. She recalled her friend who had been a spokesperson for the [REDACTED]. His name is Mr. [REDACTED]. Ms. [REDACTED] stated that she saw Mr. [REDACTED] right before she joined the [REDACTED]. At that time he had gained some of the weight back. He told her that he had gained weight and was having a difficult time losing it again. She stated that he did not believe the diet program caused his problems and continued to promote the program as a success.

Ms. [REDACTED] stated that Mr. [REDACTED] had complained that his metabolism was not the same. She believes that the dietary supplements may have affected her friend's metabolism. I asked if she knew his number or his address. She stated that she does not know how to get in touch with him.

Ms. [REDACTED] stated that she hopes the FDA takes some action against the [REDACTED]. She believes that they are giving people a drug and are not informing people of the side-effects and potential problems that can occur from taking the drug.

Ms. [REDACTED] provided copies of her food diary and stated that she would have her mother send her a copy of her court documents by mail.

I thanked Ms. [REDACTED] for her time. I told her that once the copies of her court documents were received I would set up a time to meet with her to obtain a second affidavit on the receipt of the documents. To date I have not received the court documents.

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A sample of the dietary supplement was collected under Sample #98-755-227. The product collected was a dietary supplement containing Ephedra (Ma Huang) labeled in part:***The Herbal Approach To Weight Loss***Herbal Balance***Sold Exclusively by Authorized Distributors***180 Capsules***INGREDIENTS:***Ephedra sinica (Ma Huang, stem,)**LOT#***139601C***EXP.***5 98***DISTRIBUTED BY: SLIM FOR LIFE, INC., PLANTATION, FL 33313***".

Sample was sent to the Denver Lab per the 3/13/98 memo entitled, "Follow-up Investigations and Sample Collection - Dietary Supplements" (attached).

Enclosed is a copy of the Adverse Reaction Information (IOM 910-D), a good quality copy of the product label, a copy of the affidavit signed by Ms. [REDACTED] on 10/31/97, a copy of her food diary, and (3) medical releases.

Iris C. MacInnes
Iris C. MacInnes, Investigator
[REDACTED]

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