



Date: April 11, 2005

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number 2005N-0016
Response to FDA Call for Comments
Agency Information Collection Activities; Proposed Collection; Comment Request
Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer
(DTC) Print Advertisements for Prescription Drugs: Study1

Dear Sir or Madam:

Reference is made to the Federal Register notice of February 8, 2005 announcing the request for comments on Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs: Study 1.

AstraZeneca has reviewed this proposed collection of information, and the proposed survey instrument and we support the FDA's plan to conduct in-context consumer research regarding DTC print advertising, specifically to understand the nature of consumer' goals when reading risk information and to measure the relative usefulness of that risk information. Since we know what consumers say does not always align with what they do in real world situations, we agree that exposing consumers to actual print advertisements will produce significantly more accurate results than general surveys that are detached from actual print advertising.

The FDA has requested comments on the proposed collection in specific areas, three of which will be addressed below.

- 1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

While we feel this study will not necessarily provide all the data necessary for guidance on policy around the presentation of risk information in print advertising, it is a necessary first step. We support the overall objective of first understanding what consumers are trying to learn from the print ad. Without this base understanding of consumer behavior specific to print advertising, we cannot expect to successfully fulfill consumers' information needs. While this is not a segmentation exercise to develop different approaches for different consumer needs, it could be potentially short-sighted to dive into the development of print ad concepts to test without first

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short-sighted to dive into the development of print ad concepts to test without first understanding how and why we need to provide this information in the minds of target consumers. Uncovering those needs in the context of actual advertising (as proposed) is critical, in our opinion.

- 2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used and 3) ways to enhance the quality, utility, and clarity of the information to be collected

Phase I Design Recommendation:

One of our questions is whether a quantitative study focused on altering severity of risk using hypothetical product concepts is the optimal first approach to deliver the objective of uncovering consumer goals in a print advertising context. We recognize there are always resource constraints in the amount of research that can be executed, resulting in strategic tradeoffs. However, in an optimal world we would recommend qualitative one-on-one interviews for this phase of research, where the goal is depth of understanding of consumer objectives and needs across conditions, education levels and treatment scenarios (i.e. diagnosed treaters, diagnosed non-treaters, at-risk and caregivers). Having in-depth conversations will be more insightful in helping us map consumer goals and perceptions around the presentation of risk information in print advertising. Conversely, the structure of a quantitative questionnaire will not allow as rich a discussion, limiting understanding. We feel such in-depth understanding of the status quo is a base requirement before considering alternative print communication approaches to test quantitatively.

Also please note that when it comes time to quantitatively understand how much of the risk information is being read and how much time consumers spend with the ad, there are eye-tracking technologies that can provide more accurate insight into that process vs. self-reporting.

Product Concepts Recommendation:

Assuming our recommendation of qualitative research, we recommend presenting real ads for products currently marketed in the relevant therapeutic categories. We do not feel in our recommended qualitative approach that there is a need to create hypothetical product concepts, assuming FDA can identify products across the categories of interest with a range of risk severity. We feel we should replicate as real world a situation as possible for these base understanding discussions. Reality is that consumers will sometimes be aware of a product they read about, sometimes be taking a product they read about and sometimes be contemplating treating their condition but not yet be aware of any related treatments. The current quantitative study assumes everyone is new to the product, which may not represent the breadth of consumer goals. Exploring needs and perceptions using actual ads for actual products across the possible awareness scenarios would be more representative and insightful in developing a baseline understanding.

Survey Tool Comments and Recommendation:

We think it is appropriate that the current questionnaire starts out with a focus on the ad overall, without focusing too quickly into the risk information. That is a more real world discussion. However, we recommend uncovering as much of those needs and perceptions unaided, which obviously lends itself more to a qualitative discussion. If the goal is needs identification, there is a lot of benefit in initially allowing consumer needs and perspectives to bubble up vs. leading with pre-determined statements. We feel that presents a truer picture of how the consumer is reacting in a real world situation. Currently, Q4ai potentially seeds objectives that may not come up naturally, and Q3b may not be enough from an unaided point of view (i.e. “questions people have in mind” may be different than the goals they have in reading the ad). There is absolutely value in focusing in on the information of interest in an aided way, just not too quickly in the body of the questionnaire/discussion guide. If consumers do not actively bring up concerns or issues with the risk information within the context of the overall ad, for instance, that by itself may tell us something about their information needs.

Sample Comments and Recommendation:

Regarding the quantitative sample matrix recommended by the FDA, we have 2 general areas of comment. Without having more detail on the analytic plan, one area of potential further consideration is total sample size. As proposed, the current sample size will only allow the following levels of comparison assuming a minimum of 75 respondents per cell:

- High severity vs. low severity across all conditions (216 per cell)
- Diagnosed vs. at-risk vs. caregiver across all conditions (144 per cell)
- Cholesterol vs. obesity vs. asthma vs. allergies (108 per cell)
- Some high school or less vs. completed high school vs. some college or less vs. completed undergraduate college or more across all conditions (108 per cell)*

**Please note that we are recommending more segmentation in the education factor, specifically including more less educated (high school or less) respondents. Given the composition of the population at large, there is benefit in going below some college education. As we explore goals, needs and comprehension, one could make the argument that full representation from an educational level is one of the more critical factors for the study.*

The current sample size will not allow the following analytical comparisons, which could be helpful in better understanding consumer objectives and needs between groups. We’ve included the necessary total sample size, assuming a minimum of 75 respondents per cell:

- Diagnosed vs. at-risk vs. caregiver within each condition (900 respondents)
- High severity vs. low severity within each condition (600 respondents)
- High severity vs. low severity within diagnosed/at-risk/caregiver (450 respondents)
- Education level (4) within each condition (1,200 respondents)

Secondly, we also suggest ensuring a mix of currently treating and currently not yet treating (excluding lapsed/stoppers) within the diagnosed population, as that reflects reality.

If a qualitative study were pursued, we recommend a good mix of the groups proposed by the FDA with our suggested additions. We would conduct no less than 10 interviews per each of the four therapeutic areas outlined, ideally 15, to ensure some representation of the sub-groups noted above. Again, the goal would be depth of understanding initially, not statistical representation. We feel this would better optimize the development of alternative concepts to test and the survey tool used to test them.

We have no additional comment on the 4th area: ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

AstraZeneca appreciates the opportunity to provide comments for consideration during the development of this study. Please do not hesitate to contact us should you have any questions.

Sincerely,



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Enclosure