DATE: 10/4/11

FROM:

SUBJECT: **P**960007/S21
TransCyte®/Advanced BioHealing, Inc.

CONTACT: Ms. Andrea Loewen-Rodriguez

TO: **THE RECORD**

BACKGROUND/ REASON FOR SUPPLEMENT

Advanced BioHealing (ABH) requests authorization from the FDA to harmonize the use of Bovine Calf Serum (BCS) across the Cell Expansion and TransCyte Growth processes.

REVIEW TEAM

(b) (4)

INDICATIONS FOR USE

The device is indicated for use as a temporary wound covering for surgically excised full-thickness and deep partial-thickness thermal burn wounds in patients who require such a covering prior to autograft placement. It is also indicated for partial thickness burns that are mid-dermal to indeterminate depth burn wounds that typically require debridement and that may be expected to heal without autografting.

DEVICE DESCRIPTION

TransCyte is a human fibroblast-derived temporary skin substitute indicated as a wound covering for burn injuries as indicated. The product consists of human (b) (4) -derived fibroblasts from (b) (4) grown on a nylon mesh. The nylon mesh is coated with (b) (4) which is bound to the nylon with silicone. After the cells reach confluency, the grafts are (b) (4) to (b) (4) cells. The (b) (4) cells and the extracellular matrix proteins, as well as other secreted cytokines, are considered to be left on the nylon mesh.

PRECLINICAL/BENCH

BIOCOMPATIBILITY/MATERIALS

The sponsor proposed to change from use of fetal bovine serum (FBS) to bovine calf serum (BCS) as a tissue culture medium supplement. The sponsor used the following product parameters as a means of demonstrating product equivalence:

- In-process cell yield
- In-process cell viability
- In-process cell morphology

- Final product DNA content
- Final product collagen content

These parameters are considered indicators of the cell expansion process, whether as in-process determinations or final product specifications. All in-process and final product specifications, including evaluations for sterility, endotoxin and mycoplasma were determined as "passed".

ANIMAL STUDIES – None conducted or required

ELECTRICAL SAFETY - N/A

MECHANICAL SAFETY - N/A

SOFTWARE – N/A

CLINICAL DATA – N/A

SUMMARY OF INTERACTIVE REVIEW/CORRESPONDENCE - No interactive review or correspondence was required.

CONCLUSION

The information provided shows that the BCS supplemented medium supports human fibroblast cell growth to the same degree as FBS supplemented medium. The new calf serum caused the cells to grow with the same proliferative rates yielding the same numbers of cells/DNA and collagen as the fetal bovine serum supplemented medium. In terms of safety, endotoxin, mycoplasma and sterility determinations, as well as the serum lot certificate of analysis showed that the new calf serum was equally safe as the fetal bovine serum.

RECOMMENDATION - I recommend that the supplement be **Approved**.

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Reviewer name Date

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Name, Chief, Branch Date