SOLVD
ALTERATION IN STUDY DRUG DOSAGE FORM

VERSION A / 3-6-86

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 between SOLVD visits. The visit number entered should be the last SOLVD visit attended by the participant. The sequence number is needed to indicate the number of times this form has been used between any two visits. Sequence number should 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.

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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..... | |

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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 each pill type 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)	b) Q B	c)	d)
5.0 mg	e)	f) Q B	g)	h)
10.0 mg	i)	j) Q B	k)	l)

D. CURRENT (NEW) MEDICATION

5. Pills dispensed today:

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

	# Pills dispensed today	Dose (Circle: Q=QD or B=BID)
2.5. mg	a)	b) Q B
5.0. mg	c)	d) Q B
10.0. mg	e)	f) Q B

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6. Type of change in dosage.....Increase I
Decrease D

If Decrease (D), go to section F. REASON FOR DECREASING DOSE, Question 8.1.

E. REASON FOR INCREASING DOSE

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

8.1. Side effects?.....Yes Y
No N

If No, go to Question 9. on page 3.

If Yes, indicate the following side effects:

	Yes	No
8.2. Symptomatic hypotension.....	Y	N
8.3. Taste abnormalities.....	Y	N
8.4. Skin rash.....	Y	N
8.5. Azotemia.....	Y	N
8.6. Other.....	Y	N

If No (Other), go to Question 9. on page 3.

If Yes (Other), specify:

9. Myocardial Infarction.....Yes Y

No N

10.1. Cardiac surgery other than transplant.....Yes Y

No N

If No, go to Question 11.

10.2. If yes (cardiac surgery), specify:

	Yes	No
11. Cardiac transplant.....	Y	N
12. Noncardiac surgery.....	Y	N
13. Worsening CHF with need for treatment with "open label" medication identical or similar to the study drug.....	Y	N
14. Requested by the referring physician.....	Y	N
15. Requested by participant.....	Y	N
16. Other.....	Y	N

If No (Other), EXIT THE FORM.

If Yes (Other), specify:
