

Joint session of the
Nonprescription Drugs Advisory Committee
and the
Endocrinologic and Metabolic Drugs Advisory Committee

January 13 and 14, 2005

NDA 21-213- proposing over-the-counter Mevacor™(lovastatin) 20mg

Index

- Tab 1 Discussion Points to Consider
- Tab 2 Background
- ❖ Attachment 1: Guidance to Industry
 - ❖ Attachment 2: NCEP ATP-III Guidelines
 - ❖ Attachment 3: NCEP report/update to NCEP ATP-III
 - ❖ Attachment 4: Abstract from Ahmed F. and Jacobson IM
 - ❖ Attachment 5: Publication – Chalasani et al.
 - ❖ Attachment 6: Letter from Dr. Paul Watkins
 - ❖ Attachment 7: Letter from Dr. Keith Tolman
- Tab 3 Memo: Statistical Review (AFCAPS/TexCAPS)
- Tab 4 Memo: Pharmacology/Toxicology Review (Pregnancy Category X)
- Tab 5 Memo: Consumer Behavior Issues Related to the Marketing of Mevacor OTC
- Tab 6 Review of the Mevacor™ OTC Label Comprehension Study
- ❖ Executive Summary
 - ❖ Label Comprehension Study Review
 - ❖ Attachment 1: Questions from Label Comprehension Study
- Tab 7 Consumer Behavior Safety Data (Review of the CUSTOM Actual Use Study)
- Tab 8 Draft Label