QxQ updated: 07/21/2004

HALT-C Trial Q x Q

Lost Drug Accountability

Form # 926 Version A: 06/15/2000

<u>Purpose of Form #926:</u> The Lost Drug Accountability form documents all lost/misplaced study medication (vials of peginterferon alfa-2a and lost/misplaced tablets of ribavirin) that were never returned to the coordinator/pharmacist by the patient.

When to complete Form #926: This form should be completed each time the patient reports a lost/misplaced vial of peginterferon alfa-2a and lost/misplaced tablets of ribavirin.

Where to add Form #926: This form is an addable form in the DMS and can be added at every visit except S00 and W00. To add a form to a visit, click on the "Additional Forms" button at the bottom of the screen. Choose "#926: Lost Drug Accountability" from the pull down menu, and then click the "OK" button. To see where this form has been added, please click on the "More" link in the upper right hand corner of the screen.

SECTION A: GENERAL INFORMATION

- A1. Affix the patient ID label in the space provided.
 - If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date of this visit (the date the lost drug was reported) in MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

SECTION B: LOST DRUG PEGASYS® 180 μg VIALS

- B1. Are there any Pegasys® 180 μg vials reported as lost?
 - If YES, circle 1.
 - If NO, circle 2 and skip to question C1.
- B2. Number of vials of Pegasys® 180 μg lost:
 - Record the number in the spaces provided. Record the total number, regardless of whether the vials were full or empty.
- B3. Date reported as lost:
 - Record the month, day, and year the Pegasys® 180 μg vials were reported as lost in MM/DD/YYYY format. If the day is not known, enter MM/YYYY.

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SECTION C: LOST DRUG PEGASYS® 90 μg VIALS

- C1. Are there any Pegasys® 90 µg vials reported as lost?
 - If YES, circle 1.
 - If NO, circle 2 and skip to question D1.
- C2. Number of vials of Pegasys® 90 μg lost:
 - Record the number in the spaces provided. Record the total number, regardless of whether the vials were full or empty.
- C3. Date reported as lost:
 - Record the month, day, and year the Pegasys® 90 μg vials were reported as lost in MM/DD/YYYY. If the day is not known, enter MM/YYYY.

SECTION D: LOST RIBAVIRIN TABLETS

- D1. Are there any ribavirin tablets reported as lost?
 - If YES, circle 1.
 - If NO, circle 2 and the form is complete.
- D2. Number of ribavirin tablets lost:
 - Remember that there are 180 tablets in a bottle.
 - Record the number in the spaces provided. If the patient does not know how many tablets were in the bottle, record the bottle as full (180).
- D3. Date reported as lost:
 - Record the month, day, and year the ribavirin tablets were reported as lost in MM/DD/YYYY format. If the day is not known, enter MM/YYYY.