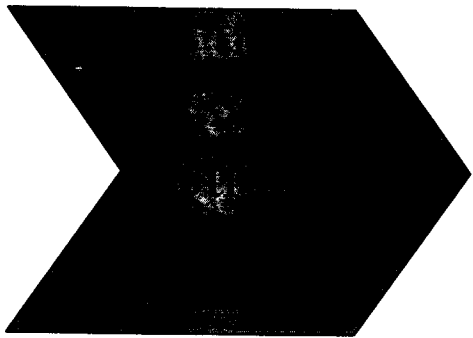
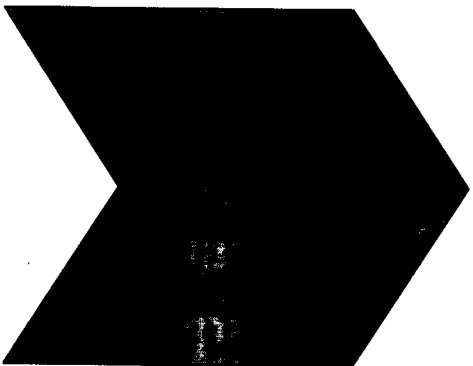


# Trademark Development: Marketing Activities

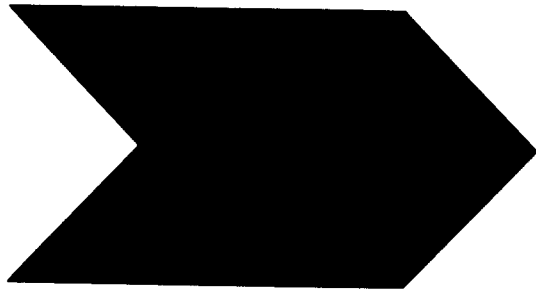


- \* Brand attributes
- \* Competitive marketplace

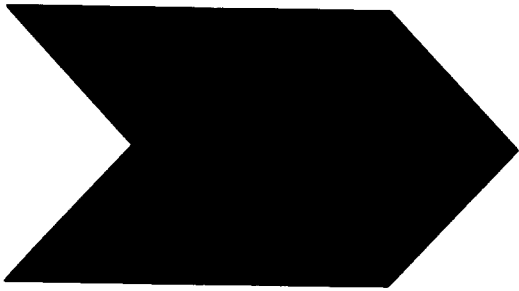


- \* Focus groups
- \* Develop candidates

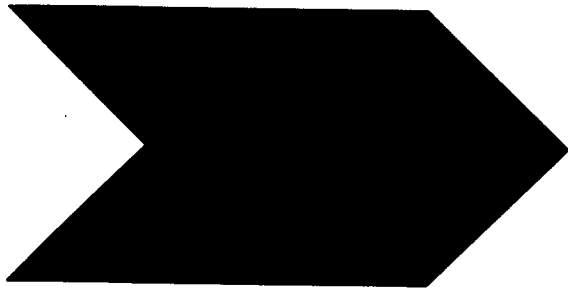
# Trademark Development: Legal Activities



- \* Search for similar marks
- \* Risk assessment

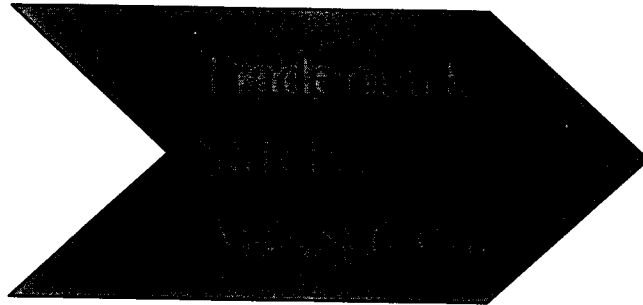


- \* Review / filing
- \* Notification / publication
- \* TM issuance (2 years)

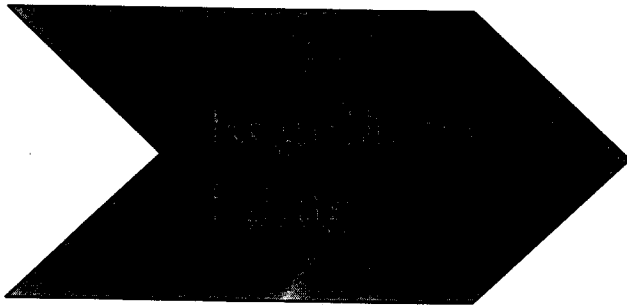


- \* TM filings
- \* New drug approvals

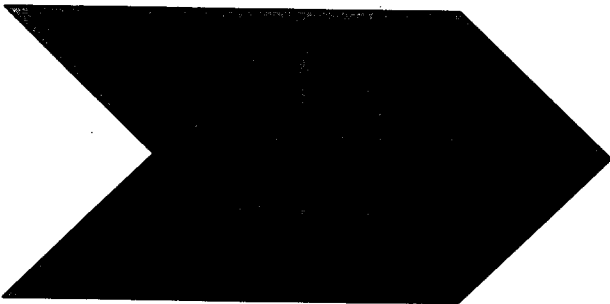
# Trademark Development: Regulatory Activities



- ★ Dispensing testing
- ★ Recommendations



- ★ Regulatory submission
- ★ Preliminary approval



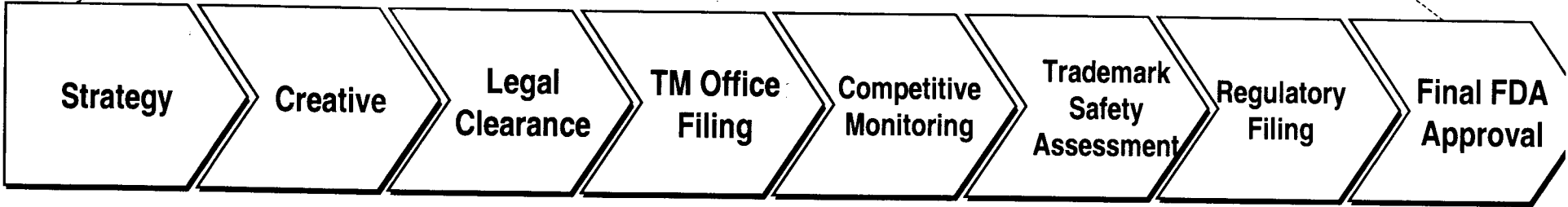
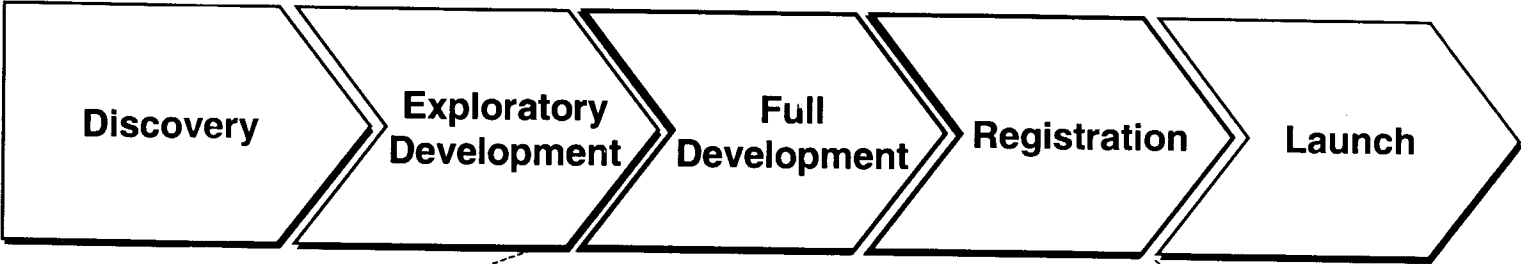
- ★ NDA submission
- ★ Additional testing
- ★ RM plan or alternate name selection



# Current Regulatory Challenges in Trademark Evaluation Process

- ✱ Predictability of medication error model
  - ✱ Validation of methods
  - ✱ Level of evidence to FDA clearance
- ✱ Error threshold
  - ✱ Zero-tolerance vs. risk/benefit
  - ✱ Risk management toolbox
- ✱ “Train wreck” scenario
  - ✱ Timing of submission
  - ✱ Alternatives to last-minute name change

# Product Development Process



# Trademark Development Model