

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

ARMS#

12537



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**COMPLAINT / INJURY REPORT**

1. COMPLAINT NUMBER  
PHI-7-0821 12537  
2. DATE OF COMPLAINT (Month / Day / Year)  
9/11/97

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 Complainant took product for 3 days and during that time, felt dizzy, shaky, light-headed and weak. She took pills to her dr. for her to check, and she said dr. stated that she would not take them, but did not have a book on herbs to check on ingredients. Complainant stated that she has a leaky heart valve, and she didn't notice at first the warning on label for people with heart problems to not take product. See Remarks.		b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "Yes" Explain in Remarks)
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7. INJURY OR ILLNESS RESULTED  (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES  *(If "yes" complete items a through d)	a. EIB (HFC - 167) NOTIFIED (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES DATE: _____	b. TYPE SYMPTOMS ONSET (HR.) (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/EYE IRR. _____ (6) <input type="checkbox"/> HEADACHE _____ (7) <input checked="" type="checkbox"/> OTHER 1 day See 6a.	c. ATTENDING HEALTH PROFESSIONAL? (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "Yes" give name, address, and phone number) Dr. [REDACTED] [REDACTED]	d. HOSPITALIZATION REQUIRED? (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "Yes" give name, address, phone number and dates)
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8. PRODUCT AND LABELING	a. BRAND NAME Fit America	b. PRODUCT NAME Weight Loss Product
	c. SIZE AND PACKAGE TYPE 3 btls., plastic	d. NAME AND LOCATION OF STORE WHERE PURCHASED [REDACTED]
	e. PACKAGE CODE / SERIAL NUMBER / ETC. EXP. / USE BY DATE: 06/99 & 07/00	f. DATE PURCHASED 8/26/97

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

10. EVALUATION AND DISPOSITION	a. PROBLEM KEY WORD (1) CODE : (2) DESCRIPTION RX : multiple	b. DISPOSITION (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	11. PRODUCT CODE 54YCY99
	b. EVALUATION (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		12. INFORMATION COPIES TO: <input type="checkbox"/> HFM-660 <input type="checkbox"/> HFS-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  
She said warning isn't easy to see. She said there are young girls working there that take orders and no one asks about any existing health problems.

14. NAME AND TITLE OF DISPOSITION OFFICIAL Ruth E. Prestia RUTH E. PRESTIA, SECRETARY, PGH-RP	15. DATE 9/12/97
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