Study ID: _	
Visit Date:	
	Mo - Day - Year
	Visit 6

Vital Signs	Please mark if evaluation was not done	
Any significant findings afte	r the start of the study drug should be recorded on the Adverse Events page.	
Please circle the correct mea	surement, when applicable.	
Weight	kg or lbs	
Sitting Pulse	bpm	
Sitting Blood Pressure	systolic/diastolic MmHg	
Respirations	/minute	
Temperature	degrees Centigrade or Fahrenheit	

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returned

Full Blood Count	Serum Chemistry
Month Day Year	Month Day Year
0No	0No
1Yes	1Yes
Collect Symptom Diary	Physical Examination
Month Day Year	Month Day Year
0No	0No
1Yes	1Yes
Collect Medication Diary	Urine Pregnancy Test
Month Day Year	Month Day Year
0No 1Yes	0 Negative
	1Positive
	9N/A
Compliance Count	N. 1. 677.11.4
Number of Tablets or doses	Number of Tablets expected to be returned

Study ID: _		
Visit Date:		
	Mo	- Day - Year
		Visit 6

Scintigraphy (Gastric Emptying)	SCG			
Scint Completed 0 = No 1 = Yes 9 = Unknown	bed			
Date of Scintigraphy				
Results: 0				
30 min				
60 min				
120 min				
240 min				
Mins GET ½				
% CF 6 hrs				
Results 0Normal				
1Delayed				
Date of last dose of study medication: Month Day Year				
Gastric Accommodation (Mayo Sites only)				
Spect Completed 0 = No 1 = Yes 9 = Unknown				
Date of Test: Month Day Year				
Results:				

 $\frac{12/01/2009}{\text{Please mail or fax to the FDTT Data Coordinating Center per the Data and Event Reporting Information SOP.}}{\text{Please mail or fax to the FDTT Data Coordinating Center per the Data and Event Reporting Information SOP.}}$

Study ID: _			_
Visit Date:			_
	Mo	- Day - Yea	ır
		Visit	6

Liquid Nutrient Drink Test

 $\begin{array}{ccc} Drink \ Test \ Completed & \underline{\hspace{1cm}} & 0 = No \\ & 1 = Yes \\ & 9 = N/A \end{array}$

Date of Test:

| ______ | ______

Total Volume ____ml

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Study ID: _			
Visit Date:			
	Mo	- Day	– Year
			Visit 6

Concomitant Medication/Significant Non-Drug Therapies prior to and after start of study drug					
 Please list all medication and significant non-drug therapies. If there are no changes from previous visit, enter NO CHANGES (on line 1 below). 					
Period covered by this form: Start Date (visit 5) Month Day Year	End Date (visit 6) Month Day Year				
Medication/Non-Drug Therapy (use trade name if possible)	Reason (Including Prophylaxis)				
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
Is an additional Concomitant Medications/Significant Non-Drug Th	erapies page used? 0No 1Yes				
Please ensure that the data on this page are consistent with the data on the page of Visit 1.	e Relevant Medical History/Current Medical Conditions				

 $12/01/2009 \\ Please \ mail \ or \ fax \ to \ the \ FDTT \ Data \ Coordinating \ Center \ per \ the \ Data \ and \ Event \ Reporting \ Information \ SOP.$

Study ID: _	
Visit Date:	
	Mo - Day - Year
	Visit 6

Participant i	s to complete the following	ing survey form	ns:		
Semi – Struc	ctured Interview Complete	☐ Incomplete	Reason:		
CGI	☐ Complete	☐ Incomplete	Reason:		
HADS	☐ Complete	☐ Incomplete	Reason:		
SF - 36	☐ Complete	☐ Incomplete	Reason:		
NEPEAN	☐ Complete	☐ Incomplete	Reason:		
GSRS	☐ Complete	☐ Incomplete	Reason:		
Somatic Syr SSC	nptom Checklist ☐ Complete	☐ Incomplete	Reason:		
SCL-90	☐ Complete	☐ Incomplete	Reason:		
Profile of M POMS	food States ☐ Complete	☐ Incomplete	Reason:		
State – Trait STAI	Anxiety Inventory ☐ Complete	☐ Incomplete	Reason:		
Pittsburgh S PSQI	leep Quality Index ☐ Complete	☐ Incomplete	Reason:		
Eating Disor EDE-Q	rder Examination Questio ☐ Complete	onnaire □ Incomplete R	eason:		
Changes: Were any changes made on any of the above questionnaires? □ NO □ YES (If yes, see below)					
•	coordinator initial and date HI letion of questionnaires.	ERE that the chang		y the study part	icipant at the

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