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

ARMS#

13351

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER: CIN - 8458 13351

2. DATE OF COMPLAINT (Month / Day / Year): 1/19/99

3. FORM OF COMPLAINT
a.
(1) [X] TELEPHONE
(2) [ ] LETTER
(3) [ ] VISIT

4. SOURCE OF COMPLAINT
a.
(1) [X] CONSUMER (3) [ ] TRADE SOURCE
(2) [ ] GOVERNMENT (4) [ ] OTHER
[ ] L [ ] S [ ] F (Indicate in Remarks)

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

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT / INJURY
This past year Dr. [redacted] has performed 5 DNC's on post menopausal women. In each case, the patients had been using the referenced pdct for 1 to 5 mths. Dr. [redacted] called the mfr & was told that 1 of the ingredients is bovine extract from the endocrine organs. Dr. [redacted] stated this could result in the suspect (see Rmks)
b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [X] NO (2) [ ] YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [X] YES *
*(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED
(1) [ ] NO
(2) [X] YES
DATE: 1/19/99

b. TYPE SYMPTOMS — ONSET (HR.)
(1) [ ] VOMITING
(2) [ ] NAUSEA
(3) [ ] DIARRHEA
(4) [ ] FEVER
(5) [ ] SKIN/EYE IRR.
(6) [ ] HEADACHE
(7) [X] OTHER UK
post menopausal bleeding

c. ATTENDING HEALTH PROFESSIONAL?
(1) [ ] NO (2) [X] YES
(If "Yes" give name, address, and phone number)
see 5a

d. HOSPITALIZATION REQUIRED?
(1) [ ] NO (2) [X] YES
(If "Yes" give name, address, phone number and dates)
UK

RECEIVED FEB 1 1999

8. PRODUCT AND LABELING
a. BRAND NAME: Metabolife
b. PRODUCT NAME: Weight Loss Product
c. SIZE AND PACKAGE TYPE:
d. NAME AND LOCATION OF STORE WHERE PURCHASED:
e. PACKAGE CODE / SERIAL NUMBER / ETC.:
EXP. / USE BY DATE:
f. DATE PURCHASED:
g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [ ] YES
Date:
h. AMT. REMAINING:

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: LOS
b. C.F. NO.: —
c. NAME AND LOCATION OF FIRM (Include ZIP Code)
Metabolife Int. Inc.
5070 Santa Fe St FAX (619) 490-0644
San Diego, Ca 92109 (619) 490-5222
d. IMPORT PRODUCT
(1) [ ] NO
(2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD
(1) CODE: 14
(2) DESCRIPTION: Bleeding
b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [ ] FDA ACTION INDICATED
(4) [X] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) [ ] IMMEDIATE FOLLOW-UP
(2) [ ] F / U NEXT EI
(3) [X] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) [ ] REFERRED TO OTHER FDA _____ DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54GCT01

12. INFORMATION COPIES TO:
[ ] HFM-660 [ ] HFZ-343
[ ] HFD-730 [X] HFC-161
[ ] HFV-210 [X] HFS-635
[ ] OTHER _____

13. REMARKS being a source of unopposed estrogen. This estrogen could be the stimulus for the post menopausal bleeding & could lead to ovarian or endometrial cancer. 1/20/99 [redacted] (Metabolife) not aware that there is a problem. Dr. Kanzaria in pdct will send copy of label. Pdct is mfrd by 2 different firms. Can't determine which is a code

14. NAME AND TITLE OF DISPOSITION OFFICIAL
David C Robb PDM

15. DATE: 1/21/99

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FORM FDA 2516 (1/96)

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