



U.S. Pharmacopeia
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**2005-2010 Biologics & Biotechnology –
Cell, Gene, and Tissue Therapies
Expert Committee
Meeting #5
Tuesday, May 14, 2008
USP Headquarters, Rockville, Maryland**

Preliminary Agenda

Goals and Anticipated Outcomes

1. Updates on the Expert Committee Current Activities
2. Discuss the BB CGT EC General Information Chapters and Monographs
3. Discuss New Opportunities for the BBCGT EC

Attendees

Please see attached attendee list

Tuesday, May 13, 2008

6:00 p.m. Transportation from Hilton Rockville Hotel to Restaurant

6:30 p.m. Dinner

Wednesday, May 14, 2008

7:30 a.m. Chair Meeting with Dr. Williams/Dr. Abernethy Mr. Tente

8:00 a.m. Continental Breakfast

8:30 a.m. **1. Opening, Procedural and Administrative Matters** Mr. Tente

- a. Welcome, Call Meeting to Order
- b. Approval of Minutes of the Previous Meeting
- c. Approval of the Agenda
- d. Procedural and Administrative Announcements

Ms. Simpson

8:45 a.m. **2. Review and Update of Expert Committee Workplan**

- a. Progress against Set Targets
- b. Updates to Workplan
- c. CBER/OCTGT Visit to USP- Meeting Report
- d. Comments on FDA Guidance on Rapid Methods
- d. Comments on ICH Document on Viral Shedding
- e. Updates from the tissue-based products workshop

Mr. Tente
Dr. Atouf
Mr. Tente/Dr. Atouf
Dr. du Moulin /All
Dr. Hutchins/All
Mr. Tente/Dr. Weber

10:15 a.m. Break

10:30 a.m. **3. Monographs under Development**

- a. Human Acellular Dermal Matrix
- b. Collagen Nerve Conduit
- c. Non-Crosslinked Bovine Collagen Matrix
- d. Fibrillar Bovine Tendon Collagen
- e. Crosslinked Collagen-Chondroitin Sulfate Scaffold
- d. Collagen Nerve Guide
- f. Crosslinked Collagen-GAG Scaffold with Silicone Membrane
- g. Naming Cell and Tissue therapy products

Dr. Weber
Dr. Croyle
Dr. Croyle
Dr. Atouf
Dr. Atouf
Dr. Atouf
Dr. Atouf
Dr. Weber

12:00 noon Lunch

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- 1:00 p.m. **4. Ancillary Materials**
a. Cytokines in Cell Manufacturing- IL-4, <92>
b. Bovine Serum Chapters, <1024> and <90>
Dr. Provost
Dr. du Moulin
- 1:45 p.m. **5. Cell and Gene Therapy Products <1046> Revision**
a. Cell and Tissue-Based Products <1046> Status
b. Gene Therapy Products <1047> Status
c. Committee Discussion
Dr. Weber
Dr. Hutchins/Dr. Ridgway
- 2:45 p.m. **6. Test Kits Ad hoc Advisory Panel**
a. Validation of Assays using Commercial Kits <1098> Status
b. Committee Discussion
Dr. Hutchins
- 3:15 p.m. **7. Flow Cytometry Ad hoc Advisory Panel**
a. Flow Cytometry <1027> Status
b. Committee Discussion
Dr. Read
- 3:45 p.m. **8. Next Steps and Action Items- Next Meeting**
Mr. Tente
- 4:00 p.m. **Adjourn**