Figure 5. Examples of MIPER Files

5a. Email record of a telephone conversation

From: Redacted
Posted At: Monday, November 29, 1999 8:23 AM
Conversation: Redacted menstrual irreg
Posted To: Medical Group

Subject: Redacted menstrual irreg

Sensitivity: Private

Categories: Menstrual Irregularity

Redacted
27 yrs 210 lbs
customer reports taking 1 1/2 caps tid ac for 1 month - eats adequate, drinks qs - now experiencing menstrual irreg an is 5 days late for her cycle
recommended contact gyn and discuss whether to continue taking- may be able to just decrease to 1 or 1 1/2 caps a day or may need to completely stop- be sure to continue to eat 3 healthy high protein meals qd and drink 64 oz of water

Figure 5. Examples of MIPER Files (continued)

5b. Typed or handwritten letter from the consumer to the company

Dear Sir.
I tryed Metabolife & got a
bad rash. I went to the doctor & he
Gave me some medication, I waited over
a mouth & tryed again & the rash came
back. I hope its not to late for a refund
Lorry

REDA(

CONFIDENTIAL MIPER020990

Figure 5. Examples of MIPER Files (continued)

5c. Handwritten note of telephone conversation with consumer written on a rudimentary form. Note more than one case is recorded on a single MIPER file.

HEALTH INFORMATION CALL DOCUMENTATION
DATE 11/2/99

Name ___ (F) Age 32 Weight 164 Phone# ___
# of caps qd 2 Timing tid Duration 3 days (2nd time on product)
Side effect? indigestion Breakfast intake ___
Lunch (poor diet) ↑ protein
Dinner
Water intake 8 gls. Caffeine intake fake meat & food
Medications 0 Medical history/similar symptoms ___
Exercise ___ Other pertinent info / desired # does not want
Recommendations ___ write to know. 5'2"

Name ___ Age 23 Weight 136 Phone# ___
# of caps qd 2 Timing bid. Duration 1 month (7 wks)
Side effect? 0 wt. loss Breakfast intake Bagel / coffee
Lunch fruit
Dinner meat.
Water intake 90 oz. Caffeine intake juice
Medications Depo Prov Medical history/similar symptoms ___
Exercise ___ Other pertinent info ___
Recommendations ↑ protein, ✓'d website.

Name ___ Age 18 Weight 170 5'3" Phone# ___
# of caps qd 1.5 Timing ~~tid~~ bid Duration 5 days ↑ energy
Side effect? constipated Breakfast intake skips
Lunch diet poor
Dinner ___
Water intake 2-3 ↑ H2O Caffeine intake ___
Medications BCP Medical history/similar symptoms ___
Exercise ___ Other pertinent info ___
Recommendations ___

Name (F) Age ___ Weight ___ Phone# ___
# of caps qd 1 Timing bid Duration 2 days
Side effect? kidney back pain Breakfast intake adequate low protein / low carbo.
Lunch
Dinner
Water intake 4-6 Caffeine intake Decaf. Chocolate Coffee
Medications ___ Medical history/similar symptoms ___
Exercise ___ Other pertinent info STOPPED / consulted MD.
Orange color urine Sx subsided after stopped.
Return for refund.

CONFIDENTIAL
CONFIDENTIAL & NON RESPONSIVE REDACTION

MIPER022677

Figure 5. Examples of MIPER Files (continued)

5d. Handwritten note of telephone conversation with consumer written on a piece of paper

1 Friday May 1998

Williams AZ

Time	Note
7:00	3 hrs - chest
7:30	arm, head neck
8:00	stunned -
8:30	husband - came home
9:00	took to clinic -
9:30	hospit - [illegible]
10:00	EKG -
10:30	angioplasty -
11:00	cardiac meds
11:30	[illegible]
12:00	blood thinner
12:30	
1:00	Zestril
1:30	isosorbide
2:00	plavix
2:30	ASA
3:00	
3:30	told MD - in hospital
4:00	[illegible] not tell MD
4:30	
5:00	

Figure 5. Examples of MIPER Files (continued)

5e. A form developed for systematically collecting information about possible adverse events

Nurses Database - Caller Info

First Name / *Last Name*	Redacted	*AGE(years)*	0	*Current Dose*	1	*Times per day*	1
		WT(LBS)	180	*Suggested Dose*	0.5	*SD Times per day*	BID
		HT(INCHES)	0	*TIME ON METABOLIFE*	1	*UNITS*	DAYS

USER	cela	*D/C met use* ☐	*Chinac formula* ☐	*formula*	
Date	11/1/199 *Time* 8:36:27 A	*Refund Policy Reviewed* ☐	*356 +Chinac* ☐		

Recommendations

Current Water Intake oz	*Caffeine Intake*	*Current Diet*	*Increase Water*	*High Protein*	*Other Recommendations*
64	0	low protein breakfasts	☐	☑	start slowly, inc fiber, try with meals, if sx recur, stop, see PCP

☐ *Ok to call back* ☐ *Do not call back* ☐ *Customer Understand Recommendati* ☐ *Eat w/10min to 1hr*

☐ *Usage Guidelines Sent* ☐ *Declined Usage Guidlines* ☐ *Customer to Call Meta PR* ☐ *Ate After 1hr* ☐ *Did Not Eat*

64	0	low protein breakfasts	☐	☑	start slowly, try with meals, if sx recur, stop, see PCP

☐ *Ok to call back* ☐ *Do not call back* ☐ *Customer Understand Recommendati* ☐ *Eat w/10min to 1hr*

☐ *Usage Guidelines Sent* ☐ *Declined Usage Guidlines* ☐ *Customer to Call Meta PR* ☐ *Ate After 1hr* ☐ *Did Not Eat*

☐ Abdominal Pain	☐ Dizziness	☐ Irregular Heartbeat	☐ Pregnancy on BCP
☐ Abnorm Lab Values	☐ Dry Mouth	☐ Irritability	☐ Prupitis
☐ Acne	☐ Edema	☐ Joint Pain	☐ Psychosis
☐ Addiction	☐ Elevated Liver Functions	☐ Joint Stiffness- General	☐ Rash
☐ Anesthesia Complication	☐ Excitation	☐ Joint Stiffness - Local	☐ Seizure
☐ Anxiety	☐ Eye Twitching	☐ Joint Swelling - General	☐ Sexual Disfunction
☐ Back Pain	☐ Facial Swelling	☐ Joint Swelling - Local	☐ Shortness of Breath
☐ Bloating/Gas	☐ Fatigue	☐ Kidney Stones	☐ Stroke
☐ Blood in Stool	☐ Fever	☐ Liver Enzyme Elevation	☐ Sweating
☐ Blood in Urine	☐ Fluid Retention	☐ Menstrual Irregularity	☐ Tachycardia
☐ Breast Pain	☐ Glaucoma	☐ Mood Swings	☐ Tingling Hands
☐ Briusing	☐ Hair Loss	☐ Muscle Cramps -General	☐ Tinnitis
☐ Chest Pain	☐ Headache	☐ Muscle Cramps - Leg	☑ Tremors
☐ Chills	☐ Heart Burn	☐ Myocardial Infarction	☐ Urinary Infection
☐ Cold Hands	☐ High Blood Pressure	☐ Nausea	☐ Urine Retention
☐ Constipation	☐ Hives	☐ NoseBleeds	☐ Vasodilation
☐ Cough	☐ Hypertension	☐ Numbness	☐ Vision Disturbance
☐ Death	☐ Hypoglycemia	☐ Palpitations	☐ Vomiting
☑ Diarrhea	☐ Insomnia	☐ Parestrsias	☐ Yeast Infection

Other/Comments: ☐ No Weight Loss/Gain

☐ Medical Release Form Sent ☐ Customer Denies any other signs or Symptoms

CONFIDENTIAL MIPER018211