

FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)  
Meeting of the Nonprescription Drugs Advisory Committee

September 25, 2006

Questions

Design, Statistical Considerations and Study Conduct

1. There are no clear guidelines regarding the number of people that should be enrolled into label comprehension, self-selection, and actual use studies. Please discuss the sample size that should be used in each type of study and describe the basis for your response.
  - a. In some applications, there is a need to be assured that certain populations at risk for serious harm are excluded from using the drug. We often ask for a self selection study in a group of these patients to assess whether they may consider using the drug. Please describe what sample size should be considered for these types of studies.
2. Please discuss how the data from consumer studies should be presented for interpretation with regard to point estimates, confidence intervals, or statistical measures.
  - a. Can a threshold of success be defined where anything above the threshold is considered some guarantee that the sponsor met the standard for switch? Please discuss when this should be considered, for what types of studies and how we should determine at what level of success (e.g. 75%, 95%).
3. In assessing the ability of consumers to self select, it is often difficult to ask the question without the potential for biasing the answer. Please discuss how self selection may be ascertained with minimal bias to the consumer.
4. Many companies want to use purchase decisions as the metric for assessing self selection. FDA has refrained from using this metric because there may be other factors that influence the decision which may be totally unrelated to the consumer understanding the label (e.g. lack of interest in the product, cost). How should this type of data be viewed by FDA in the assessment of self selection?
5. It can be difficult to verify specific aspects of a self-selection decision. For example, verification of a consultation with a participant's personal doctor can be burdensome. Under what circumstances is it necessary to verify these components of the self-selection decision and how should verification be accomplished?
6. Consumer behavior studies are generally open label single arm studies. Discuss under what circumstances FDA should request that multiple arm studies be considered whereby the differences in the arms reflect a comparison of different labels or differences in ancillary measures (e.g. package insert versus no package insert).

7. OTC products may be used intermittently, or have limits on the duration of continuous use (e.g. internal analgesics have 10 day limit for pain treatment), or have a set period of use to achieve clinical benefit (e.g. nicotine replacement products). Please discuss the factors that should be considered in determining the duration of actual use studies.

### Labeling

1. How should we determine which information is essential for self-selection and use and therefore must be on the Drugs Facts Label and what information could be provided in a package insert?

### Data Analysis and Interpretation

1. Some products may have multiple criteria for a consumer to consider when determining whether they are eligible to use the product (e.g. cholesterol lowering agents). What standard should be applied when interpreting self-selection data for these types of products?
2. Companies often want to include responses as being correct, even though they do not conform exactly to the labeled information. How should these types of responses be evaluated in the assessment of consumer behavior? If they are going to be permitted, should they be pre-specified in the protocol of the study?
3. How should data from low literate subjects be evaluated relative to data from the general population of subjects included in the studies? Alternatively, should FDA just require a certain percentage of low literate subjects be included in the study and conduct analysis only on the whole population?
4. What type of information can provide more confidence that these studies are predictive of actual consumer behavior in the marketplace?