Advancing Quality Healthcare Through Over-the-Counter Medicines and Nutritional Supplements

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

February 25, 2004

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

FAX: 301/827-6870

Re: FDA Docket No. 2003N-0496; Food Labeling: Health Claims; Dietary Guidance. 68 Fed. Reg. 66040-66048 (November 25, 2003)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) is pleased to provide FDA comments regarding the Advance Notice of Proposed Rulemaking (ANPR) for Food Labeling: Health Claims and Dietary Guidance, 68 Fed. Reg. 66040-66048 (November 25, 2003). CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplements and over-the-counter drug products.

CHPA welcomes the opportunity to be a participant in this rulemaking process for health claims and dietary guidance and supports the Agency's efforts to develop a process that facilitates the communication of truthful and non-misleading information to consumers about health claims on food and dietary supplement products (hereinafter collectively referred to as "food products"). We are aware FDA is engaged in ongoing consumer testing of health claim language and we support these activities. Given the wealth of experience industry has in communicating with the consumer, we encourage active dialogue about these studies as the outcome of this research will be used to convey important health concepts to consumers through our product's labeling. Consumer confidence in and understanding of health claims is a goal that is shared by both industry and FDA.

We support the development of a regulatory process by which scientifically-based, qualified health claims can be communicated to the consumer. In response to the ANPR's request for comments, CHPA provides comments and recommendations as to (1) the proposed options for regulating qualified health claims, (2) the issues raised by the Task Force on Consumer Health Information for Better Nutrition (Task Force), and (3) the use of dietary guidance statements on food labels.

I. Health Claims

FDA proposed three options for regulating health claims that do not meet the significant scientific agreement (SSA) standard of evidence; i.e., qualified health claims. FDA requested comments on the strengths and weakness of each option as well as which option or additional option is the best for regulating qualified health claims. CHPA's evaluation of the options and recommendations are as follows:

1150 Connecticut Avenue, N.W. • Washington, D.C. 20036-4193 • Tel: 202-429-9260 • Fax: 202-223-6835 • www.chpa-info.org

2003N-0496 C13

1. **CHPA recommends adoption of option 1 (i.e., codify the current interim procedures, or codify a variation of the current interim procedures and evidence-based ranking system into a regulation) with modifications as described below.** We concur with the Agency that the current procedures are consistent with the spirit of the Nutrition Labeling and Education Act (NLEA) of 1991 in that it maintains a system in which the data supporting qualified health claims are evaluated by the Agency prior to authorization. This process establishes common scientific standards and standardization of the health claims across industry. Although this option does not include a notice-and-comment rulemaking process, it does provide for public comment. We also support the use of enforcement discretion letters, as this provides the most efficient, flexible and rapid mechanism by which FDA can revise a decision based on subsequent data. Thus, this process includes a system that addresses emergent changes in scientific evidence. We recommend, however, that Option 1 be modified to allow interested parties to work with the Agency to develop qualified health claim language which promotes consumer understanding.

   We also propose below three mechanisms by which FDA may establish and ensure adherence to a reasonable timeframe for review.

   - First, as proposed by FDA, review of petitions for a new qualified health claim will be completed within 270 days after receipt of the petition. Qualified health claims could be used after 270 days unless the FDA concludes within the 270-day review period that the data do not support the proposed health claim. We proposed that, in addition, priority review and shorter approval time within the 270-day period (such as 180 days), should be given to those petitions that include competent and reliable scientific data and an assessment of the evidence in support of the claim by qualified experts in the appropriate field. This approach should allow FDA to decrease the resources required to review the evidence supporting the claim.
   - Second, we propose a shorter review time be established for qualified health claim petitions that are accompanied by a non-government review panel report. These non-government review panels would be comprised of independent scientific experts in the appropriate areas of research and are further defined in our responses to issues raised by the Task Force (See discussion at Section II, Issue #6). Qualified health claims submitted under this process could be used after 120 days unless the FDA concludes within the 120-day review period that it does not agree with the review panel's conclusion. A recognized body of qualified experts from international bodies should also be considered as appropriate to provide an independent review of data.
   - Third, we propose that modifications to the qualifying language of existing claims, based on new scientific data submitted to the Agency, can be used 90 days after the submission of the new data unless FDA objects to such modification.

   It is important to the dietary supplement industry that FDA establishes and adheres to reasonable time-frames for review and approval. These above- mentioned modifications will facilitate a more timely review of qualified health claim petitions yet provide the Agency with adequate time to review the data supporting the claim prior to its use in labeling.

2. **Option 2 (i.e., require each qualified claim to undergo notice and comment rulemaking) is not acceptable because it does not link the weight of the scientific evidence to the claim, provides too long a review period and does not provide the flexibility needed to respond to emerging science.** Under Option 2 the focus is on the words of the proposed qualified health claims rather than on the scientific evidence that supports the substance/disease relationship. We support Option 1 because it focuses on the weight of the scientific evidence that supports the qualified health claim versus Option 2 that focuses on the qualifying language of the claim. Under Option 2, while the qualified health claim could be truthful and not misleading, significant gaps in the scientific support for the qualified health claim could exist and not be conveyed to the consumer. Further, because of the requirement of a notice-and-comment rulemaking, the review period could be up to 540 days. This period is too long to restrict the use of qualified health claims that may provide important information to consumers. Additionally, this option does not provide the necessary flexibility to address new emerging scientific information in a timely manner.

3. **Option 3 (i.e., treat qualified health claim as wholly outside NLEA) is not acceptable because we are concerned about FDA's limited resources to ensure enforcement, the potential for consumer confusion, and the lack of a role for FDA in the review of qualified health claims.** While Option 3 provides the potential to educate the public about important new health benefits in a timely manner, we are concerned about FDA's limited resources to allow for appropriate enforcement to stop and remove unsupported qualified health claims. Because each individual company would determine the standard of scientific evidence needed to support each type of qualified health claim, the lack of FDA review and standardization has the potential to allow qualified health claims in the marketplace that are confusing to the consumer. We believe the Agency has a role in assuring consistency and validity of the qualified health claims based on the weight of the scientific data and thus we support review of qualified health claims before their use on labels. While Option 3 has some merits, such as avoiding a time-consuming preclearance process, the potential enforcement issues, potential for consumer confusion and lack of pre-review of qualified health claims weigh against the benefit of this approach.

II. Issues Raised in the Task Force Report

The FDA is seeking comment on several additional issues that were raised by the Task Force. The following are CHPA's comments and recommendations.

1. **Data and Research on Substance/Disease Relationship**

   Issue: How can FDA provide incentives for manufacturers to develop the data needed to obtain SSA for an unqualified health claim? How can FDA help to develop more effective public-sponsored research on substance/disease relationships?

   CHPA Comment: CHPA supports the use of incentives for manufacturers to undertake research and develop the high quality scientific data necessary to obtain the SSA to support an unqualified health claim. As the development of data to establish SSA will require substantial resources both in terms of clinical cost and personnel, the sponsor(s) who provide(s) the data for an unqualified health claim should be afforded a period of marketing exclusivity (e.g., 12 months). This approach does not restrict another petitioner from submitting its own data to support an unqualified health claim. As an

incentive, data submitted in support of the unqualified health claim should be confidential until the end of the 12-month market exclusivity period, after which any party may use the unqualified health claim.

Additionally, we urge the Agency to consider greater flexibility in how unqualified health claim language is used on the product label. Alternative language, which may include simpler statements, should be permitted as long as it conveys the same message to consumer.

We also encourage additional research on substance/disease relationships. One suggestion is to develop an industry/academic/consumer steering board to provide guidance to the NIH and other government agencies engaged in research on substance/disease relationships that are of interest to the public and industry.

2. **Revised Claim Language for Unqualified Health Claims**
   Issue: Should FDA remove the word "may" from unqualified health claims? Are there alternatives to this change and will these changes assist the consumer in identifying the level of science supporting such health claims?

   CHPA Comments: CHPA supports the Task Force's recommendation that FDA consider removing the requirement for the word "may" from unqualified health claims. Use of the word "may" can be confusing to consumers, especially for unqualified health claims where SSA has been established for the substance/disease relationship. Unqualified health claims that are written in layman's language and clearly indicate the substance/disease relationship will be most understandable by the consumer. For example, the statement "calcium reduces the risk of osteoporosis" clearly indicates the disease/substance relationship and should be permitted on product labeling as long as the other requirements of the health claim also appear on the label.

3. **Interim Final Rules (IFR) for Unqualified Health Claims**
   Issue: Should FDA continue use of the IFR process for some or all unqualified health claims as a means of expediting the Agency's processing of these petitions? Are there specific circumstances when IFRs should or should not be considered appropriate?

   CHPA Comments: We support the continued use of the IFR process as means of providing the public with important health information as long as this process is shown to be effective in expediting the Agency's processing of the petitions. This process allows for use of a substance/disease health claim while also allowing for additional public comment and evaluation of the validity of the scientific evidence before such a claim is authorized. Provided there is competent and reliable scientific evidence under the SSA standard that supports the unqualified claim, an IFR should be appropriate in all circumstances.

4. **Use of Phrases Such as "FDA authorized" in Qualified and Unqualified Health Claims**
   Issue: Will phrases such as "FDA authorized/FDA says. . ." provide the consumer with more confidence in the claim? Would such a phrase, when used with claims supported by different levels of science, confuse or potentially confuse consumers?

CHPA Comments: We are not aware of any data that address the value of such phrases as "FDA authorized or FDA says. . ." and whether use of such phrases will enhance consumer confidence or be more confusing. We believe, however, that such phrases will be helpful to consumers and encourage FDA to conduct consumer research to address this question.

If FDA reviews the data provided in the petition to support a particular health claim, the applicant should have the opportunity to use such a phrase on the label. Use of such a phrase, however, should be optional. Phrases such as "FDA authorized/approved" should be used for unqualified health claims while qualified health claims might use statements such as "FDA reviewed." For example for unqualified health claims, "FDA authorized or FDA approved," may be useful to connote there is significant scientific agreement supporting unqualified claims. For qualified health claims in which significant scientific agreement has not been determined, use of a phrase such as "FDA evaluated or FDA reviewed" may be useful to convey to the consumer the level of scientific support of qualified health claims.

5. **Consumer Education**
Issue: How is the consumer best educated about the role of qualified health claims and how can such claims be used by consumers to advance their own understanding of diet and health matters?

CHPA Comment: We applaud the steps FDA is considering in this ANPR, which of themselves are an important element in educating consumers: allowing manufacturers to more readily provide truthful, non-misleading health information with their products. In addition, FDA can and should continue to use existing outreach vehicles – the FDA website, "FDA Consumer," joint educational projects with private groups, etc. – to effectively provide consumers with important educational messages on health and diet.

6. **Evaluations of Outside Scientific Groups**
Issue: Should non-governmental groups be given weight in evaluating the strength of the science supporting a health claim? If so, how should this weight be determined?

CHPA Comment: We support the inclusion of non-government expert review panel reports as a part of any petition for a health claim, as these reviews should facilitate and accelerate FDA review of the data. We believe that weight should be given to those evaluations performed by groups that are qualified and knowledgeable about the area of interest and are independent of the petition's sponsor. Thus, the Agency should give priority review and shorten the review time (See CHPA recommendation: modified option 1) for any petition that contains an expert review by a panel of qualified experts.

For allowing health claims, FDA should consider opinions from independent, established, non-governmental scientific groups as found in: 1) professional societies (e.g., American Heart Association, American Dietetic Association, American Pediatric Association, Life Science Research Organization for the Federated Societies of Experimental Biology, American Society of Clinical Nutrition, American Society of Nutritional Sciences), 2) academic and medical centers with experience in particular areas as defined by NIH or

any of the above professional societies, 3) groups of standing experts who have established themselves based on their experience in reviewing petitions and expertise in the field, and 4) scientifically credible international government or non-government bodies. The Food Advisory Committee should review the qualifications of these non-governmental scientific groups and make recommendations on their acceptability annually. If petitions are reviewed and supported by such independent, established non-governmental scientific groups, then FDA should accept the conclusions of these groups.

7. **Competent and Reliable Scientific Evidence**
   Issue: What should be the standard of "competent and reliable scientific evidence" for qualified health claims?

   CHPA Comments: CHPA supports the use of the same criteria used by the Federal Trade Commission (FTC) in determining competent and reliable scientific evidence. These criteria include tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area. Studies providing this evidence must be conducted and evaluated in an objective manner by person(s) who are qualified to do so and use procedures that are generally accepted. However, determining the relevance of competent and reliable scientific evidence for qualified health claims is a very complex issue and we encourage the Agency to work with industry to further define these criteria.

III. Dietary Guidance on Conventional Foods and Dietary Supplement Labels

CHPA agrees with the use of dietary guidance statements that are used to assist and encourage consumers in making better food choices and establishing better eating habits. The use of such dietary guidance statements, as long as they are truthful and not misleading, can provide consumers with valuable information about the health benefits of broad classes of foods while more definitive research is being conducted on the food class to determine the substance that is producing the health effect and for which a specific health claim may be made. This approach also provides a reasonable response to the First Amendment concerns identified in *Pearson* by providing consumers with truthful and not misleading information. In addition, CHPA supports the definitions of "dietary guidance" and "substance" as presented in the proposed rulemaking for qualified health claims (68 Fed. Reg. at 66047).

The FDA also asked for comments on the following questions:

1) Whether providing a list of dietary guidance statements that FDA recommends for inclusion on food labels would be desirable or useful to manufacturers?

   CHPA Comment: CHPA does not believe a list of FDA-recommended dietary guidance statements would be helpful because a prescribed list may impede the ability to convey new information to consumers based on new science. Given that science continues to evolve in the area of diet and its relationship to health, dietary statements must have the flexibility to convey new emergent data that may not have been considered when the FDA-recommended statements were developed.

2) Whether and how the Agency should partner with other Federal agencies to identify and agree upon recommended dietary guidance statements for food labeling?

CHPA Comment: CHPA supports the option for FDA to partner with other Federal agencies in order to provide consumers with dietary guidance statements based upon the best understanding and interpretation of the data. These other agencies may provide FDA with perspectives about diet and health that are not known to the FDA.

3) What are the appropriate criteria for evaluating the scientific validity of dietary guidance statements which appear on products in the marketplace?

CHPA Comment: CHPA supports the use of scientifically valid dietary guidance statements that are supported by qualified experts in the particular field. To assess the scientific validity of any particular statement, CHPA supports the use of those criteria outlined by the FTC and further enumerated in our response to FDA's question concerning the standard for competent and reliable scientific evidence (See Section II, Items 6 and 7).

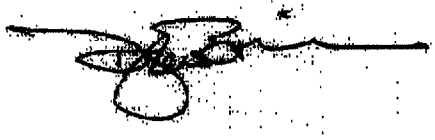
4) Whether and how the Agency should address dietary guidance statements from non-federal sources (e.g., States, trade associations, professional associations, etc.)?

CHPA Comment: CHPA is supportive of any dietary guidance statement that is truthful, not misleading and which is supported by scientific evidence as well as supported by qualified experts in the particular field. Thus, such statements should be acceptable regardless of the source as long as the above criteria are met (See response to Question 3 in Section III).

Conclusion

CHPA looks forward to continued cooperation with the FDA in the development of a regulatory process for qualified health claims. We encourage development of a process that is transparent, flexible to the needs of emerging science, prevents unfair market advantages and provides review of the petitions on a timely basis. We welcome the opportunity to work with the Agency and other interested parties towards this end.

Respectfully submitted,



Douglas Ws. Bierer, Ph.D.
Vice President – Regulatory & Scientific Affairs

DB/mm

cc: Paulette Gaynor, HFS-800

I:\Committees\DSC\ANPR Health Claims comments - final.doc