

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

ARMS#

12536



0 - FRONT

1. COMPLAINT NUMBER
PHI-7-0820 12536
2. DATE OF COMPLAINT (Month / Day / Year)
9/11/97

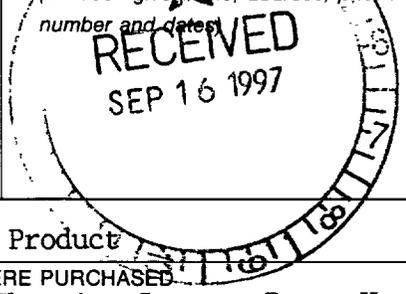
COMPLAINT / INJURY REPORT

3. FORM OF COMPLAINT	a.	4. SOURCE OF COMPLAINT	a.
	(1) <input checked="" type="checkbox"/> TELEPHONE (2) <input type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT		(1) <input checked="" type="checkbox"/> CONSUMER (3) <input type="checkbox"/> TRADE SOURCE (2) <input type="checkbox"/> GOVERNMENT (4) <input type="checkbox"/> OTHER <input type="checkbox"/> L <input type="checkbox"/> S <input type="checkbox"/> F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION	a. NAME AND ADDRESS (Include ZIP Code)	b. AREA CODE AND TELEPHONE NUMBER
	[REDACTED]	HOME ([REDACTED]) WORK ([REDACTED])

6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT / INJURY	b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
	Complainant took diet product for around 10 days and while taking it, she had several symptoms, including headaches, nausea, a urinary tract infection, fever, sweats and low energy. She didn't think about the diet product being the cause until her friend, who was also taking it, said she'd been light headed since she started taking it; and she only took it for a few days and then discontinued. Please see REmarks.	(1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED	a. EIB (HFC - 161) NOTIFIED	b. TYPE SYMPTOMS	ONSET (HR.)	c. ATTENDING HEALTH PROFESSIONAL?	d. HOSPITALIZATION REQUIRED?
	(1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES DATE: _____	(1) <input type="checkbox"/> VOMITING (2) <input checked="" type="checkbox"/> NAUSEA (3) <input type="checkbox"/> DIARRHEA (4) <input checked="" type="checkbox"/> FEVER (5) <input type="checkbox"/> SKIN/EYE IRR. (6) <input checked="" type="checkbox"/> HEADACHE (7) <input checked="" type="checkbox"/> OTHER XXX sweats	4-5 days 7-8 days 4-5 days 4-5 days	(1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "Yes" give name, address, and phone number) Dr. [REDACTED]	(1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "Yes" give name, address, phone number and dates)



8. PRODUCT AND LABELING	a. BRAND NAME	b. PRODUCT NAME	
	Fit America	Weight Loss Product	
	c. SIZE AND PACKAGE TYPE	d. NAME AND LOCATION OF STORE WHERE PURCHASED	
	3 btls., plastic	[REDACTED]	
e. PACKAGE CODE / SERIAL NUMBER / ETC.	f. DATE PURCHASED	g. PRODUCT USED (If "Yes" enter date)	h. AMT. REMAINING
06/99& EXP. / USE BY DATE: 07/00	8/26/97	(1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES Date: 8/27-9/6/97	little more than 2/3

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT	c. NAME AND LOCATION OF FIRM (Include ZIP Code)	d. IMPORT PRODUCT
	FLA	Fit America 2101 W. Commercial Blvd., Ste. 5500 Ft. Lauderdale, FL 33309	(1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES

10. EVALUATION AND DISPOSITION	a. PROBLEM KEY WORD	b. DISPOSITION	11. PRODUCT CODE
	(1) CODE RX (2) DESCRIPTION multiple	(1) <input type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input checked="" 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	54YCY99
	b. EVALUATION		12. INFORMATION COPIES TO:
	(1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input checked="" type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		<input type="checkbox"/> HFM-660 <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFC-161 <input type="checkbox"/> HFV-210 <input checked="" type="checkbox"/> HFS-635 <input type="checkbox"/> OTHER _____

13. REMARKS Complainant stated that she had high blood pressure, and she ordered this product over the phone, and no one asked her about any health problems she might have. She said there is a warning label on the bottles stating not to use with the existence of certain health problems, with high blood pressure being one. However she didn't see it at first as bottles are bound together and warning is covered until all the plastic material is removed. She feels company should warn consumers before taking an order or at least place label where it's easier to see.

14. NAME AND TITLE OF DISPOSITION OFFICIAL	15. DATE to see.
Ruth E. Prestia, SECRETARY, PGH-RP	9/11/97