



Industry  
Recommendations on  
Evaluating OTC  
Consumer Behavior

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# Industry/FDA History on Consumer Behavior Research

- CHPA Regulatory and Scientific Conference workshops
  - Consumer Behavior Roundtable – 2005
  - Points-to-Consider Document
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# Recommendations for Evaluating Consumer Behavior

*Decisions about whether  
consumer behavior is “acceptable”  
should be based on actual risk to  
consumer*

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# When Evaluating Consumer Behavior

- ❑ No magic overall number for success/failure
  - ❑ All non-compliance is not the same
  - ❑ An “incorrect” response may be an appropriate behavior
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# No “Magic Number”

- Risk of non-compliance not the same for all label statements
  - Each label statement/drug must be analyzed separately
  - No one overall number of acceptance
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# All Non-Compliance Not The Same

- Non-compliance dosing w/low tox drug  $\neq$  non-compliance w/contraindicated drug
  - Evaluation of consumer behavior based on consumer risk
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# An “Incorrect” Response May Be An Appropriate Behavior

- Response may be benefit/risk decision
  - Need to understand thought process
  - Must consider medical significance of “incorrect answer/action”
  - “Talk to doctor” should not be incorrect in self-selection studies
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# Recommendations

- Pre-define OTC label elements critical to safe use
  - Focus on the basis for consumer decisions
  - Consider wide variety of real-world consumer behavior data
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# Pre-Define OTC Label Elements

- Risks are captured in OTC labeling
    - Based on Rx use history
    - Consumer behaviors that may lead to potential risk
  - Predefine label elements critical for safe use in an OTC setting
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# Focus on Understanding Consumer Decisions

- Understand basis for consumer decision
  - Self-reported information is valid
  - OTC drugs should be approved if:
    - Risk of non-compliance to critical label elements is low
    - Lack of intermediary doesn't present an additional risk to the consumer
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# Must Consider Real-World Consumer Behavior Data

- Consumer habits and practices
  - Consumer surveys
  - In-market use patterns
  - Targeted educational programs
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# Remarkable OTC Safety Record

- >25 Rx-to-OTC switches approved
    - in part on consumer behavior data
  - Consistent record of overall safety
  - No products removed
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# Summary

Evaluating whether consumer behavior  
is “acceptable” should be  
based on actual risk to consumer

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