





*Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

May 22, 2001

Docket No. 01D-0058

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

Re: Docket No. 01D-0058: Comments on "Guidance on Applying the Structure/Function Rule; Request for Comments"

Dear Madam or Sir:

These comments are submitted by the Consumer Healthcare Products Association (CHPA) in response to the agency's notice in the Federal Register: February 22, 2001 (Volume 66, Number 36) concerning "Guidance on Applying the Structure/Function Rule; Request for Comments." CHPA's comments focus on the two topics on which FDA is seeking comments; these are the need for guidance documents that 1.) provide examples of labeling claims that would and would not be considered disease claims under the structure/function rule, including examples of product names; and 2.) provide guidance on the citation of a publication or a reference implying the treatment or prevention of a disease (Sec. 101.93(g)(2)(iv)(C)).

The Consumer Healthcare Products Association (CHPA) is the 120-year-old trade organization representing companies involved in the manufacture, distribution, supply, advertising and research of dietary supplements and nonprescription medicines. We have been actively involved in commenting on the evolving regulatory framework on structure/function and health claims for dietary supplements, and the substantiation of these types of claims.

8365 01 MAY 23 AM 1:04

01D-0058

C 2

CHPA Comments

As outlined by FDA in its February 22, 2001 Federal Register notice, the Dietary Supplement Health and Education Act (DSHEA) authorizes manufacturers of dietary supplements to claim effects on the “structure or function” of the body, but not to make claims to mitigate, treat, prevent, cure, or diagnose disease (21 U.S.C. 343(r)(6)). To explain how this part of DSHEA was to be implemented, FDA published the structure/function final rule on January 6, 2000 (65 FR 1000) (21 CFR 101.93(f) and (g)). This final rule distinguishes between disease claims and structure/function claims, which pertain to health promotion and maintenance.

In the preamble to the January 6, 2000 structure/function final rule, FDA stated that it would provide, through guidance, examples of labeling claims that would and would not be considered disease claims under the rule, including examples of product names. FDA also stated that it would issue guidance, if necessary, on the citation of a publication or a reference implying the treatment or prevention of a disease (Sec. 101.93(g)(2)(iv)(C)). As requested by the agency, CHPA’s comments focus on the two topics on which FDA is seeking comments, as outlined below.

- 1. CHPA does not support the development of a guidance document, that provides a framework for the construction of labeling claims that would and would not be considered disease claims under the January 6, 2000 final structure/function rule, as the preamble to this final rule provides adequate guidance to industry.**

CHPA does not support the development of a guidance document that provides a framework for the construction of labeling claims that meet the requirements under 21 U.S.C.343 (r) (6) and do not violate section 21 U.S.C. 321(g)(1)(B) of the Act. CHPA members believe that the preamble to the final rule and actions taken by the agency through courtesy letters are adequate in guiding industry at this time.

In the preamble to the January 6, 2000 final rule, the agency provides examples to demonstrate how a structure/function claim should be worded without violating the drug provisions of the act. Further, the preamble also provides adequate explanation on the rationale behind the use of certain terms in constructing claims for specific conditions. As an illustration, the agency provided an example on use of the word “promote” in certain types of maintenance claims as in “helps promote digestion,” versus “promotes low blood pressure.” In this example, it is the agency’s viewpoint that the word “promote” in the context of digestion versus “promotes” in the context of blood pressure changes materially the meaning of the claim. The rationale provided by the agency for the use of the word “promotes” in this situation, is as follows.

*“Maintenance claims also can be made under the provision that authorizes statements that “describe the role” of a supplement “intended to affect the structure or function” of the body (section 403(r)(6)(A) of the act). In response to the comment asking FDA to limit claims to “maintaining,” rather than “promoting” or “improving,” structure/function, the agency agrees that “improving” often suggests some abnormality or deficiency that can be treated, so a claim to “improve” a structure or function of the body would be more likely to be a disease claim. On the other hand, a claim to improve memory or strength would be a permitted structure/function claim, unless disease treatment were implied. Use of the term “promote” may be acceptable under the portion of section 403(r)(6)(A) of the act which authorizes claims that “describe[] the role of a * * * dietary ingredient intended to affect the structure or function.” Whether a claim for “promoting” structure or function is a disease claim will depend on the context and nature of the claim. For example, a claim that a product “helps promote digestion” would be a structure/function claim because it does not refer explicitly or implicitly to an effect on a disease state, but a claim that a product promotes low blood pressure would be considered a disease claim. Both the preamble to the proposed rule and the Commission recognized that statements using the word “promote” can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition that consumers cannot evaluate (see 63 FR 23624 at 23626).” (See Vol. 65, No. 4: II Comments, A. (8.), page 1006).*

Courtesy letters are an important information source used by industry for constructing structure/function claims. Given the value of this resource to industry, CHPA requests that the agency makes these more accessible. Through an improved system of indexing and website linkages, for example, companies could search and locate these letters more easily on the agency website.

2. CHPA does not support the development of a guidance document on the citation of a publication or a reference implying the treatment or prevention of a disease.

CHPA does not support the development of a guidance document on the citation of a publication or a reference implying the treatment or prevention of a disease, as this has been adequately addressed in the preamble to section § 101.93(g)(2)(iv)(C) of the final rule, in paragraph K. “Citation of Publication Titles” (65 FR 1023-25). In this preamble, the agency has explained how it arrived at its final decision on the use of publications or reference.

3. CFSAN’s limited resources should be directed to high priority issues, particularly safety and quality.

If the agency were to develop a guidance document on structure/function claims, it would likely expend considerable resources compiling, re-reviewing and integrating past

policies defined in courtesy letters and, potentially, publishing a proposed guidance for further public comment. The burden to CFSAN staff to undertake this activity would be great, and thus would likely undermine the ability of CFSAN to achieve its annual top priorities on dietary supplements.

Given the limited resources at the agency, CHPA recommends that it focus these resources on its safety-related programs. As stated by CHPA in its comments of August 25, 2000 on the agency's 2001 Program Priorities for Dietary Supplements in the Center for Food Safety and Applied Nutrition, consumers and the industry would be better served if FDA continued to focus its activities on safety, as its number one priority in 2001. As we have long maintained, CFSAN should have an effective safety plan for dietary supplements in place in FY-2001 that includes enforcement, Good Manufacturing Practices (GMPs) regulation and Adverse Event Reporting (AER) management.¹ CHPA would like to reinforce that the agency should continue to make these programs their top priority for dietary supplements.

Conclusion

In conclusion, CHPA does not support the issuance of guidance documents on structure/function labeling claims or on the citation of a publication or a reference implying the treatment or prevention of a disease. The preamble to the final rule and the agency's courtesy letters provide adequate guidance to the industry at this time. An improved system of indexing and website linkages would be helpful and have a limited resource impact on CFSAN.

We thank for your consideration of our comments.



R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology



Leila G. Saldanha, Ph.D., R.D.
Vice President – Nutritional Sciences

Attachment: CHPA comments to the agency dated August 25, 2000 on 2001 Program Priorities for Dietary Supplements in the Center for Food Safety and Applied Nutrition

¹ See enclosed CHPA comments to the agency dated August 25, 2000.



Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

COPY

August 25, 2000

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

**RE: Docket No. 98N-0359: 2001 Program Priorities for Dietary
Supplements in the Center for Food Safety and Applied Nutrition**

Dear Madam or Sir:

The Consumer Healthcare Products Association (CHPA)¹ submits these written comments in response to FDA's notice in the June 26, 2000 *Federal Register* concerning Program Priorities in the Center for Food Safety and Applied Nutrition (CFSAN).

Summary

FDA should place safety as its number one priority in 2001. CFSAN should have an effective safety plan for dietary supplements in place in FY-2001 that includes enforcement, Good Manufacturing Practices (GMPs) regulation and Adverse Event Reporting (AER) management.

¹ CHPA is a 119-year-old trade organization representing the manufacturers and distributors of national and store brand dietary supplements and nonprescription medicines. CHPA's membership includes over 200 companies involved in the manufacture and distribution of these self-care products and their affiliated services (e.g., raw material suppliers, research testing companies, contract manufacturing companies, advertising agencies, etc.).

The priority "A" List below, is a list of items CHPA recommends FDA place in CFSAN's priority "A" List of activities for dietary supplements in FY-2001. It contains items that industry has encouraged CFSAN to implement on several occasions, in written and oral comments, in the last 12-18 months. It also includes items that the Agency had indicated that it planned to execute, but has not yet delivered on, in 2000. This is not a list of "new" items, but a list of much-awaited actions by the Agency. CHPA, therefore, urges CFSAN to develop a two-three year program of work for dietary supplements that outlines how and when in FY-2001 it proposes to implement this "A" List of items. A two-three year program of work that focuses on these items will address the one central question the Agency uses in its priority-setting process, which is: "*Where do we do the most good for consumers?*"

"A" List

Dietary Supplements Activities

- 1) **Enforcement:** Put into place in FY-2001 an effective enforcement policy that removes unsafe products from the marketplace, and ensures claims made on dietary supplements are truthful and substantiated.
- 2) **Dietary Supplement GMPs:** Publish the much-awaited dietary supplement GMP proposed rule before the end of 2000.
- 3) **Create an Ad Hoc AER Working Group:** Create an AER Ad Hoc Working Group that would provide recommendations to FDA how they could reengineer the current or create a new AER system for dietary supplements.

- 4) **Reverse Decision in February 29, 2000 letter:** Reverse decision announced in the February 29 "Dear Colleague" joint letter from Joseph Levitt and Janet Woodcock, and restore CFSAN to its previous leadership position in making final decisions on structure/function claims.

- 5) **Pearson Ruling:** Implement the "Strategy for Implementation of Pearson Court Decision" FDA outlined in the December 1, 1999 *Federal Register* notice (Volume 64, Number 230).

- 6) **Citizen Petitions:** Respond to the St. John's wort and Pregnancy/Nursing label statements, and other Citizen Petitions filed by CHPA in 2000.

Detailed Comments

Enforcement: CHPA requests FDA put into place in FY-2001 an effective federal enforcement policy for dietary supplements that removes unsafe products from the marketplace, and ensures claims made on dietary supplements are truthful and substantiated.

- In passing DSHEA, Congress intended that consumers would use dietary supplements for health promotion, health maintenance and disease risk reduction. Consumer confidence is essential to product use. Allegations that the dietary supplement industry is "unregulated" or that FDA is not using its statutory authority to act can undermine that confidence. Lack of an effective federal enforcement policy can lead to inconsistent state legislative actions that will cause problems with products that move in interstate commerce. Therefore, foundational to CFSAN's overall strategy for dietary supplements is an effective enforcement policy that removes unsafe products from the marketplace and ensures truthful, not misleading, and substantiated

claims on dietary supplements, so consumers are able to trust in these products and use them as Congress had intended.

Good Manufacturing Practices: CHPA requests FDA to publish the much-awaited dietary supplement GMP proposed rule before the end of 2000. On February 6, 1997, the Agency published an advanced notice of proposed rulemaking in the *Federal Register*. It has been over three years since the publication of this document. Although the Agency has indicated in several public forums that it has placed publication of a proposed rule on high priority, its appearance in the *Federal Register* appears to be a moving target date for the Agency. Without GMPs specific to dietary supplements, it is difficult to demonstrate to the public that FDA is serious about consumer safety and its obligation to regulate dietary supplements.

- GMP regulations for dietary supplements are important for the following reasons: a) differing needs of dietary supplements vs. foods, specifically related to manufacturing processes, laboratory controls and quality control (QC)/quality assurance (QA) specifications, and b) there are at least three sets of GMPs now in use for dietary supplements, specifically, the food GMPs, the dietary supplement industry-proposed GMPs and GMPs used under the voluntary program of the National Nutritional Foods Association. GMP regulations would lead to uniformity in how manufacturing processes are evaluated, thus raising the level of quality of products in the market place. In addition, GMPs will raise the level of awareness among suppliers, manufacturers and distributors regarding the need for quality operations.

Create an Ad Hoc AER Working Group: CHPA asks FDA to create an AER Ad Hoc Working Group, which would provide recommendations to FDA how they could reengineer the current or create a new AER system for dietary supplements.

- An effective AER system for dietary supplements is important to ensure that safe products continue to remain in the marketplace. A science-based discussion on

realistic approaches to AER management, which includes topics such as the analysis of AER's and science-based approach to AER filtering is important. Therefore, CHPA recommends that CFSAN create an Ad Hoc AER Working Group. This group should include representation from industry, and provide a review of and recommendations for changes to FDA's existing AER system to better serve the needs of consumers, professionals, industry and the agency.

Reverse Decision in February 29, 2000 letter: CHPA asks FDA to reverse the decision announced in the February 29 "Dear Colleague" joint letter from Joseph Levitt and Janet Woodcock, and restore CFSAN to its previous leadership position in making the final decision as to what constitutes a structure/function claim.

- CHPA recognizes that CFSAN may need to consult with CDER on a case-by-case basis as to the distinction between a "disease" and a "non-disease" when considering a particular health claim, structure/function claim or statement of nutritional support. However, CFSAN improperly abdicates its responsibility to act as the principal decision making authority about the status of products represented as dietary supplements by giving to CDER the primary authority to make status determinations. Moreover, the placement of this important function within CDER suggests an improper bias by the agency toward drug classification.

Pearson Ruling: CHPA requests FDA to implement the "Strategy for Implementation of Pearson Court Decision" FDA outlined in the December 1, 1999 *Federal Register* notice (Volume 64, Number 230).

- In that notice FDA outlined the components of this strategy, which include: (1) updating the scientific evidence on the four claims at issue in Pearson; (2) issuing guidance clarifying the "significant scientific agreement" standard; (3) holding a public meeting to solicit input on changes to FDA's general health claim regulations for dietary supplements that may be warranted in light of the Pearson decision; (4)

conducting a rulemaking to reconsider the general health claims regulations for dietary supplements in light of the Pearson decision; and (5) conducting rulemakings on the four Pearson health claims. Although the Agency has acted on items 1, 2 and 3 listed above, it has yet to issue a proposed rule on the four Pearson health claims or on health claims for dietary supplements. CHPA urges FDA to act expeditiously in implementing the Pearson strategy.

Citizen Petitions: CHPA still awaits a response to the St. John's wort and Pregnancy/Nursing label statements, and other citizen petitions filed by CHPA in 2000.

The following is a list of petition filing dates:

<u>Citizens Petition</u>	<u>Date Filed</u>
<i><u>St. John's wort:</u></i> Requests FDA to issue a regulation requiring a label statement on dietary supplements containing St. John's wort.	June 20, 2000
<i><u>Pregnancy/Nursing:</u></i> Requests FDA to issue a regulation requiring label statements on certain dietary supplements pertaining to their use in pregnancy and/or when nursing a baby.	May 11, 2000
<i><u>Structure/Function Final Rule:</u></i> Petition for Reconsideration and Stay of Action to reverse a decision announced in the preamble to the final structure/function claims rule concerning claims for conventional foods and for dietary supplements having nutritive value.	February 7, 2000
<i><u>Structure/Function Final Rule:</u></i> Petition for Stay of Action asking FDA to stay the 30-day compliance date for parts of the final structure/function rule for products ready for launch but not marketed by January 6, 2000.	February 7, 2000

Conclusion: In conclusion, CHPA asks FDA to make safety its number one priority for dietary supplements in 2001. CFSAN should have an effective safety plan in place in FY2001 that includes enforcement, dietary supplement GMP regulation and AER management. CHPA urges CFSAN to develop a program of work in FY2001 that focuses on implementing the "A" List of activities outlined on page two of this comment. In doing so, the Agency will address the one central question the Agency uses in its priority-setting process, which is: "*Where do we do the most good for consumers?*"

Sincerely yours,

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

Leila Saldanha, Ph.D., R.D.
Vice President, Nutritional Sciences