

SOLVD ALTERATION IN STUDY DRUG DOSAGE FORM

VERSION B / 12-28-87

RAND ID:

--	--	--	--	--	--	--	--	--	--

FORM:

S	D	C
---	---	---

VISIT:

--	--

SEQUENCE NUMBER:

--	--

INSTRUCTIONS:

This form is to be used whenever a dosage change is needed. This form is to be used at or between SOLVD visits. When using this form between visits use the last SOLVD follow-up visit attended by the participant. For dose changes at a visit use the current (new) SOLVD visit number. The sequence number is needed to indicate the number of times this form has been used between any two visits. Sequence number will start with 01 the first time the form is used for the participant for a specific visit number. Print clearly when entering a response in the appropriate boxes. For multiple choice questions, circle the one appropriate letter corresponding to the response chosen. Specific instructions for various questions are enclosed in boxes directly below the question. See the SOLVD General Instructions for Completing Forms for details.

SOLVD ALTERATION IN STUDY DRUG DOSAGE FORM (screen 1 of 4) (SDC page 1 of 3)

A. IDENTIFYING INFORMATION

1. Today's Date:

		//			//		
Month			Day			Year	

2.1. Last Name:

2.2. First Name:

2.3. Middle Name:

**B. INITIALS OF PERSON
COMPLETING THIS FORM**

3. Initials.....

--	--

C. FORMER STUDY MEDICATION
(Medication the participant is taking up until the use of this form.)

4. Pills dispensed/returned:

Instructions: Enter the following information for pills dispensed either at the last SOLVD visit or last use of this form: # pills dispensed, dose (Q=QD=once daily, B=BID=twice daily), pills returned and # days since the pills were dispensed.

Pill type	# Pills previously dispensed	Dose (Circle: Q=QD or B=BID)	# Pills returned today	# days since last visit
2.5 mg	a) <input type="text"/>	b) <input type="radio"/> Q <input type="radio"/> B	c) <input type="text"/>	d) <input type="text"/>
5.0 mg	e) <input type="text"/>	f) <input type="radio"/> Q <input type="radio"/> B	g) <input type="text"/>	h) <input type="text"/>
10.0 mg	i) <input type="text"/>	j) <input type="radio"/> Q <input type="radio"/> B	k) <input type="text"/>	l) <input type="text"/>

D. CURRENT (NEW) MEDICATION

5. Pills dispensed today:

Instructions: For pills dispensed today, enter the # pills dispensed and the dose.

	# Pills dispensed today	Dose (Circle: Q=QD or B=BID)
2.5 mg	a) <input type="text"/>	b) <input type="radio"/> Q <input type="radio"/> B
5.0 mg	c) <input type="text"/>	d) <input type="radio"/> Q <input type="radio"/> B
10.0 mg	e) <input type="text"/>	f) <input type="radio"/> Q <input type="radio"/> B

5.1. Is more study drug needed at the new, altered dose?..... Yes No

6. Type of change in dosage..... Increase I
 If Decrease (D) or Stopping (S) go to section F, REASON FOR DECREASING OR STOPPING, Q. 8.1 Decrease D
 Stopping S

E. REASON FOR INCREASING DOSE

7.1. Increase toward prescribed maintenance dose following dose reduction..... Yes No
 Y N

7.2. Increase toward prescribed maintenance dose by protocol.... Y N

7.3. Other..... Y N

If No (Other), EXIT THE FORM.

If Yes (Other), specify:

EXIT THE FORM.

F. REASON FOR DECREASING OR STOPPING DOSE

8.1. Side effects?.....Yes Y
 [If No, go to Question 9 on page 3.] No N

If Yes, indicate the following side effects: Yes No

8.2. Symptomatic hypotension..... Y N

8.3. Altered Taste..... Y N

8.4. Skin rash..... Y N

8.4a. Dizziness/fainting..... Y N

8.4b. Fatigue..... Y N

8.4c. Nausea..... Y N

8.4d. Angioneurotic edema..... Y N

8.4e. Cough..... Y N

8.5. Azotemia..... Y N

