

Site Number: _____ Participant ID: _____ Participant Letters: _____

Complete this form if the participant will not be taking any more study drug.

A. REPORT INFORMATION

- 1. Date of report:
- 2. Last visit day and date of treatment:

_____/_____/_____
DAY MONTH YEAR
_____/_____/_____
DAY MONTH YEAR

B. CHANGE IN STUDY DRUG

- 1. Date change in study drug status effective:
- 2. Reason the study drug was stopped (*check one – complete for discontinuation only*):

_____/_____/_____
DAY MONTH YEAR

- Participant refused further treatment
- Adverse event
- Pregnancy

- Study discontinuation
- Protocol specified drug withholding
- Other

a. IF OTHER, specify:

- 3. Was the participant informed of his/her treatment group assignment? Y N

With the exception of a pregnancy, if the participant was told of his/her treatment group assignment the **Protocol Deviation Form** must be completed

- 4. Is there a change in study status at this time? Y N

If **YES**, complete **Change in Status Form**

Initials (first, middle, last) of person completing this form: _____
F M L

Date form completed: ____/____/_____
DAY MONTH YEAR