

Seventy-first Meeting of the
Obstetrics and Gynecology Devices Panel

Tuesday, March 28, 2006
Gaithersburg Hilton, Gaithersburg, MD

**General Topic Discussion – Pivotal Studies to Evaluate New
Treatment Modalities for Symptomatic Uterine Fibroids**

General Topic Overview

Interest in the development of new device systems for treating symptomatic uterine fibroids continues to grow. In the past 2-3 years, FDA has cleared two embolic agents and one new focused ultrasound system for this indication. As FDA provides input on the design of clinical trials for these new treatment modalities, panel input on some of the key clinical trial design issues will be helpful.

In particular, FDA is interested in developing a model (or models) for clinical trial design of devices intended to treat symptomatic fibroids. Although one design may not be uniformly applied due to the differences in the device designs and their mechanism of action, establishing a general model would help us to maintain an even playing field while obtaining relevant and clinically meaningful scientific information on new treatment modalities.

We have included several articles from peer reviewed journals describing studies on fibroid treatment or outcome measures.