

CALIFORNIA



June 25, 2003

Ms. Brenda Derby, Ph.D.
 Food and Drug Administration
 Center for Food Safety and Applied Nutrition
 Office of Scientific Analysis and Support
 Division of Market Studies (HFS-727)
 5100 Paint Branch Parkway
 College Park, Maryland 20740

Dear Brenda:

During our meeting on June 3, 2003 to review issues presented by the health claim petition submitted on behalf of the California Walnut Commission (CWC), you brought to our attention the agency's consideration of a study of consumer perception of nutrition information referred to as "The Burke Study". There was some dialogue concerning the findings of the Burke Study, and I identified a number of methodological limitations which prevent more generalized conclusions from being drawn concerning the perception of nutrition and health information presented to consumers in contexts differing from those presented in the Burke Study. I emphasized that these limitations make it impossible for valid scientific conclusions to be drawn concerning the perceptions of the walnut/CHD health claim proposed in the health claim petition submitted on behalf of the CWC in the contexts in which that information would be presented to consumers in the marketplace.

Following our meeting, I submitted the Burke Study to Mr. Steven Rose of the *rose research*, for evaluation. *rose research* is the marketing research firm that is responsible for conducting the majority of market research studies concerning consumer perceptions relating to walnuts in the United States and internationally for more than 10 years. Prior to founding *rose research*, Mr. Rose served as executive vice president and partner of Yankelovich Market Research and is credited with developing many of the state-of-the-art market research models for evaluating consumer perceptions and behavior that have been well established and widely used since the late seventies. The majority of the market research that has been conducted concerning walnuts is aimed at assessing the "consumer climate" – which affects how walnut information is likely to be received and processed by consumers in varying contexts. The existing knowledge, understanding, and misconceptions consumers have concerning walnuts is characterized in such research so that these factors can be

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Ms. Brenda Derby, Ph.D.
June 25, 2003
Page 2

considered in the development of specific marketing information aimed at improving consumer knowledge concerning the benefits offered by walnuts.

Mr. Rose has conducted thousands of consumer studies over his thirty plus years in the market research business.

Based on the evaluation provided by *rose research*, the following comments on the methodology and findings of the Burke Study are offered on behalf of the CWC. Our comments address the validity and reliability of the research, in view of the sampling methods and sample size employed, and key design features of the survey. We also comment on some of the basic tenants that govern market research as well as packaging issues which merit consideration in the interpretation of the finding reported in the Burke study. Finally, we address the impact of brand dynamics and how brand versus brand or commodity versus commodity differs in such an exercise. The last item for discussion in this letter will cover the issues that govern consumer choices.

1. **Sample size** - Sample size is critical to the reliability of any consumer research. A sample having a size of 200 respondents is the minimum standard for a simple consumer survey designed to assure some level of reliability and predictive value. The statistical reliability of a sample composed of 200 respondents (if it is representative of the target audience and/or the U.S. population in general) is plus or minus 12-15%. A sample size of 500 would reduce that range down to 6-7%. Thus, the probability of a sample size of 500 yielding a more accurate result is approximately twice that of a sample size of 200, based on established standards governing survey evidence.

Quite often, however, a larger sample size is necessary to achieve particular study objectives. Specifically, the need for a larger sample size becomes important when multiple variables are being tested (and compared) against one another. For example, when comparing and analyzing the distinctive findings for different cells (i.e., comparing different packaging designs, commercials, positionings, and/or claims), a minimum of 200 respondents is needed for each cell. I will clarify this in more detail. For example, if there are three different packaging designs to be compared (packages A, B, and C) and each of these provides the context for the same health claim statements, there are six possible package/claim combinations ($3 \times 2 \times 1 = 6$) for presenting the information to be tested to the consumer. A minimum sample size of 1200 (6 cells of 200 each) would be desirable in that case. In addition, if three health claim iterations were tested with a total sample size of 400, this would be equal to a sample size per cell of 66 subjects making such a study qualitative not quantitative.

Note: It is critical that a quantitative study utilize a sample of respondents that is statistically representative of the United States. If this is not done, the research results cannot be relied upon to predict any behavior or response.

Ms. Brenda Derby, Ph.D.
June 25, 2003
Page 3

2. **Controlling for Regional Bias** - The sampling methodology used in the Burke Study failed to control for regional bias. The study was done in only one urban area. In determining the sample size and/or the number of cells to be utilized in market survey research, one must account for sources of bias which are related to the regional characteristics of consumers and which may affect their responses to survey questions. To illustrate regional bias, one may consider consumer coffee preferences. Coffee products are specially blended to appeal to the distinctive taste preferences of consumers in different regions of the country and this can affect consumer perceptions. Claims expressing state of origin information also illustrate the role of regional bias. Consumer perceptions and acceptance of "California" grown oranges may differ in Florida, than in other states. In the case of nuts, the Southeast and Southwest have a natural preference for peanuts and pecans. Because of the complex variables which may interact to bias survey findings on a regional basis, there must be control through appropriate sampling methodologies (size and scope of survey sample). The findings from survey data in the Burke Study were collected from isolated markets and relied on relatively small survey samples. The findings, therefore, cannot support generalized scientific conclusions that are predictive of target consumer group behavior.
3. **Statistical Sampling Methodology** - The Burke Study relied on survey samples drawn from specialized venues characterized by populations that are unlikely to reflect the demographic features and diversity of the general consumer population. Based on the profiles of the study subjects reported, there is no evidence that statistical sampling methodologies were employed, or that the subjects are representative statistically of the general consumer population in the United States. It is not apparent in the Burke Study as to whether or not there were adequate controls and in addition, since there were three packages, the packages should have been presented in six different orders. Given the size of the sample, six cells would have yielded nothing more than qualitative data.
4. **Collecting Information versus Proving Hypothesis** - In the case of the Burke Study, the development of hypotheses makes this study more akin to a positioning study than to the collection of information regarding behavior. One must be consistent in developing the hypothesis to be tested so that the research does not generate a predetermined end point by its design.
5. **Packaging Design** - Packaging design is a critical component affecting consumer perception and purchasing behavior. In the Burke Study, there is no evidence that the survey methodology was constructed to account for the common sources of bias that must be controlled in consumer tests of product packaging to yield reliable scientific results. The issues that must be considered to eliminate bias are similar to the regional bias but also may include category

Ms. Brenda Derby, Ph.D.
June 25, 2003
Page 4

specific identification such as package color. Private label products rely on borrowing equity from leading brands using similar colorization and graphic design.

In the Burke Study, in order to measure the new packaging and consumer receptivity towards it, consumers were asked the following battery of questions:

- Purchase intent—how likely would you be to buy brand X if you were shopping today and it were available at an acceptable price?
- Would you buy brand X regularly or would it be a one time only purchase?
- How different is brand X's package from other similar brands in the market?
- Does the new package fit with your image of brand X?
- How likely would you be to switch to brand X if it were sold in this package?

Subsequently, the consumer would be asked to provide attribute ratings to the packages in question. Again, if three packages are tested, six different orders of presentation are necessary in order to eliminate the bias that one package can lead to in evaluating another. Further, if any of the packages appeared to represent an existing brand (design elements, coloration, etc.) that brand would have more equity and therefore the test would be biased.

The Burke Study provides no information establishing that the methodology was implemented in a manner that adequately controlled for influence attributable to the sequence used to present the different packaging designs to consumers, or the choice of brand names used for the test packaging. These would be two critical factors in determining whether or not one brand had equity over any of the others.

Package tags and flags normally bring about stimulate increased consumer attention and interest in the packaging tested. However, the degree and nature of the enhanced consumer interest will depend on the design, color and positioning of the tag or flag. If the information presented is obscure, then logically one would assume the researcher would call attention to this information. That would automatically result in a bias. If we rely on the consumer to locate the claim on the package it may not be noticed, therefore it could be that this study would have provided better data if the claims were evaluated without packages.

There are other key questions about evaluating a brand for a particular commodity or a line of products. The reputation of existing brands in the category would be one of the factors and the appropriateness of the brand for that particular product would be another. It could very well be that the sameness of the reaction to the package stimuli is a result of the nonexistence of the brands image (quality, price, value, etc.). One could argue that this would make the test "cleaner." However, in the real world, the brands that carry these tags or flags

Ms. Brenda Derby, Ph.D.

June 25, 2003

Page 5

would have equity. Therefore, they would impact the result of this test in a far different fashion.

6. **Factors Motivating Consumer Brand Selection are Distinguished from those Motivating Food Choices** - In the case of the Burke Study, peanut oil claims were evaluated using different packaging contexts. This is to say that all consumers were offered the choice of one product, peanut oil. The selection of which peanut oil was based on stimuli, such as package, brand name and a labeling claim/information. The factors which influence consumer brand selection for a given product are substantially different and more limited than the multiplicity of factors influencing consumer behaviors concerning the choice of one food versus another. Findings related to brand selection (brands of peanut oil) cannot be generalized to predict consumer behavior concerning different foods (e.g., walnuts versus almonds versus peanuts).
7. **Complexity of Factors Motivating Consumer Food Choices** - For more than 30 years annual studies have been conducted to characterize the factors which determine consumer acceptance of food products. The "taste" of a food consistently is found to be most important in determining consumer acceptance, including for nuts. This means that a consumer who prefers the taste of "walnuts" to other nuts will choose to consume walnuts when presented with that choice. The same would be true for Brazil nuts, hazel nuts, almonds, etc. It is highly unlikely that a consumer would shift to another nut that they dislike or like less than a Brazil nut, for example, because of other information provided including a health claim. The same would be true for Brazil nuts, hazel nuts, almonds, etc. Survey data evaluating different brands of the same product (peanut oil) do not account for the number one factor predicting the choices between foods - - taste. However, if one brand of Brazil nut carried a claim while another brand did not, that would conceivably make a difference in choice or it could simply raise the consumer's awareness of the fact that Brazil nuts as a category are healthful. These data help expose the limitations of the Burke Study in supporting more general conclusions concerning consumer behavior with respect to different nut products.

Obviously, brand and brand reputation drives choice as well as price. The end use of a product will also drive choice in the selection of brand, type and quality. The case of cooking oils is interesting because oils are often chosen based upon their end use. Olive oil is often favored for salads if the consumer is willing to pay the price. Thus, taste and use occasion would seem to be the most important drivers of purchase. In the same studies referenced at the beginning of this section, as an example SAMI, the importance of health was second to taste and usually convenience. Finally, again regional biases come into play. Baked beans, corn beef on rye and grits are just a few foods that immediately

Ms. Brenda Derby, Ph.D.
June 25, 2003
Page 6

bring to mind regional preferences in taste and use. These factors will drive purchase.

In summary, because of the scientific limitations of the Burke Study, including those briefly characterized here, there is no valid scientific basis for drawing generalized conclusions concerning consumer perceptions or behavior that are relevant to the agency's evaluation of the health claim proposed by the California Walnut Commission in its pending health claim petition.

Thank you for this opportunity to offer comment on the methodology and findings of the Burke Study. We are pleased to present our research findings regarding our proposed health claim at our meeting on June 26, 2003.

Sincerely,



Dennis A. Balint
Executive Director