Food and Drug Administration

Center for Drug Evaluation and Research

JOINT MEETING BETWEEN
THE ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE (EMDAC)
AND
THE ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)

October 4, 2006

Gaithersburg Hilton, The Ballrooms
620 Perry Parkway
Gaithersburg, MD

Proposed Questions for Discussion

1. Does a 10% loss in potency over shelf life raise clinically significant concerns?

2. If there are clinically significant concerns, should the potency specifications for levothyroxine sodium products be narrowed (e.g., from a minimum potency loss of 10% (a 90-110% potency specification) to a minimum loss of 5% (e.g., 95-105% potency specification)?