Study ID: _		
Visit Date:		
	Mo	- Day - Year
		Visit 5

Vital Signs		Please mark if evaluation was not done	П
		y drug should be recorded on the Adverse Events page.	
Please circle the correct mea	surement, when appli	icable.	
Weight		kg or lb	
Sitting Pulse		_bpm	
Sitting Blood Pressure	systolic/diastolic MmHg	-	
Respirations		/minute	
Temperature		degrees Centigrade or Fahrenheit	

 $01/04/2009 \\ Please \ mail \ or \ fax \ to \ the \ FDTT \ Data \ Coordinating \ Center \ per \ the \ Data \ and \ Event \ Reporting \ Information \ SOP.$

Collect Medication Diary	Dispense Medication Diary
Month Day Year	Month Day Year
0No 1Yes	0No 1Yes
Dispense Study Drug	Compliance Count
Month Day Year	Number of Tablets or doses returned
0No 1Yes	Number of Tablets or doses expected to be returned
Collect Symptom Diary	(please circle tablets or doses) Dispense Symptom Diary
Month Day Year	Month Day Year
0No 1Yes	0No 1Yes

Study ID: _		
Visit Date:		
	Mo	- Day - Year
		Visit 5

THANK YOU FOR YOUR CO-OPERATION.

Concomitant Medication/Significant Non-Drustart of study drug Please list all medication and significant non-drug therapies. If there are no changes from previous visit, enter NO CHANGE.	
Start Date (visit 4) Period covered by this form: Month Day Year	End Date (visit 5) 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 Therapies Please ensure that the data on this page are consistent with the data on the Relevance of Visit 1.	-

Page 26 of 29 01/04/2009

Study ID: _		
Visit Date:		
	Mo	- Day - Year
		Visit 5

Weekly Phone Calls for Weeks 1-3 After Visit 5

1. How are you feeling?	
2. In the past week, have you had adequate relief of your stomach symptoms?	No = 0 $Yes = 1$
3. Have you missed any doses of the study medication? If yes, how many doses and reason. Number of missed doses Reason for missed doses	No = 0 $Yes = 1$
4.Have you started any new medicines (either prescribed or last visit? If yes, what medicines?	No = 0 $Yes = 1$
5. Since starting the study have you noticed a change in your If yes, obtain description from the participant	
If the participant describes a depressed mood, obtain a a. I still enjoy the things I used to enjoy:	nswers to the following questions: 1Definitely as much 2Not quite as much 3Only a little 4Hardly at all
b. I can laugh and see the funny side of things:	 As much as I always could Not quite as much now Definitely not as much now
	4Not at all

01/04/2009 Page 27 of 29

Study ID: _		
Visit Date:		
	Mo	- Day - Year
		Visit 5

(Phone Call Date//)	
d. I have lost interest in my appearance:	 Definitely I don't take as much care as I should I may not take as much care I take as much care as ever
e. I feel cheerful:	1Not at all 2Not often 3Sometimes 4Most of the time
f. I look forward with enjoyment to things:	 As much as I ever did Rather less than I used to Definitely less than I used to Hardly at all
g. I can enjoy a good book or radio or TV progra	am: 1Often 2Sometimes 3Not often 4Very seldom
Ouestion 5 To	tal:
If the participant's score for the questions is $>$ or $=$ to 11, the study visit. The Principal Investigator at each site will enco	e participant is to be seen for an unanticipated
6. Have you seen your health care provider since the last ca	11? No = 0 Yes = 1
Date of Doctor visit Date///	
If yes, why?	
7. Thank you for answering my questions. Please contact _ coordinator) prior to stopping the study medication . If yo please go to your nearest ER and contact us during business	ou feel you can not wait until business hours,

01/04/2009 Page 28 of 29

NIDDK U01 DK 065713
Functional Dyspepsia Treatment Tria

NIDDK U01	DK 065713		Study ID: _	
	rspepsia Treatment	Trial	Visit Date:	Mo - Day – Year Visit 5
Participant	is to complete th ☐ Complete	e following survey forms: ☐ Incomplete Reason:		
SF – 36	☐ Complete	☐ Incomplete Reason:		
NEPEAN	☐ Complete	☐ Incomplete Reason:		
GSRS	□ Complete	☐ Incomplete Reason:		
Changes:				

Were any changes made on any of the above questionnaires?

□ NO ☐ YES (If yes, see below)

If yes, study coordinator initial and date HERE that the changes were made by the study participant at the time of completion of questionnaires. Study coordinator initial Month Day Year

01/04/2009 Page 29 of 29