ATTACHMENT A – 2007

Voluntary Questions Added to the MedSun Data Collection Over Time:

These were approved at the initial implementation of the project- 2001. (Refer to Part A , supporting statement, item # 2, for additional discussion.)

- Respondents will be asked not only to report deaths and serious injuries to FDA (as they are required to do under the statute), but will also be asked to voluntarily report if an event resulted in minor injury to the patient or if an event had the potential for patient harm (including "close-call") events.
- Rationale: Both facilities and FDA wish to become more proactive in improving patient safety. If reports are only received after someone has been seriously injured or has died as a result of a medical-device-related event, it is too late to help the injured person. By obtaining information that a potential hazard exists before a serious consequence has occurred, FDA will be able to alert the health care community as to potential problems so that patient safety may be promoted. User facilities will be able to view redacted "potential for harm" events that have been reported into the system in the newsletter that is provided to them. The facilities will be able to learn from the reported events, and can take steps to avoid similar problems in their own facilities.
- If the facility checks that the event took place in the hospital, they are then asked to fill in this voluntary question: "Area in the hospital where the event took place" (they are given choices).
- In D4 on the 3500A it asks for the operator of the device, then gives choices of (health professional) (lay user/patient) (other). This is not very helpful to FDA in deciding what "type" of person had trouble with the device, so we asked for more detail in this voluntary question: "Who was operating the device: (doctor) (allied health professional) (patient) (nurse) (family member/visitor) (other)"

These questions were approved in 2001, but have been discontinued because the sites either were not routinely answering them, were confused by them, or the answers were found, over time, not to be helpful to FDA.

- What time of day did the event occur?
- Has the facility discontinued use of the device due to the adverse event? (this is a yes or no response).
- Check all of the factors you think may have contributed to the event:

○ Inadequate systems
○ Poor device design
○ Poor device maintenance
○ Inadequate equipment
○ Unfamiliarity with device
○ Training
○ Unfamiliar environment (clinician)
○ Other: _____

- Check all of the factors you think could prevent future occurrences of this type of event:

○ New or improved devices
○ Additional equipment: _____
○ Better device maintenance
○ Appropriate training
○ Other: _____

These were approved in 2004 by Memo

Additional questions **about in-vitro diagnostic products added to the MedSun form:**

Did the problem involve (check all that apply):

1. The reagent?..... ☐
2. The instrument?..... ☐
3. Single use test?..... ☐
4. Something else? (specify)..... ☐

_____

Is this a recurrent problem with this assay, test kit, or instrument?

1. Yes..... ☐
2. No..... ☐

Additional comments_____

_____

_____

_____

Which of the following problems did you observe? (Check all that apply and include additional comments as needed)

1. Calibration ..... ☐
2. Repeated error message..... ☐
3. Reproducibility..... ☐
4. Analytical sensitivity ..... ☐
5. Analytical specificity ..... ☐
6. Quality control ..... ☐
7. Questionable patient results..... ☐
8. Reagent(s)..... ☐
9. Inadequate/unclear instructions for use..... ☐
10. Poor test/instrument design..... ☐
11. Performance described in package insert not met..... ☐
12. Specimen problems..... ☐
13. Patient related problems..... ☐
14. Other (specify) ..... ☐

Product not available to return to manufacturer ☐

9. Discontinued all use of product..... ☐
10. Not known..... ☐
11. Not applicable..... ☐
12. Other (specify):..... ☐

_____

Additional Comments: _____

Please describe any follow-up actions below (check all that apply and include additional comments as needed):

1. Repeated assay, results OK, reported out..... ☐
2. Repeated assay, still problems..... ☐
3. Replaced reagents..... ☐
4. Opened new lot..... ☐
5. Manufacturer notified..... ☐
6. Called for service..... ☐
7. Product returned to manufacturer..... ☐

(Date of return: ___/___/____)

Additional Comments_____

8. Product not available to return to manufacturer ☐
9. Discontinued all use of product..... ☐
10. Not known..... ☐
11. Not applicable..... ☐
12. Other (specify):..... ☐

_____

_____Additional Comments:

_____

These were approved in 2006, by Memo

These questions were added to gain more information about tissue and cell products

1. Transplant Product Distinct Identification Code (or other identifiers)

_____

2. Indicate any pre-implant problems that were found with the human cell or tissue product: (Check all that apply)

- € **No problem was detected with the product.**

- € **Product damage, describe_____**
- € **Packaging problem, describe_____**
- € **Product contamination, describe_____**
- € **Labeling problem, describe_____**
- € **Product Irregularity, describe_____**
- € **Other_____**

3. Was the human cell or tissue manipulated following removal from the packaging prior to transplantation?

- € **Yes. Please describe (e.g., stretched, rinsed in saline):**

  _____
- € **No** (SKIP TO 4)
- € **Unknown** (SKIP TO 4)

4. Was a pre-transplant <u>gram stain</u> of the tissue performed?

- € **Yes, pre-transplant gram stain was performed.**
- € **No, pre-transplant gram stain was not performed.** (SKIP TO 5)
- € **Do not know** (SKIP TO 5)
- € **Other** (Specify) _____

4a. The <u>gram stain</u> result was:

- € **Negative for organisms**
- € **Positive for organisms: RESULT_____**
- € **Unknown**
- € **Other** (Specify) _____

5. Was a pre-implant culture performed?

- € **Yes, pre-implant culture was performed**
- € **No, pre-implant culture was not performed** (SKIP to 6)
- € **Unknown** (SKIP to 6)
- € **Other** (Specify) _____

5a. The culture showed:

- € **No growth of organisms**
- € **Positive growth of organism(s). Identification of organism:** _____
- € **Unknown**
- € **Other** (Specify) _____

6. Was the cell or tissue product actually used (transplanted or infused)?

- ☐ **Yes, used**
- ☐ **No, not used** (Skip to 8)
- ☐ **Not known** (Skip to 8)
- ☐ **Other** (Specify) _____

7. Date of Transplant/Infusion _____/____/_____
mm/ dd/ yyyy

8. Were any devices transplanted with the tissue?

- € **Yes** (Please provide information in the DEVICE section of the MedSun database)
- € **No**
- € **Unknown**

9. Post-Transplant Adverse Event

Was there a post-transplant adverse event or close call?

- € **Yes, adverse event**
- € **Yes, potential adverse event (or close call)**

€ **No (**Please skip to end to record any additional comments.)

10. For Infection Related Events

(☐ Check here if there was not an infection-related adverse event and skip to 11.)

10a. Culture Results (post-transplant):

Anatomic Site_____ Date___/____/_____
Results_____ mm/ dd/ yyyy

Anatomic Site _____ Date___/____/_____
Results_____ mm/ dd/ yyyy

Anatomic Site _____ Date___/____/_____
Results_____ mm/ dd/ yyyy

10b. Other Study Results:

Test _____ Date___/____/_____ Results_____
mm/ dd/ yyyy

Test _____ Date____/____/_____ Results_____
mm/ dd/ yyyy

Test _____ Date____/____/_____ Results_____
mm/ dd/ yyyy

11. For Non-Infection Related Events (Check all that apply)

(☐ Check here if this does not apply. Proceed to 12.)

- € **Allograft malfunction: Describe_____**
- € **Allograft rejection: Describe_____**
- € **Other**_____

12. Medical Intervention in Response to the Event (Check all that apply)

- € **No intervention**

- € **Antibiotics for prophylaxis**
- € **Antibiotics for treatment**
- € **Required hospitalization**
- € **Required prolonged hospitalization for patient already hospitalized**
- € **Required additional procedure**:
  Specify Procedure_____
  Date Performed: _____
- € **Required explantation** (Specify Date)___/___/____
- € **Required retransplantation** (Specify Date)___/___/____
- € **Unknown**
- € **Other** (Specify) _____

Any Additional Comments:

_____