

**Introduction: Non-Prescription
Mevacor® 20 mg
Joint Advisory Committee Meeting
NDA 21-213**

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New Model for an OTC Drug

- Treat asymptomatic disease
- Long term compliance necessary to obtain benefit (prevent first heart attack)
- Laboratory monitoring to assess efficacy
- Requires highly motivated individual to decide to use the product according to product label for a long period of time

Drug Related Hurdles for OTC Marketing

- Assessment of relative safety
- Adverse events associated with therapy
 - Risk of serious muscle injury
 - Risk of liver injury
- Conditions that may increase the risk of adverse events
 - Population at risk
 - Underlying liver injury
 - Pregnancy or use by women of child bearing potential
 - Drug interactions

Disease Related Hurdles for OTC Marketing

- Multiple steps to assess eligibility criteria for self selection
- Monitoring and knowledge of cholesterol levels
- After initiating therapy, change in risk (e.g. new medication) that may necessitate stopping OTC therapy
- Benefit derived from long term use

Consumer Behavior Studies

- Label Comprehension Study
 - Results used to adjust label prior to an actual use study or prior to marketing
 - Not always predictive of behavior (e.g. Consumer understands the label but they do something different)
- Actual Use Study
 - Self selection
 - Deselection

Results from Consumer Behavior Studies

- Based on education and literacy, cannot expect 100% success for all of the objectives (some are more important than others)
- Threshold for tolerating behavior errors
 - dependent on the health consequence of the error
- Extrapolation to an OTC population



Analyses

- According to label criteria
- According to Label, Medically Acceptable for Self Management (AL-MASM)
- Closely adhering to label benefit criteria
- Complementary Assessment of Benefit and Safety (CABS)
- AB-MASM, NAB-MUSM, NAS-MUSM

Population

- Who is this product directed to:
 - People who fit the criteria on the proposed Mevacor label
 - Any person who fits the NCEP guidelines for treatment
 - People who have an interest in their health and lowering cholesterol
 - United States Population

Other Relevant Information

- OTC Drug Advertising Regulated by the FTC
 - Important because advertising will lead consumers to look into using the product
- Economic Implications of Switch
 - When considering a drug for switch, FDA does not take economic considerations into account during the decision process
 - Cost of the drug
 - Insurance coverage