FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee (NDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
November 9, 2012

DRAFT QUESTIONS TO THE COMMITTEE

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1. **VOTE:** Does the totality of the data support that consumers can appropriately self-select to use the oxybutynin transdermal system (TDS) in an over-the-counter (OTC) setting? In your answer, please discuss how the study participants in the actual use study who had ineligibilities should be viewed, bearing in mind the safety data from the actual use study.

2. **DISCUSSION:** Given that some of the pre-specified endpoints were not met in the Label Comprehension Study (LCS), which concepts, if any, are you concerned about in the LCS data? If you have concerns, please discuss.

3. **DISCUSSION:** The data show that some subjects whose symptoms did not improve or worsened continued using oxybutynin TDS beyond the two weeks proposed in the labeling, in order to see if it needed more time to work. Please discuss your level of concern regarding consumers not stopping use of the product if their symptoms have not resolved.

4. **DISCUSSION:** Please discuss any safety concerns about potential delay to diagnosis of conditions with similar symptoms.

5. **DISCUSSION:** Based on the information included in the briefing materials and presented today, please discuss whether the content of the proposed package label is acceptable for OTC marketing. If you think that the content of the label should be improved, please discuss additional concepts that should be conveyed to the consumer on the OTC package label. (Current prescription labeling and proposed OTC labeling are in Appendix 1 and 2 of the FDA briefing document.)