

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

***Endocrinologic and Metabolic Drugs
Advisory Committee Meeting
September 8, 2004***

Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave, Bethesda Maryland

FDA Background Package

Table of Contents

- Tab 1** Division Memo
- Tab 2** Draft Agenda
- Tab 3** FDA Draft guidance document “Guidance for the
Clinical Evaluation of Weight-Control Drugs”
- Tab 4** FDA approved obesity drugs
- Tab 5** Article: National Trends in Antiobesity Medication Use;
Randall Stafford, M.D., Ph.D., and David C. Radley, BA
- Tab 6** FR Notice 69; January 26, 2004; Request for Comments
on Draft Guidance on the Clinical Evaluation of Weight-
Control Drugs
- Public comments submitted to Docket No. 2003-0570,
In response to FR Notice 69
- Tab 7** ICH -E1A guidelines March 1995
- Draft Guidance for Industry Pre-marketing Risk
Assessment