GASTROENTEROLOGY AND UROLOGY DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE

June 25, 2008
Hilton Washington DC North, Gaithersburg, MD
DRAFT Agenda
Panel Chair: Mark Talamini, M.D.

Location: Gaithersburg, Maryland

NOTE: Two fifteen-minute breaks and a one-hour lunch break will be determined at the discretion of the panel chair

CALL TO ORDER: **8:00 a.m.**

Deputization to Voting Member Status Statements
Introductions
Office of Surveillance and Biometrics Post Market Studies Update: Danica Marinac-Dabic, MD, PhD

OPEN PUBLIC HEARING* **8:30 a.m.**

Public attendees will be given an opportunity to address issues specific to the matter before the committee. Public observers may not participate except at the specific request of the Chairperson.

OPEN COMMITTEE DISCUSSION

1. **Sponsor Presentation:** **8:45 to 10:00 a.m.**
   (75 Minutes)

1.	Introduction	Dr. Yagel Koren, Medical Director, MEL
2.	Treatment Options	Michael O'Donnell, MD, University of Iowa
3.	Device Description and Preclinical Studies	Ahava Stein, Consultant
4.	Clinical Studies	Fred Witjes, MD, Radboud University, The Netherlands
5.	Summary and Conclusions	H. Barton Grossman, MD, MD Anderson Cancer Center
6.	Post Approval Study	Michael O'Donnell, MD, University of Iowa

Break (optional) **10:15 a.m.**

2. **FDA Presentation**: **10:30 to 11:45 a.m.**
   (75 Minutes)

   1. Regulatory History / Pre-Clinical Studies – John Baxley, M.S. (10 minutes)
   2. Clinical Overview of the Disease – Hector Herrera, M.D., MPH (10 minutes)
   3. Clinical Considerations – Robert Kane, M.D. (30 minutes)
   4. Statistical Considerations – Xuefeng Li, Ph.D. (15 minutes)
   5. Post Market Review – Shaokui Wei, M.D., MPH (10 minutes)

3. **Questions on the Presentations** **11:45 a.m. to 12:00 p.m.**

Lunch - 1 hour **12:00 p.m. to 1:00 p.m.**

4. Panel Discussion:

The committee will discuss, make recommendations, and vote on a premarket approval application, sponsored by Medical Enterprises, Ltd., for a drug/device combination product designed to prevent recurrence of bladder cancer. Synergo SB-TS 101.1 Device with Mitomycin C is indicated for use for prophylactic treatment of recurrence in patients following endoscopic removal of Ta-T1 and G1-3 superficial transitional cell carcinoma of the bladder (STCCB). Ta-T1 refers to the stage of the tumor, which is a measure of how deep the tumor penetrates into the bladder wall, with Ta and T1 being the most superficial stages for raised bladder tumors. G1-3 refers to the tumor grade, which is a measure of how aggressive the tumor is likely to grow, with G1 being the least aggressive, and G3 the most. Synergo and Mitomycin C treatment is clinically indicated for STCCB patients of intermediate and high risk.

1. General Discussion
2. Reading of Questions for the Panel and Discussion.

Break (optional) **2:45 p.m.**

OPEN PUBLIC HEARING* **3:00 p.m.**

Public attendees will be given an opportunity to address issues specific to the matter before the committee. Public observers may not participate except at the specific request of the chairperson**.**

6. Final Comments **3:30 p.m.**

1. FDA Comments
2. Sponsor Comments

7. Panel Deliberations and Vote **3:45 p.m.**

8. Adjournment **5:00 p.m.**

*OPEN PUBLIC HEARING

Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.

NOTE: All times are approximate.