# Meeting of the Advisory Committee for Reproductive Health Drugs

# December 2, 2004

## Overview

Donna Griebel, MD
Division of Reproductive and Urologic Drugs

# Testosterone Transdermal System

For the treatment of hypoactive sexual desire disorder in surgically menopausal women receiving concomitant estrogen therapy

# Agenda

- 8:00 - Opening Remarks
- 8:20 - Dr. Judith Hsia - Assessing Risks of Hormonal Interventions
- 8:40 - Procter and Gamble Presentation
- 10:10 - Break
- 10:25 - Dr. Adrian Dobs - Safety of Exogenous Testosterone in Women
- 10:45 - FDA presentation
- 11:30 - Open Public Hearing

# Agenda

- 12:30 - Lunch
- 1:30 - Questions from the Committee to Applicant and FDA
- 2:30-5:30 - Committee Discussion and Vote on FDA Questions

# Questions to the Committee

- **Question #1 –**

  **Do the efficacy data represent a clinically meaningful benefit above that of placebo for surgically menopausal women with Hypoactive Sexual Desire Disorder (HSDD) who are taking concomitant estrogen?**

- **Question #2 –**

  **In the safety database, 494 surgically menopausal women were treated with TTS in combination with estrogen for 12 months. Of these, 127 were treated for 18 months. There are no long-term placebo comparative safety data beyond 6 months. The expected TTS use will be chronic in the intended population.**

  **Is this exposure (total number of women treated and duration of treatment) adequate to demonstrate long-term safety?**

- **Question #3a. –**

  **Are there safety concerns or unanswered questions associated with use of TTS in combination with estrogen that need to be studied (e.g., questions about cardiovascular or breast cancer outcomes, or questions about risks and benefits in populations who are likely to use this product off-label)?**

- **Question #3b. -**

  **If yes, what are these safety concerns or unanswered questions?**

- **Question #3c.**

  **Should these safety concerns or questions be studied prior to approval of the product?**

  - **If yes, what study(ies) do you recommend? Please comment on study populations, designs, endpoints, etc.**
  - **If no, what type of study(ies) do you recommend post-approval? Please comment on the Applicant's proposed claims based cohort study.**

- **Question #4 –**

  **Are the efficacy and safety data adequate to support approval of TTS?**