

Supporting Statement

**Formative Evaluation of Adults' and
Children's Views Related to
Promotion of Healthy Food Choices**

Project Officer:

Reba P. Griffith, MPH

HHS/NCCDPHP/CDC/DNPA

Mailstop K-46

4770 Buford Highway, NE

Atlanta, GA 30341-3724

Telephone: 770/488-554

Fax: 770/488-5369

Email: rkg4@cdc.gov

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A. Justification

A-1. Circumstances Making the Collection of Information Necessary

In its 2004 budget, Congress funded the Centers for Disease Control and Prevention (CDC)'s Division of Nutrition and Physical Activity to conduct several important activities to combat the escalating levels of chronic diseases associated with overweight, poor nutrition, and physical inactivity.

Legal authority is provided in Title 42, The Public Health and Welfare Chapter 6A – Public Health Service, Subchapter II, General Powers and Duties [United States Code (USC), i.e., 42 USC 241k] (See Appendix A). In addition, the research project being submitted for this OMB review is part of a specific mandate from Congress. The 2004 Congressional directive includes the requirement for CDC to research and recommend ways to promote healthy food choices to children and parents. The language from the 2004 Conference Report states Congressional intent this way:

*“Within the amount for Nutrition and Physical Activity, the conference agreement includes \$1,000,000 to support a comprehensive review of the effects of food marketing on children’s diet and health, including the characteristics of effective marketing of foods to children to promote healthy food choices. The conferees request that upon completion of the review, a report detailing the review’s findings be submitted to the appropriate Committees of jurisdiction of the Congress.”*¹

To accomplish the objectives of the language above, CDC funded the Institute of Medicine to conduct a scientific review. The mandate refers to the topic of this OMB application and is being addressed by conducting qualitative research to understand the “characteristics of effective marketing of foods to children to promote healthy food choices.”

Specifically, CDC proposes to execute a series of focus groups with elementary and middle school children and their parents, and with parents of young children (ages 2-4). An already-completed literature review, an in-progress environmental scan of existing strategies, programs, and campaigns, the findings

of the IOM activity, and an upcoming expert panel all are guiding the development of these focus groups. The research will explore consumer attitudes about nutritious foods, what factors influence their decisions (including marketing), how family dynamics enter into these decisions, and how one might successfully promote healthy food choices.

Effective promotion or marketing of any product or behavior, including healthy food choices, is grounded in the need for an in-depth understanding of the audience.² Conducting original audience research is critical given the limited research available in the public sector on consumer attitudes about food choices and about how to incorporate these attitudes in promoting a nutritious overall diet. Although it is likely such information is available to industry in their proprietary databases, little information about marketing of healthy food choices is evident in publicly-available research literature or programs.

Without OMB approval, CDC will not be able to fulfill their Congressional requirement, and will be unable to develop audience-based, more effective programs and campaigns promoting healthy eating to children and parents.

The primary need for the proposed research results from CDC's role as the Nation's primary agency for disease prevention and preventive health communication. The agency is mandated to develop effective health education campaigns to motivate people to live healthier lives. The health recommendations communicated through CDC campaigns are grounded in scientific research. To ensure that these health recommendations are communicated clearly and persuasively, it is equally important that the communication campaigns be grounded in rigorous market research with the target audiences. Moreover, CDC must also assess the effectiveness of its communications programs and thereby contribute to public knowledge concerning effective health promotion and disease prevention strategies.

In terms of qualitative research, there are no public sector data collections of research directly applicable to this proposed study. Yet the need for prevention and reduction of overweight and obesity has been shown in numerous empirical studies. In the U.S., 65% of adults are overweight or obese (obesity is defined as having a body mass index of 30 or more).³ Over the past three decades, the prevalence of childhood

obesity has more than doubled in preschool children aged 2 to 5 years and in adolescents aged 12 to 19 years. Among children aged 6 to 11 years, it has more than tripled. Approximately 9 million American youngsters over the age of 6 are considered obese.⁴ This epidemic is occurring in boys and girls in all 50 states, although specific subgroups – African Americans, Hispanics, and American Indians – are disproportionately affected.⁵

Childhood obesity trends parallel similar increases among adults both in the U.S. and in developing and developed countries. As a result, this epidemic may reduce overall life expectancy for our children as they mature into adulthood – even in an era when remarkable medical advances otherwise are capable of extending life and improving quality of life at every age.⁶

While overweight and obesity are linked to multiple chronic diseases – including diabetes, heart disease, stroke, and depression – perhaps the most public attention has been devoted to the startling rise of diabetes among children. Once known as “adult onset diabetes,” this disease is rapidly becoming a lifetime impairment that starts in childhood and adolescence.⁷ For children born in the U.S. in 2000, the lifetime risk of being diagnosed with diabetes in their lifetimes is estimated at 30 percent for boys and 40 percent for girls – if obesity rates level off.⁸ The risk is higher for ethnic minorities.⁹ Type 2 diabetes accounted for 8 to 45 percent of all new childhood cases of diabetes, compared with fewer than 4 percent before the 1990s.¹⁰ Adults with a body mass index of 40 or more have a seven-fold increased risk for diabetes.¹¹

Beyond its influence on diabetes, excess weight brings to children and adults increased disease prospects later in life. Based on current trends, these prospects are settling in earlier than ever. In a recent population-based sample, 60 percent of obese children aged 5 to 10 years had at least one physiological cardiovascular disease risk factor (elevated total cholesterol, triglycerides, insulin, or blood pressure); and 25 percent had two or more such risk factors.¹² Pediatricians are joining the efforts to urge parents and children to take their diets and physical activity more seriously.¹³

In addition to the burden of disease, there are concerns about the economic costs of obesity. One estimate is that medical expenses related to this epidemic accounted for 9.1% of total U.S. medical expenditures in 1998 and may have reached as high as \$78.5 billion (an estimated \$92.6 billion in 2002 dollars).¹⁴ Implications are potentially far-reaching. Such an epidemic may place at risk the long-term welfare and readiness of the U.S. military services because it can reduce the pool of individuals eligible for recruitment, and decrease the ability to retain new recruits.¹⁵ Journalistic reports have identified the need to make costly adjustments for a population in which 60% are overweight or obese – from the need for larger coffins to more spacious easy chairs, seatbelt extenders, and wider seats on airplanes.¹⁶

Additionally, obesity and overweight have substantial social costs. Research documents how excess weight has resulted in stigmatization and marginalization of children.^{17,18} At a stage in life when learning to form friendships with peers and important adult relationships are paramount in their minds and aspirations, children with excessive weight issues often also are dealing with issues of shame, self-blame and low self-esteem.^{19,20} These mental and psychological burdens can affect academic and social confidence well into adulthood.²¹ Extreme perceptions of weight are emerging as significant risk factors for suicidal ideation among teens.²²

Nutrition science lays the theoretical groundwork for weight maintenance and control by identifying the modifiable factors of caloric intake and output and how they influence a person's weight. This fundamental concept, the "energy balance equation," depicts the principle of energy (calories) in and energy (calories) out: $E_{in} = E_{out}$. On the left side of the equation, energy "in" refers to food choice, preparation, and consumption (all of which involve elements such as caloric density, fat, sugar, quantity, etc.). On the right side, "energy out" refers to energy or calories expended, including behavior patterns such as leisure activities (TV, video/computer, walking, errands, perceived safety), physical activity, organized sports, and access to facilities for physical activity.²³ In simple terms, the *2005 Report of the Dietary Guidelines* states it this way: "Energy expended must equal energy consumed to stay at the same weight."²⁴ Thus, "caloric intake and physical activity go hand in hand."²⁵

To stem the obesity epidemic, most Americans need to take action on both sides of the energy equation -- reduce caloric intake and increase caloric output. CDC's "VERB: It's What You Do" campaign for youth addressed the right side of the equation and showed success at influencing young people to increase their physical activity (energy expended). In addition, many leaders in the food industry are promoting the importance of physical activity.

In this OMB request, CDC's proposed project is focused more on the "energy in" or left side of the equation. Much less public information is available on how to influence energy intake – how to engage audiences – as compared to the audience research and programmatic infrastructure now being devoted to physical activity. The goal in this new project is to ultimately encourage Americans to watch not only the quantity of calories but also the quality or nutritional content of their calorie intake – starting with children and parents. In terms of energy intake, changes are needed in both quantity and quality of calories to reverse current obesity trends. The intersection of the dilemma over how much and what kind is well expressed in the new *Dietary Guidelines*: "Many Americans consume more calories than they need without meeting recommended intakes for a number of nutrients...This means that most people need to choose meals and snacks that are high in nutrients but low to moderate in energy content."²⁶ In sum, in the land of plenty, Americans are consuming plenty of calories but not necessarily plenty of nutrients.

The need for more healthful eating patterns among Americans is startling in view of just a sampling of specific trends. For example:

- Average daily total calories increased from 2,450 to 2,618 for men and 1,542 to 1,877 for women between 1971 and 2000.²⁷
- Total calories consumed by teen boys aged 12-19 increased by 243 between 1977-1978 and 1994-1996 – from 2,523 to 2,766 calories.²⁸
- Total calories consumed by teen girls ages 12 to 19 increased by 123 – from 1787 to 1,910 calories.²⁹

- Among adolescents aged 12 to 19 years, only 18% of girls and 14% of boys consumed the recommended servings of vegetables and only 24% of girls and 23% of boys met the fruit recommendations, based on a 1994-1996 survey.³⁰ The new 2005 Dietary Guidelines has increased the recommended number of fruits and vegetables.³¹
- By age 14, 32% of adolescent girls and 52% of adolescent boys consume three or more 8-ounce servings of soda daily.³²

Although the scientific literature on the statistical prevalence and clinical effects of obesity has been growing, less information is available to the public health community on the effects of marketing overall, and specifically the effects of food marketing and whether or how to use marketing to influence healthier decision-making around food. Amid the questions around the impact of marketing, one trend is clear: American's exposure to marketing is wide-reaching. On average, Americans devote much of their leisure and commuting time to interacting with media, including TV, Internet, video games, radio, and certainly billboards that line their paths homeward. The Kaiser Family Foundation released a media study in 2005 citing these key trends on media use by youth:³³

- A typical 8- to 18-year-old is exposed to 8.5 hours of recreational media content daily.
- U.S. children average just over 1 hour per day using the computer for recreational use, more than double the 27 minutes per day reported in 1999.
- Younger children watch more TV than older children. Teens ages 15-18 report almost $\frac{3}{4}$ of an hour less daily TV than younger groups.

A 2005 Federal Trade Commission preliminary study also shows the shifting of youth media behavior. Although children's exposure to TV food ads has declined from 1977-2004,³⁴ FTC panelists noted that many ads now refer viewers to web sites. More advertising dollars are being spent on advertising through the Internet -- designed as "branded environments" with games, puzzles, contests, and other activities for children linked to food brands and products.³⁵

Looking only at TV, it is estimated that the average American child views 40,000 commercials each year.³⁶ Of those ads, 80 percent promote toys, cereal, candy, and fast food restaurants.³⁷ Of the ads involving food and drinks, 40 to 50 percent promote candy, fast food, snack foods, soft drinks, and sweetened breakfast cereals that are high in calories and fat, low in fiber, and low in nutrient density.^{38,39} “Snack, convenience, and fast foods and sweets continue to dominate food advertisements watched by children,” noted one recent content analysis of children’s programming. “Advertised foods exceed RDVs of fat, saturated fat, and sodium, yet fail to provide RDVs of fiber and certain vitamins and minerals.”⁴⁰

Currently, children and parents make most food choices in a highly competitive and prolific food marketing environment. Much of the food advertising they see promotes large portion sizes, sweetened beverages and foods, and less nutrient-dense choices.^{41,42} The *Dietary Guidelines for Americans 2005* recommend that an average day’s diet be balanced to ensure that high-fat, high-calorie, and low-nutrient foods do not fill one’s entire plate for most meals and snacks.⁴³

Food and drink providers are now the second largest advertising sector in the American economy, devoting \$27 billion a year targeting children and youth alone.⁴⁴ Children’s exposure to these ads may contribute to energy imbalance and weight gain.⁴⁵ Studies have found that children ask for food and drink choices they see advertised frequently.^{46,47,48} At the same time, children in today’s families have more influence on food buying decisions than in the past.⁴⁹ Marketing experts refer to this phenomenon as the “nag factor” or “pester power.”⁵⁰ As a result, tweens are the target of a substantial portion of commercial marketing dollars and efforts, not only with food but with a wide array of products formerly promoted to adults.^{51,52}

With this proposed CDC project, it is hoped that CDC can learn how to use audience insights that ultimately will lead to public health messages that can broaden awareness of possibilities and help parents, tweens and younger children be more educated and motivated to make balanced food choices. These audience insights will be shared broadly with Congress, partners, private sector groups, and others interested in seeing positive change in dietary patterns that can reduce obesity and the burden of related chronic diseases.

A-2. Purpose and Use of Information Collection

The purpose of this project is to provide insights into children's and parent's decision-making around food and the influence of marketing so that effective messages and strategies can be created and disseminated that influence preferences for healthy eating habits. The results will be used by CDC, and they will be shared with other HHS offices and other federal agencies (e.g., USDA), states and local communities, and nonprofit partners.

Results and recommendations will be provided to Congress, as required. Findings will also be disseminated to state health departments, partners, private and public sector groups, additional HHS agencies and government entities, researchers, physician groups, and others interested in promoting healthy food choices among parents and children. Here is just one specific example: CDC plans to share these findings with the national "Fruits & Veggies: More Matters" program (newly rebranded name, formerly 5 A Day program) and its key retail partner, the Produce For Better Health Foundation, in their efforts to promote more consumption of fruits and vegetables. In addition, CDC expects to use these audience insights to test messages and message concepts for the development of CDC web and print materials to share with the general public.

The goal is to ensure synergy among these groups by providing them with science-based and audience-tested strategies and messages for their outreach activities and campaigns. As such, this proposed research will provide a unique and substantial contribution to public health efforts to promote healthy decision-making around food.

The report will be available to anyone interested in promoting healthy food choices to children. This shared information could help pave the way to new and more effective partnerships both in the public and private sectors, as well as state and local community participation. In addition, findings will be provided in a mandated report to Congress, along with recommendations on how to effectively promote healthy food choices to children and their parents.

A-3 Use of Improved Information Technology and Burden Reduction

We propose to use in-person focus groups because they provide in-depth information that cannot be captured in quantitative surveys or in on-line focus groups. This is especially the case when researching attitudes of children, whose body language can be as expressive as their actual words. Also, participants nearly always say they enjoy the experience. Many times they reflect to moderators that this process is much more convenient than filling out long forms. The group dynamics often play a positive role, and the moderators are well-trained and coached to keep the dialogue interesting and fast-paced.

Audience research of this type is routinely a part of private sector marketing practices when developing a new product, or the promotion of that product. This is just as helpful in government-sponsored messaging efforts – particularly when tight resources dictate that knowing the audience is essential to communicating effectively with them. Hearing directly from the consumer – or in the case of this project, the target audience – can reveal invaluable insights toward benefits, barriers, and other attitudes and knowledge that can help make future acceptance of making healthier food choices more likely.

A number of steps have been planned to ensure the least burden possible is shouldered by the public. These steps include:

(1) Recruitment “screeners” have been designed for recruiters to quickly identify qualifying participants (children and their parents/caregivers) in a brief telephone conversation. These screeners will use a questionnaire called the Recruitment Tool/Screening (Appendix D1-D3) with carefully thought out questions so that the process is short, easy to-understand, friendly, and efficient.

(2) All information from participants will be provided orally.

(3) Moderator’s guides have been developed specifically to ensure that the discussion is limited to no more than 2 hours, so that the questions are well-organized and flow well together, and are easy to understand and answer. Also, the guides have been tailored to be culturally appropriate to specific audiences.

(4) Participants are chosen from lists of individuals who have expressed an interest in being in a focus group. Focus groups are common practices among private and public sector organizations, and many individuals look forward to learning about new products and/or ideas. It is a familiar process to them, and often, they comment that it's easier than filling out lengthy forms or being stopped for a mall intercept.

A-4 Efforts to Identify Duplication and Use of Similar Information

CDC has made a significant effort to avoid duplication by conducting an environmental scan, literature review, interviews with experts, data base searches, and participation in workshops and conferences. Early into the project, CDC and the contractor, AED, conducted an “environmental scan,” or, as it is called in private sector marketing, a “competitive analysis,” of other programs and activities that might be similar. This avoids duplicating efforts and also enables learning from other related projects. The scan produced very few comparable projects and none that were so similar that it warranted not doing the work. It included research of both private- and public-sector efforts at promoting healthy food choices and of availability of audience research related to those efforts. Initially, the scan identified more than 40 healthy food promotions that represented six categories of healthy foods. From that group, however, 30 were deleted from the scan for lack of an actual promotional campaign for children. Internet research included blogs, online newsletters and other forms of communication the relayed information on current or soon-to-be-launched healthy food promotions.

The environmental scan features the 10 companies and/or products that met the criteria of the search. It identifies marketing strategies most used, benefits touted for consuming these products, and promotion and distribution methods.

The team also performed a review of both scientific and business-oriented articles around the general topic of marketing of food to children and parents, and with an eye specifically toward effective ways to do this. The review summarized what is known about differences in regard to food marketing to various audience segments, and how marketing strategies and tactics influence the factors that lead to children's food choices. This data base approach helped CDC

- 1) Identify audience segments;

2) Develop a working definition of “healthy foods” for this particular project, which resulted in narrowing it down to fruits and vegetable given the market and health needs;

3) Construct a more detailed conceptual model of how children’s behaviors are affected by marketing influences;

4) Ascertain gaps for the qualitative research.

Through these efforts, CDC is aware that the private sector has conducted extensive proprietary research on marketing a wide range of food and beverage products to children and parents. However, this private-sector research is not readily available to CDC in that it ranges from being prohibitively expensive to being proprietary.

Based on these reviews, it is clear that the topic of marketing *healthy* food choices to children—and components of a healthy lifestyle based on the new dietary guidelines and food system—is inadequately addressed in the literature and research available to the public health sector, despite substantial interest. Several public health community-based educational programs about food and energy balance exist, such as “Calories Count” by the Food and Drug Administration, “We Can” by the National Institutes on Health, and “Fruits & Veggies: More Matters,” (formerly 5-A-Day). However, much more needs to be done, particularly in the area of *how* to overcome attitudinal barriers and *how* to engage youth decision-making.

Throughout 2005, in-depth telephone discussions were held with nationally-renowned private sector marketing experts. In early 2005, discussions were held with several marketing and behavioral science experts who were serving on the Institute of Medicine (IOM) Committee on Food Marketing and the Diets of Children and Youth. Also, one member of the CDC project team was the key CDC liaison with the IOM study that was released in November 2005. In that capacity she attended all key IOM meetings and workshops and assisted with release of the final IOM report.

In July 2005, the project manager for this project attended a Federal Trade Commission workshop (“Perspectives on Marketing, Self-Regulation, and Childhood Obesity”), where a broad range of relevant topics were broadly addressed. The project objectives and methods also were shared with appropriate officials in HHS and the FTC.

These interviews and conversations found that the particular issues to be addressed in this study are not being addressed by others and that, not only will this project avoid duplication of efforts, it will complement if not boost other Federal activities, particularly the promotion activities around the *Dietary Guidelines for Americans*, the *Food Guidance System*, and CDC's More Matters: Fruits and Veggies program, which focuses on fruits and vegetables only.

To boost our research, CDC is completing in 2007 a series of consultations with carefully selected, nationally recognized private sector experts in the area of marketing fruits and vegetables to children. This is an expert panel, but it is being executed in a rather nontraditional way. Instead of gathering six experts at one time, we are bringing them in one at a time to meet one-on-one with us. We opted for this method because it became clear in our initial exploration that due to the highly competitive nature of marketing firms and their top-flight strategists, we are more likely to get honest and open dialogue when meeting individually. This definitely has proven to be the case.

CDC has hosted Ried Leslie, director of food and beverage consumer products at Disney; and Richard Buday, president and founder of Archimage and a key developer for Nintendo; Elizabeth Moore, PhD, a specialist in online marketing of food to youth and associate professor of marketing at Notre Dame University; and Richard Juzang, MBA, president and founder of M.E.E. (Motivational Educational Entertainment), a Philadelphia-based marketing firm that specializes in outreach to communities of color. Two other experts, yet to be confirmed, also will be invited.

A-5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A-6 Consequences of Collecting the Information Less Frequently

This is a one time data collection, which is essential to CDC's capacity to effectively respond to the obesity epidemic. Because little information exists on how the public sector can successfully promote or market healthy food choices to children and

families, this project fills a gap in the knowledge needed to jump-start approaches that can reduce obesity.

Inability to collect these data in a timely manner will prevent CDC from fulfilling its mandate to Congress to provide a report on promoting and marketing healthy foods to children. It also will prevent CDC from effectively building on the release of the new *Dietary Guidelines for Americans* and the *Food Guidance System* and the Institute of Medicine (IOM)'s report to Congress, "Food Marketing to Children and Youth: Threat or Opportunity" released December 2005.⁵³

This study has been designed to fill a public health gap in knowledge of how to effectively influence children to make healthy food choices. Findings from this project will be used by CDC and provided to other public health agencies and partners to inform messages and strategies for the general public that will motivate them to adopt healthy eating patterns in preventing obesity, reducing risk of chronic disease, and prepare children for a lifetime of healthy nutritional choices.

There are no legal obstacles to reduce the burden.

A-7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the guidelines of 5 CFR 1320.5.

A-8. Comments in Response to the Federal Register Notice

A 60-day Notice was published in the *Federal Register* on December 13, 2007 (Vol. 72, No. 239, pp. 70865-70866; see Appendix B). Three public comments were received, and responses were provided (Appendix C).

A. Persons consulted inside the agency are as follows:

William H. Dietz, MD, PhD
Director
Division of Nutrition and Physical Activity
Centers for Disease Control and Prevention
4770 Buford Hwy, NE, MS K-24

Atlanta, GA 30341-3717
(770) 488-6042
wdietz@cdc.gov

Casey Hannan, MPH
Team Leader of Planning, Policy, and Evaluation
Division of Nutrition and Physical Activity
Centers for Disease Control and Prevention
4770 Buford Hwy, NE, MS K-24
Atlanta, GA 30341-3717
(770) 488-6211
channan@cdc.gov

Barbara Polhamus, MPH, PhD, RD
Public Health Nutritionist
Division of Nutrition and Physical Activity
Centers for Disease Control and Prevention
4770 Buford Hwy, NE, MS K-25
Atlanta, GA 30341-3717
(770) 488-5657
bpolhamous@cdc.gov

Judith McDivitt, PhD
Team Leader, Nutrition and Physical Activity Communication Team
Division of Nutrition and Physical Activity
Centers for Disease Control and Prevention
4770 Buford Hwy, NE, MS K-46
Atlanta, GA 30341-3717
(770) 488-5555
jmcdivitt@cdc.gov

Mary McKenna, PhD, MS
Health Scientist
Division of Adolescent and School Health
Centers for Disease Control and Prevention
4770 Buford Hwy, NE, MS K-12
Atlanta, GA 30341-3717
(770) 488-5187
mmckenna@cdc.gov

Debra Torres, MPH
Project Officer
Office on Smoking and Health
Centers for Disease Control and Prevention
4770 Buford Hwy, NE, MS K-50
Atlanta, GA 30341-3717

(770) 488-1220
dtorres@cdc.gov

Persons consulted outside the agency are as follows:

Mary Story, PhD, RD
Professor of Nutrition and Associate Dean for Student Affairs
University of Minnesota School of Public Health
1300 South Second Street, Suite 300
Minneapolis, MN 55454
(612) 626-8801
story@epi.umn.edu

Nina Diamond, PhD, MA
Assistant Professor
DePaul University
25 East Jackson Blvd, Suite 1600
Chicago, IL 60604
(312) 362-5472
ndiamond@depaul.edu

Paul Kurnit, MA
President
Kurnit Communications and Kidshop
15 Hitching Post Lane
Chappaqua, NY 10514
(914) 666-4800
paul@kurnit.com

J. Michael McGinnis, MD, MPP
Senior Scholar
Institute of Medicine
Keck Center of the National Academies
500 Fifth Street, NW, 864
Washington, DC 20001
(202) 334-3963
mmcginnis@nas.edu

Christine Dobday
Prevention Communications Advisor
Office of Disease Prevention and Health Promotion
U.S. Department of Health and Human Services
The Tower Building
1101 Wootton Parkway, Suite LL100, Room 115
Rockville, MD 20852

(240) 453-8255
cdobday@osophs.dhhs.gov

Mary Engle
Associate Director
Division of Advertising Practices
Federal Trade Commission
600 Pennsylvania Ave, N.W.
Washington, D.C. 20580
(202) 326-3161
mengle@ftc.gov

Reid A. Leslie
Director, Food and Beverage Lines
Disney Consumer Products
1201 Flower St.
Glendale, CA 91201
(818) 544-0413
Reid.leslie@disney.com

Richard H. Buday, PhD, President
Archimage, Inc.
4200 Montrose Blvd., Suite 330
Houston, TX
(713)523-3425
RBuday@ArchimageOnline.com

Ivan J. Juzang, MBA, President
M.E.E. Productions (Motivational Educational Entertainment)
340 N. 12th St., Suite 503
Philadelphia, PA 19107
(215) 829-4920
IJuzang@meeproductions.com

A-9. Explanation of Any Payment or Gift to Respondents

Recruitment incentives will be provided to ensure an adequate response rate. Research on participation in focus groups indicates that, without providing minimal levels of monetary compensation, insufficient numbers of participants will attend and results will not be useful, particularly given that this is such a common practice within private sector marketing activities.⁵⁴ Incentives may vary slightly across sites based on local differences in the cost of living. Each parent who participates in a focus group will

receive \$50. A parent who does not participate in a focus group, but who brings the child to the group, will receive \$25. Each child who participates will receive \$25.

A-10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this submission and has determined that the Privacy Act does not apply. The contracted focus group/research facility in each city will be the only parties with phone numbers, addresses or other such identifying information, which will only be used to schedule participation in a focus group. The prime contractor, Academy for Educational Development, will have access only to the respondent's name on the consent form; however, neither the respondent's name nor other identifiers will be linked to response data at any time.

Focus group response data will be collected by AED and their subcontractor, Alan Newman Research (ANR). Transcripts derived from the focus groups will be read and analyzed by only AED and ANR research staff. The only personal identifiers that will be obtained by AED and ANR are the participants' names for scheduling purposes, and this information will not be linked to the response data or shared with CDC. In addition, results will be aggregated so that it will not be possible for an individual to be identified. First names only will be used during the group discussion, and only first name, without any identifying information, will be included in transcripts. The audiotapes and videotapes of focus group sessions will be erased within 12 months.

Respondents will be advised of the nature of the activity, the length of time it will require, and that participation is purely voluntary. Respondents will be assured that they will not incur penalties if they wish not to respond to the information collection as a whole or to any specific questions. These procedures conform to ethical practices for collecting data from human participants based on the federal policy for Protection of Human Subjects (45 CFR 46). All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Respondents will be informed prior to participation that their responses will be treated in a secure manner. (See attached Consent and Assent forms, which describe procedures for safeguarding respondent privacy, in Appendix E1-E3). IRB approval was originally

provided through Feb. 9, 2007. IRB approval was extended prior to its original expiration date, and it now will be allowable through Feb. 9, 2008 (see Attachment H). Continued renewal of IRB approval is pending as of the date of this submission.

A-11 Justification for Sensitive Questions

There are no sensitive questions in the moderator's guides, however, the recruitment screener includes several questions that may be viewed as sensitive by a portion of participants. These sensitive questions are limited to race, household income, and educational level. These questions are necessary in order to ensure equal participation in this research study by members of various demographic groups. This diversity will increase the amount of information available from a broad range of respondents. Demographic questions, although potentially sensitive, are required to support assignment of respondents to the appropriate focus group. This is standard focus group methodology.

Before any screener questions are asked, recruiters will confirm that respondents' participation is purely voluntary and will inform respondents that their answers will be maintained in a secure manner [See Section A-10, which addresses the strict measures that will be taken to safeguard the privacy of all responses to the recruitment screener]. In addition, all sensitive questions on the screener will include an "I prefer not to answer this question" response option for all potential participants who feel uncomfortable responding to that particular question(s).

Both the format and the administration of questions regarding race and ethnicity will conform to both HHS and OMB policies regarding the collection of this information. Therefore, according to OMB standards, race and ethnicity will be asked separately to gather the most accurate data. Additionally, respondents will be able to choose more than one option about race, in order to allow them to best describe their identity.

The question regarding household annual income will allow respondents to select the income range that best reflects their current economic situation. The question about educational level will allow respondents to select the answer that reflects the highest level of education they have achieved.

A- 12. Estimates of Annualized Burden Hours and Costs

A. The proposed data collection will involve a total of 720 respondents: 384 children participating in 48 focus groups (8 respondents per group) and 336 parents participating in 42 focus groups (also 8 respondents per group). It is estimated that two screening calls will be required in order to recruit each respondent, thus, the burden table includes 720 screening attempts that do not result in recruitment of a focus group participant. The proposed focus group data collection will be conducted in three phases.

Phase 1 will consist of 12 focus groups of children ages 9-12 years, and 12 groups of parents. Parents and children will be recruited by telephone as Parent-Child dyads (see Appendix D1, Recruitment Screener for Parent-Child Groups). The recruitment process for Parent-Child dyads is expected to take a total of 10 minutes (7 minutes for the parent, and 3 minutes for the child), since both must agree to participate and will be involved interactively in the telephone call with the interviewer. When the parent and child arrive at the focus group facility, however, they will be separated so that parents participate in focus groups with other parents, and children participate in focus groups with other children. The Discussion Guide for focus groups involving children is provided in Appendix F and the Discussion Guide for parent focus groups is provided in Appendix G. Burden for each focus group is estimated at 2 hours, based on our experience in conducting focus groups.

In addition to the 24 focus groups described above, Phase 1 will also include 12 focus groups of children who will be recruited to participate in focus groups although their parents will not be recruited to participate in focus groups. The recruitment screener for these groups is provided in Appendix D2, Recruitment Screener for Child-Only Groups. It is similar to the previous screener in that both the parent and child participate interactively in the eligibility and screening process (7 minutes for the parent and 3 minutes for the child), and the parent must give permission for the interviewer to speak with the child. It is different from the previous screener in that only the child is ultimately recruited to participate in a focus group.

In all, a total of 192 children (24 focus groups with 8 respondents/group) and 96 parents (12 focus groups with 8 respondents/group) will participate in focus groups during Phase 1. It is estimated that 192 children and 96 parents will also participate in the screening process, but will not be recruited to participation in a focus group.

Phase 2 is based on the same number of focus groups as Phase 1, the same organization of Parent-Child groups and Child-Only groups, and the same data collection instruments (Appendices D1, D2, F, and G). The only difference is that Phase 2 involves children ages 5-8 years.

Phase 3 will consist of 144 parents of children ages 2-4 years, organized in 18 parent-only focus groups. Children in the age range of 2-4 years will not be directly involved in the proposed data collection. The data collection instrument for Parents will be unchanged (Appendix G), but a modified version of the Screener (Appendix D3) will be used for parents participating in Phase 3. All screeners have been designed with specific instructions for recruiters that facilitate efficient completion of the screening process.

The total number of respondents is 720 (384 children and 336 parents), organized in 90 focus groups of 8 respondents each. The total estimated burden hours are 1,556. For additional information on the composition of focus groups by phase, respondent type (parent or child), age group, Race/Ethnicity, etc., see Table B.1-1 and Table B.1-2.

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden (in hours)	Total Burden (in hours)
Children	Screener D1 for Parent & Child Groups	384	1	3/60	19
	Screener D2 for Child Only Groups	384	1	3/60	19
	Focus Group Moderator's Guide for Children/Youth	384	1	2	768
Parents	Screener D1 for Parent & Child Groups	192	1	7/60	22
	Screener D2 for Child Only Groups	192	1	7/60	22
	Screener D3 for Parent Only Groups	288	1	7/60	34
	Focus Group Moderator's Guide for Parents	336	1	2	672
GRAND TOTAL					1,556

B.

The financial burden on participants will be minimized because these groups will be held after work hours; i.e., parents who choose to participate will be those who either are not employed outside the home, or who work during the day, or who have that particular evening off to attend the focus group. The children being recruited for this study (Phase 1, ages 9-12; Phase 2, ages 5-8) typically are underage for regular employment, so no

wages will be lost among youth participants. Based on the estimated annual burden hours above, Table A.12-2 below shows estimated annualized cost to participants.

Table A.12-B. Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden (in hours)	Average Hourly Wage	Total Cost
Children	Screener D1 for Parent & Child Groups	384	1	3/60	\$0	\$0
	Screener D2 for Child Only Groups	384	1	3/60	\$0	\$0
	Focus Group Moderator's Guide for Children/Youth	384	1	2	\$0	\$0
Parents	Screener D1 for Parent & Child Groups	192	1	7/60	\$16.05	\$359.52
	Screener D2 for Child Only Groups	192	1	7/60	\$16.05	\$359.52
	Screener D3 for Parent Only Groups	288	1	7/60	\$16.05	\$539.28
	Focus Group Moderator's Guide for Parents	336	1	2	\$16.05	\$10,785.60
GRAND TOTAL						\$12,043.92

The average hourly wage for parents is based on average hourly rate for August 2005, Bureau of Labor Statistics - <http://www.bls.gov/news.release/pdf/empst.pdf> .

A-13 Estimates of Other Total Annual Cost to Respondents or Record Keepers

There are no costs to respondents other than their time.

A-14. Annualized Cost to the Government

Annualized costs to the government include costs for CDC personnel (project officer, co-investigator, and fellow) who are each expected to contribute approximately one-third of their time to managing the project and communicating with the contractor and subcontractor.

The contractor, the Academy for Educational Development (AED) will receive \$374,731 for work related to preparing for the focus group testing (literature and environmental scan), designing the moderators' guides, and completing final reports and transcripts.

In addition to the tasks described above, AED will oversee a subcontract with Alan Neuman Research (ANR) for recruitment of participants, providing appropriate facilities, and managing other logistics.

The total annualized project costs are estimated at \$868,636.

Cost Category	Itemized Costs	Total Costs
CDC Personnel		
33% FTE of GS-13 @93,110	\$30,726	
33% FTE of GS-12 @67,422	\$22,249	
33% FTE Fellow @ \$65,242	\$21,530	
	Subtotal, CDC	\$74,505
Contract to Academy for Educational Development		
Labor for literature review, Designing and conducting focus groups, Interim and final reports, Providing CDC with transcripts	\$288,799	
Indirect costs	\$85,932	
	Subtotal, AED	\$374,731
Subcontract to Alan Neuman Research		
Facilities rental, Recruitment and logics for 90 focus groups	\$414,000	
Travel costs for ANR moderators to 3 cities	\$5,400	
	Subtotal, ANR	\$419,400
	Grand Total	\$868,636

A-15. Explanation for Program Changes or Adjustments

This is new, one-time data collection.

A-16. Plans for Tabulation and Publication and Project Time Schedule

The findings from this activity will be provided in a report to Congress. Ideally, the due date can be set for about a year and a half from this writing; this would make the final report due around late summer or early fall of 2009. However, CDC is aware that flexibility has to be built in to allow for OMB review before any focus group research can begin. Results will be disseminated with other health professionals as appropriate.

Once a qualitative coding system is devised, investigators will apply the coding system to blocks of transcribed text. Investigators will analyze the data to assess emerging themes around how to successfully market healthy foods to children and their families. The project schedule is as follows.

Activity	Time Schedule
Focus group recruitment begins for Phase 1 (children 9-12 and parents)	1-3 days after OMB approval
Conduct focus groups (children 9-12 and parents)	2-8 weeks after OMB approval
Begin recruitment for Phase 2 focus groups (children 5-8 and parents)	9 weeks after OMB approval
Produce topline report (children 9-12 and parents)	10 weeks after OMB approval
Conduct focus groups (children 5-8 and parents)	11-19 weeks after OMB approval
Begin recruitment for Set 3 focus groups (parents of young children ages 2-4)	20 weeks after OMB approval
Produce topline report (children 6-8 and parents)	21 weeks after OMB approval
Conduct focus groups (parents of young	22-30 weeks after OMB approval

children ages 2-4)	
Produce topline report	32 weeks after OMB approval
First draft of research report	35 weeks after OMB approval
Second draft of research report	36 weeks after OMB approval
Final research report	38 weeks after OMB approval
Final report to Congress	June 2009

A-17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

A-18. Exceptions to Certification for Paperwork Reduction Act Submissions

None.

Section B: Collection of Information Employing Statistical Methods

This is qualitative data collection. Statistical methods will not be used to draw the respondent sample.

The research design proposed in this study calls for three sets of focus groups:

1) 24 focus group discussions with children ages 9-12, and 12 focus groups of a portion of the parents or primary caregivers of the children participating. Children will be split up into groups based on common age and gender. Parents will meet together in groups of eight separate from their children.

2) 24 group discussions/interactions with younger children ages 5-8, and 12 focus groups of a portion of the parents of the children in this set of groups. Other factors are the same as in set described in number one.

3) 18 group discussions with parents of preschool children (ages 2-4).

In the last case, children will not be questioned because experience has shown that they will be unable to answer the questions effectively. All groups will be stratified by race and gender and consist of a mix of family income and education levels of parents.

Groups will be held in focus group facilities in three different areas of the U.S. Expected locations will be Atlanta, GA; Gary, IN; and Austin, TX.

The focus group discussions will be moderated by a professional moderator provided with a set of open-ended questions organized around a number of themes. The groups with children will be asked questions by a moderator from the children's/youth focus group moderator's guide (See Appendix F, "Children's/Youth Focus Groups Discussion Outline"). All groups with children will be asked to discuss their perceptions of their current and ideal eating behavior, typical meal and snacking habits, perceived influences on eating behaviors, food-related interactions with their parents, food advertising, and reactions to possible message themes.

The groups with parents will be asked questions by a moderator from the parent focus group moderator's guide (Appendix G, "Parent Focus Groups Discussion Outline"). The groups with parents will discuss typical mealtimes in different environments, decision-making around foods and meals, perceptions of healthy eating, perceptions of food marketing, and reactions for recommendations from the U.S. Dietary Guidelines. After each set of groups are completed, contractors will compile a topline report to forward to CDC.

Upon completion of all the data collection, the audiotapes of the focus groups will be transcribed, the major themes analyzed, and a full report prepared.

B-1. Respondent Universe and Sampling Methods

The study design calls for a total of 90 focus group discussions to be held in three different regions of the country. The groups will consist of:

* 48 groups of children separated by ages (11-12, 9-10, 7-8 and 5-6) and gender. Of that total, 24 focus groups will be held with the older set (ages 9-11, known as "tweens"). With the younger set (ages 5-8) in Phase two, 24 focus group activities will be held. For purposes of estimated burden hours, the time estimated for this younger age group is estimated to be the same as all the other standard focus groups in this project (two hours).

* 24 groups of parents. Half of the children from both age groups (ages 5-8 and 9-12) will have one of their parents participating in parallel focus groups. Parents will meet apart from the children.

* 18 focus groups of parents of children ages 2-4. Qualifying parents must be responsible for food choices for the family.

Each group will consist of a maximum of 8 participants. Children's groups will be age- and gender-specific to ensure questions and dialog are age appropriate. All groups will be stratified by race/ethnicity and gender. Also, the focus groups will consist of a mix of family income (low to middle income) and education levels of parents. The organization of respondent groups is summarized in Table B.1-1 and Table B.1-2 below:

Table B.1-1. Number and Type of Respondents, by Phase

Phase	Type of Respondents	Number of Focus Groups	Number of Participants per Focus Group	Total No. of Focus Group Participants	Respondents Screened But Not Participating in a Focus Group	Total Screened and/or Participating in a Focus Group
Phase 1 (Tweens, ages 9-12)	Children ages 9-10	12	8	96	96	192
	Parents of children ages 9-10	6	8	48	48	96
	Children ages 11-12	12	8	96	96	192
	Parents of children ages 11-12)	6	8	48	48	96
	<i>Subtotal, Phase 1</i>	<i>36</i>	<i>8</i>	<i>288</i>	<i>288</i>	<i>576</i>
Phase 2 (Early Elementary, ages 5-8)	Children ages 5-6)	12	8	96	96	192
	Parents of children ages 5-6	6	8	48	48	96
	Children grades 7-8	12	8	96	96	192
	Parents of children ages 7-8	6	8	48	48	96
	<i>Subtotal, Phase 2</i>	<i>36</i>	<i>8</i>	<i>288</i>	<i>288</i>	<i>576</i>
Phase 3 (Parents of children ages 2-4)	Parents of children ages 2-4	18	18	144	144	288
	<i>Subtotal, Phase 3</i>	<i>18</i>	<i>8</i>	<i>144</i>	<i>144</i>	<i>288</i>
	<i>Grand Total</i>	<i>90</i>	<i>8</i>	<i>720</i>	<i>720</i>	<i>1,440</i>

Table B.1-2. Focus Groups Segmented by Phase, Age, Gender, and Race/Ethnicity

Phase	Age/Gender	Number of Focus Groups ⁽¹⁾			Total Groups (Total Participants)
		Hispanic (White or African American)	African American (non- Hispanic)	White (non- Hispanic)	
Phase 1	Girls ages 9-10	2	2	2	6 (48)
	Parents of girls ages 9-10	1	1	1	3 (24)
	Boys grades ages 9-10	2	2	2	6 (48)
	Parents of boys ages 9-10	1	1	1	3 (24)
	Girls ages 11-12)	2	2	2	6 (48)
	Parents of girls ages 11-12	1	1	1	3 (24)
	Boys ages 11-12	2	2	2	6 (48)
	Parents of boys ages 11-12	1	1	1	3 (24)
	<i>Subtotal, Phase 1</i>	<i>12</i>	<i>12</i>	<i>12</i>	<i>36 (244)</i>
Phase 2	Girls ages 5-6	2	2	2	6 (48)
	Parents of girls ages 5-6)	1	1	1	3 (24)
	Boys ages 5-6)	2	2	2	6 (48)
	Parents of boys ages 5-6	1	1	1	3 (24)
	Girls ages 7-8	2	2	2	6 (48)
	Parents of girls ages 7-8	1	1	1	3 (24)
	Boys grades ages 7-8	2	2	2	6 (48)
	Parents of boys ages 7-8	1	1	1	3 (24)
	<i>Subtotal, Phase 1</i>	<i>12</i>	<i>12</i>	<i>12</i>	<i>36 (244)</i>
Phase 3	Parents of children ages 2-4	6	6	6	18(144)
	<i>Subtotal, Phase 3</i>	<i>6</i>	<i>6</i>	<i>6</i>	<i>18 (144)</i>
	GRAND TOTALS	30	30	30	90 (720)

(1) Each focus group will be comprised of 8 participants

Potential participants will be identified using a variety of resources. Most will come from an existing database (or list) of potential participants which is owned and maintained by each focus group facility. Others will come from referrals (either from those people found in the facilities' databases or from community resources), and some may come from dialing into selected geographies (or neighborhoods) in which the facilities feel that potential participants may reside. Participants will be recruited using standard focus group recruitment methods -- by calling their household and administering a screening questionnaire to pre-qualify them (see attached Participant Screeners in Appendix D).⁵⁵

B-2. Procedures for the Collection of Information

After arriving at the focus group facility, the respondents will be given information on the study and a consent/assent form to sign (See Appendix E1-E3). Then the respondents in each group will be gathered in a room with a trained moderator and a one-way mirror, behind which will sit CDC, AED, and ANR staff. The moderator will explain the study, inform the group of taping and observation, and lead a discussion using the guides provided in Attachments F and G. Responses will be collected by audiotape and videotape, and observers will take notes. After the group, the tapes will be transcribed for qualitative analysis.

B-3. Methods to Maximize Response Rates and Deal with Non-response

Several factors will help ensure a maximum response rate, and will help reduce issues of non-response, including the following:

- Participants will be paid at a level customary for focus group participation, and sensitive subjects are not addressed. Generally, people like to talk about their children and food. Youngsters tend to be willing participants as well for lively topics such as this one.
- The focus groups will be held in locations that are convenient and easily accessible by public transportation, and where parking is safe and easy. The group

discussions will be held in clean, safe, comfortable environments and conducted by professional moderators.

- Participants are drawn from lists of individuals who have expressed an interest in participating in focus groups. These lists are developed and maintained by focus group facilities. Thus, typically, people contacted are those interested in the process.

B-4. Tests of Procedures or Methods to be Undertaken

This is qualitative data collection. Statistical methods will not be used. Standard focus group discussion procedures and analysis of findings will be used.⁵⁵

B-5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The persons who designed the data collection and who will analyze the data are:

Thomas Leman, PhD
Academy for Educational Development
1825 Connecticut Avenue NW
Washington, DC 20009
Tel: (202) 884-8863
Fax: (202) 884-8879
Email: tlehman@aed.org

Ronne Ostby-Malling, MS
Academy for Educational Development
1825 Connecticut Avenue NW
Washington, DC 20009
Tel: (202) 884-8235
Fax: (202) 884-8448
Email: kmaxwell@aed.org

Dan Hough, MBA
Alan Newman Research
1025 Boulders Parkway, Suite 401
Richmond, VA 23225
Tel: (804) 272-6100
Fax: (804) 272-7145
Email: houghd@anr.com

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List of Appendices

Appendix A: Authorizing Legislation

Appendix B: 60-day Federal Register Notice

Appendix C: Summary of Public Comments

Appendix D1: Recruitment Screener for Parent-Child Groups

Appendix D2: Recruitment Screener for Child-Only Groups

Appendix D3: Recruitment Screener for Parent-Only Groups

Appendix E1: Consent Form for Adults

Appendix E2: Parental Permission Form

Appendix E3: Youth Assent Form

Appendix F: Children's/Youth Focus Groups Discussion Outline

Appendix G: Parent's Focus Groups Discussion Outline

Appendix H: IRB approval letter