**Death, Serious Adverse Event or Elevated Amylase Fax Notification**
**DSA Version B, 2/11/2004**
**QxQ Date: 2/11/2004**

# I. GENERAL INSTRUCTIONS

The Death, Serious Adverse Event or Elevated Amylase Fax Notification (DSA) is completed upon notification of participant death, serious adverse event or when the Serum Amylase is elevated 3 times above normal. Refer to Chapter 10 "Endpoints" in the Manual of Procedures (MOP) for more information on the reporting of a participant death, and to Chapter 9 "Serious Adverse Events" for more information on adverse events.

Staff who complete this form must be familiar with and understand Chapter 14 "Administrative Procedures" in the MOP. The Participant ID is completed as described in that document.

# II. SPECIFIC INSTRUCTIONS

## A. Death Notification

Complete the Death section of the DSA and fax the form to Barbara Brown at the DCC within 24 hours of becoming aware of the participant's death. Refer to Chapter 10 of the MOP on reporting of a death event and complete all appropriate forms as described in the chapter.

1. Record the participant's date of death, using the US order (month/day/year). Code in numbers using leading zeros where necessary to fill all fields. (ex: **0**3/**0**1/2003, must be entered for March, 1, 2003)

2. Record the presumptive cause of death, if known.

CO/SN Record the Contact Occasion and Sequence Number for the corresponding Outcomes Documentation (OUT) form in the boxes provided. Since there may be delay in obtaining records needed to complete the OUT and other forms, determine the Contact Occasion and Sequence Number to be used for the OUT and record the numbers in the boxes provided.

## B. Serious Adverse Event Notification

In the reporting of a serious adverse event in a participant, refer to Chapter 9 "Adverse Events" in the MOP regarding serious adverse events associated with the FAVORIT multivitamin, and complete all appropriate forms as described in the chapter. Complete DSA section B and fax to Barbara Brown at the DCC within 24 hours of becoming aware of the participant's serious adverse event. When in doubt of whether or not to report an adverse event, submit a report.

3. Record the date of the serious adverse event onset if known, otherwise approximate the date of onset, using the US order (month/day/year). Code in numbers using leading zeros where necessary to fill all fields. (ex: **0**3/**0**1/2003, must be entered for March, 1, 2003)

4. Briefly describe the serious adverse event.

Complete FDA Form 3500A and fax **to the DCC**. FDA Form 3500A and instructions can be found in the forms section of your MOP.

## C. Elevated Serum Amylase

Only report Serum Amylase if the values are at least three times above normal.

5. Record the date the serum amylase was evaluated.

6. Record the actual serum amylase value.

7. Record the normal range (reference range) values, this can be found on the serum amylase report.

8. Record whether the participant has ever received a pancreas transplant, either Yes or No. If no, proceed to question 10.

9. Record the date the participant received the pancreas transplant, using the US order (month/day/year). Code in numbers using leading zeroes where necessary.

10. Briefly describe the elevated serum amylase.

**Death or Serious Adverse Event Fax Notification**
**DSA Version A, 7/15/2002**
**QxQ Date: 8/9/2002**

# I. GENERAL INSTRUCTIONS

The Death or Serious Adverse Event Fax Notification (DSA) is completed upon notification of participant death or serious adverse event. Refer to Chapter 10 "Endpoints" in the Manual of Procedures (MOP) for more information on the reporting of a participant death, and to Chapter 9 "Serious Adverse Events" for more information on adverse events.

Staff who complete this form must be familiar with and understand Chapter 14 "Administrative Procedures" in the MOP. The Participant ID is completed as described in that document.

# II. SPECIFIC INSTRUCTIONS

## A. Death Notification

Complete the Death section of the DSA and fax the form to Barbara Brown at the DCC within 24 hours of becoming aware of the participant's death. Refer to Chapter 10 of the MOP on reporting of a death event and complete all appropriate forms as described in the chapter.

1. Record the participant's date of death, using the US order (month/day/year). Code in numbers using leading zeros where necessary to fill all fields. (ex: **0**3/**0**1/1952, must be entered for March, 1, 1952)

2. Record the presumptive cause of death, if known.

CO/SN Record the Contact Occasion and Sequence Number for the corresponding Outcomes Documentation (OUT) form in the boxes provided. Since there may be delay in obtaining records needed to complete the OUT and other forms, determine the Contact Occasion and Sequence Number to be used for the OUT and record the numbers in the boxes provided.

## B. Serious Adverse Event Notification

In the reporting of a serious adverse event in a participant, refer to Chapter 9 "Adverse Events" in the MOP regarding serious adverse events associated with the FAVORIT multivitamin, and complete all appropriate forms as described in the chapter. Complete DSA section B and fax to Barbara Brown at the DCC within 24 hours of becoming aware of the participant's serious adverse event. When in doubt of whether or not to report an adverse event, submit a report.

3. Record the date of the serious adverse event onset if known, otherwise approximate the date of onset, using the US order (month/day/year). Code in numbers using leading zeros where necessary to fill all fields. (ex: **0**3/**0**1/1952, must be entered for March, 1, 1952)

4. Briefly describe the serious adverse event.

CO/SN Record the Contact Occasion and Sequence Number for the corresponding Follow-Up Contact (FUP) form in the boxes provided. In the event the FUP and appropriate forms are not complete, determine the Contact Occasion and Sequence Number to be used for this event and record them in the boxes provided.

Complete FDA Form 3500A and fax **to the DCC**. FDA Form 3500A and instructions can be found in the forms section of your MOP.