



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

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Formerly Nonprescription Drug Manufacturers Association

May 11, 1999

Dockets Management Branch
5630 Fishers Lane Room 1061
Rockville, Maryland 20857

Re: Docket No. 99N-0554: How to Use Health
Claims and Nutrient Content Claims in Food
Labeling

To Whom It May Concern:

The Consumer Healthcare Products Association (CHPA), formerly the Nonprescription Drug Manufacturers Association (NDMA), is the 118-year-old trade association representing manufacturers and distributors of dietary supplements and nonprescription medicines. CHPA submits these comments to the Food and Drug Administration in response to the agency's recent announcement of a public meeting concerning implementation of sections 303 and 304 of the Food and Drug Administration Modernization Act of 1997 [*Fed. Reg.* 64 (56): 14178-14180, March 24, 1999]. Those provisions provide for use, in food labeling, of health claims and nutrient content claims based on authoritative statements published by certain Federal scientific bodies or the National Academy of Sciences (NAS) or any of its subdivisions.

In FDA's announcement, the agency listed a number of questions to, and areas for input from, external constituencies. In addition to the comments made below, CHPA's appends two detailed comments on this matter:

- A CHPA's April 6, 1999, detailed written submission to Docket No. 98N-0826 onto Food Labeling: Use of Dietary Supplements of Health Claims Based on Authoritative Statements (64 Fed. Reg. 3250 (January 21, 1999));
- B CHPA's Response to FDA's Questions for the May 11, 1999 Public Meeting on Implementation of FDAMA Sections 303 and 304, which provides a point-by-point response to each of the questions posed by FDA.

CHPA supports the agency's effort to place dietary supplements on an equal footing with conventional foods with respect to health claims based on authoritative statements. However, the Association does not agree that "significant scientific agreement" standard applies to these health claims. In this regard, we make two main points in Attachment A.

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First, the Final Rule should reflect Congress' intent under FDAMA that there be an alternative mechanism to NLEA for health claims for dietary supplements, since the development of health claims has been shown to be susceptible to protracted rulemaking process (e.g., the health claim for folic acid and neural tube defects).

Second, in order to streamline and expedite health claims development, as intended by Congress, FDA should not attempt to impose its authority over other government agencies charged with public health protection by defining an over-arching standard that it would administer to approve all health claims. FDA should only define its own approval standard for health claims based on applications submitted for a health claim that would require FDA itself to develop its own authoritative statement for that claim.

In implementing these two basic principles, FDA should view the regulatory process for nutrient content and health claim based on authoritative statements as a three step process of notification, confirmation, and approval.

The notification step of this process:

- Begins with the publication of an authoritative statement by “a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;” this authoritative statement is the presumptive surrogate of a deliberative review process by FDA, were FDA to develop an authoritative statement; [see 403(r)(3)(C)(i)]
- Continues with the submission by a petitioner of a notification under the statutory 120 day procedure; the notification should include:
 - A notice of the claim
 - A copy of the statement;
 - A balanced presentation of the scientific literature;
 - The statement of the claim and dietary supplement in conformance with § 101.14(a)(5) and (c)(3) and sections 403(a) and 201(n) of the act [21 USC 343(a) and 21USC 321(n)];
 - The statement of the claim in a manner that is an accurate presentation of the authoritative statement that is the subject of the submission, so that the public can comprehend the information and be able to understand the relative significance of such information in the context of a total daily diet.

Since health claims and nutrient content claims based on authoritative statements from “a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition,” it is expected that the authoritative statement would have been based on all available safety and benefit information relevant to the current authoritative statement. As such, the substantiation in the notification of a health or nutrient content claim based on an authoritative statement should not be as extensive as that for such claims which are submitted for de novo review by FDA and which therefore are not based on authoritative statements.

The confirmation step of this process has three phases of FDA review:

- Phase I involves FDA determining if the components per 403(r)(2)(G)(ii) and (r)(3)(C) (ii) are present in the petition
- Phase II involves FDA determining what nutrient is at issue and **confirming** the authoritative statement is attributable to a “scientific body” and is published per 403(r)(2)(G)(i), 403(r)(3)(C)(i);
- Phase III involves FDA contacting the “scientific body” and confirming the authoritative statement is:
 - Currently in effect;
 - Not the statement of an employee in his/her individual capacity.

The approval step of this process involves FDA:

- Reviewing the wording of the claim per 403(r)(2)(G)(iii), (iv) and 403(r)(3)(C)(iii), (iv) so that it is:
 - An accurate representation of the authoritative statement, including whether it is taken out of context of the entire authoritative statement;
 - Able to be comprehended by the public, including its relative significance in the context of the total daily diet;
- Notifying the petitioner and the public of the approval of the health claim under the 120 day statutory deadline.

As detailed in Attachment A, it is important that FDA neither set itself above other US Government scientific bodies with official responsibility for public health protection or research directly relating to human nutrition nor invoke a “significant scientific agreement” standard as a means to supercede an authoritative statement from such a body that is published, currently in effect and not the statement of an employee in his/her individual capacity.

Applying the significant scientific agreement standard to authoritative statements as provided in the FDA's 1998 Guidance on Health Claims¹ would nullify and undermine

¹ Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body, Office of Food Labeling, CFSAN, FDA; Notice of

the language and intent of Congress in the FDAMA authoritative statement health claims provision. FDA would place itself in the position of second-guessing and potentially overruling fellow government science agencies, which is exactly what Congress sought to change when it enacted the FDAMA authoritative statement provision.

Before FDAMA, health claims development was limited to the system provided in the Nutrition Labeling and Education Act (NLEA). Under the NLEA system, FDA gathers all public scientific evidence about a possible health claim. The agency then makes an independent determination whether there is “significant scientific agreement” among qualified experts that the health claim is supported.²

Congress found this process to be seriously flawed because it failed to give sufficient weight to the authoritative statements of other government bodies with public health protection responsibility. The prime example cited by Congress was FDA's refusal from 1992 until 1996 to accept the Centers for Disease Control (CDC) determination about the relationship between folic acid and neural tube defects. Even though CDC was recognized for its authority and standing to issue scientific recommendations about public health matters, FDA would not accept the CDC folic acid/neural tube defect recommendation without a protracted rulemaking process. Congress said the process is “inefficient and fails adequately to benefit from the deliberative processes in which authoritative scientific bodies engage in issuing statements on matters of public health.”³

To correct this problem, Congress developed an alternative mechanism intended to streamline and expedite health claims authorization. The alternative process gives proper weight to the authoritative statements of other federal science bodies such as

Availability, Docket No. 98D-0389, 63 Fed. Reg. 32101 (June 11, 1998); Internet at <http://www.cfsan.fda.gov/>. In the referenced Guidance, FDA asserts that FDAMA “upholds the ‘significant scientific agreement’ standard for health claims” based on authoritative statements because FDAMA permits FDA to issue a regulation that prohibits or modifies a claim based on the significant scientific agreement standard. FDA continues, saying, “consistent with this provision, FDA intends to determine whether the standard of significant scientific agreement is met by a health claim based on an authoritative statement.”

² The provision is as follows:

“The Secretary shall promulgate regulations authorizing [health] claims ... only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is *significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.*”

21 U.S.C. § 343(r)(3)(B). [Emphasis added.]

³ Report of the Committee on Labor and Human Resources on S. 830 at 49 (July 1, 1997).

CDC, without FDA reexamination of the underlying scientific evidence. Under the alternative system, codified in FDAMA, Congress permits health claims to be made based upon duly authorized statements from federal bodies other than FDA with public health responsibility, where FDA has been given premarket notification about the claim. The provision states that a health claim “shall be authorized and may be made” if:

“[A] scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers.” 21 U.S.C. § 343(r)(3)(C).

A health claim that meets these criteria for an authoritative statement is presumptively valid under the statute. There is no basis for an independent FDA review of the science that has already been reviewed by another federal government science body. FDA reexamination of the claim under the NLEA significant scientific agreement standard would basically bootstrap the NLEA standard and procedure into the FDAMA procedure. It would mean that the agency could substitute its own judgment for the authoritative statement of another federal government body, effectively gutting the FDAMA provision. This would produce a repetition of the problem represented by the folic acid situation, which the FDAMA provision was intended to correct.⁴

Under FDAMA, FDA has the ability to supersede an authoritative statement health claim if it independently issues a regulation “prohibiting or modifying the claim” under the significant scientific agreement standard of section 403(r)(B)(i). This is different, however, from FDA’s ability to publish a health claim regulation based upon a health claim petition filed under the NLEA. The FDAMA provision cannot be read to permit FDA to approve a health claim based on an authoritative statement only where the agency would be prepared to approve an NLEA health claim petition under the significant scientific agreement standard. To do so would transform the authoritative statement health claims provision of FDAMA into a virtual clone of the NLEA health claims provision, nullifying the FDAMA provision.

The federal courts have also made clear that under the First Amendment commercial speech doctrine, FDA may not suppress health claims that are truthful and not misleading. In Pearson v. Shalala, the U. S. Court of Appeals held that health claims

⁴ While CHPA maintains that the significant scientific agreement standard does not apply to authoritative statement health claims under § 343(r)(3)(C), the Association notes that the U.S. Court of Appeals for the D.C. Circuit recently invalidated four FDA health claims regulations for dietary supplements issued under § 343(r)(3)(B), on the grounds, in part, that FDA violated the Administrative Procedure Act by failing to define the standard. Pearson v. Shalala, No. 98-5043 (D.C. Cir., Jan. 15, 1999).

enjoy First Amendment commercial speech protection, and it rejected FDA's arguments that health claims are inherently misleading unless they are pre-approved by the agency based on a "significant scientific agreement" standard. No. 98-5043, slip op. (D.C. Cir., Jan. 15, 1999).⁵ It is clear under the Pearson decision that truthful claims based upon the authoritative statements of federal scientific bodies, including qualified statements concerning diet/disease relationships, not only must be authorized under FDAMA but are constitutionally protected under the First Amendment. To the extent that the FDA Guidance document would import the significant scientific agreement standard from the NLEA health claims provision into the authoritative statement health claims provision barring truthful and nonmisleading qualified claims, the Guidance document is invalid under Pearson v. Shalala, and should be revoked or revised.

In sum, FDA should not attempt to impose its authority over other government agencies charged with public health protection by defining an over-arching standard that it would administer to approve all health claims.

Sincerely yours,



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

- Attachments A CHPA's April 6, 1999, detailed written submission to Docket No. 98N-0826 onto Food Labeling: Use of Dietary Supplements of Health Claims Based on Authoritative Statements (64 Fed. Reg. 3250 (January 21, 1999));
- B CHPA's Response to FDA's Questions for the May 11, 1999 Public Meeting on Implementation of FDAMA Sections 303 and 304, which provides a point-by-point response to each of the questions posed by FDA.

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⁵ The court also found that the agency had failed to define "significant scientific agreement" and therefore violated the Administrative Procedure Act. Id. at 20.



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*Producers of Quality
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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Formerly Nonprescription Drug Manufacturers Association

April 6, 1999

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

Re: Food Labeling: Use of Dietary Supplements of Health
Claims Based on Authoritative Statements:
64 Fed. Reg. 3250 (January 21, 1999); Docket No. 98N-0826

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA), formerly the Nonprescription Drug Manufacturers Association (NDMA), is the 118-year-old trade association representing manufacturers and distributors of dietary supplements and nonprescription medicines. The Association submits these comments in response to the above-referenced proposed rule concerning use on dietary supplements of health claims based on authoritative statements. FDA intends that its proposed rule would provide for the same process and standard for use on dietary supplements of health claims based on authoritative statements, as provided by section 403(r)(3)(c) of the act for conventional foods.

CHPA supports the agency's effort to place dietary supplements on an equal footing with conventional foods with respect to health claims based on authoritative statements. However, the Association does not agree that "significant scientific agreement" standard applies to these health claims.

I. The Approval Standard for Health Claims Based on Authoritative Statements

FDA should only define the approval standard for health claims on dietary supplements or foods for those claims which are specifically submitted to FDA for promulgation of a health claims regulation. FDA does not have the legal authority to define the standard that would be used by other authoritative bodies to define statements/policies supporting health claims for dietary supplements or foods. Indeed, FDA's own wording for proposed §101.90(a) specifies that the claims under consideration in the proposed rule are those that are "not authorized by the Food and Drug Administration."

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The proposed rule cites and incorporates by reference a document entitled "Guidance for Industry—Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body."¹ 64 Fed. Reg. at 3252 (January 21, 1999). The agency says that the Guidance and nine interim final rules² reflect the agency's current thinking as to the process and principles that FDA will apply to the health claims based on authoritative statements.

In the referenced Guidance, FDA asserts that FDAMA "upholds the 'significant scientific agreement' standard for health claims"³ based on authoritative statements because FDAMA permits FDA to issue a regulation that prohibits or modifies a claim based on the significant scientific agreement standard. FDA continues, saying, "consistent with this provision, FDA intends to determine whether the standard of significant scientific agreement is met by a health claim based on an authoritative statement."⁴

Applying the significant scientific agreement standard to authoritative statements as provided in the Guidance would nullify and undermine the language and intent of Congress in the FDAMA authoritative statement health claims provision. FDA would place itself in the position of second-guessing and potentially overruling fellow government science agencies, which is exactly what Congress sought to change when it enacted the FDAMA authoritative statement provision.

Before FDAMA, health claims development was limited to the system provided in the Nutrition Labeling and Education Act (NLEA). Under the NLEA system, FDA gathers all public scientific evidence about a possible health claim. The agency then makes an independent determination whether there is "significant scientific agreement" among qualified experts that the health claim is supported.⁵

¹ Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body. Office of Food Labeling, CFSAN, FDA; Notice of Availability, Docket No. 98D-0389, 63 Fed. Reg. 32101 (June 11, 1998); Internet at <http://www.cfsan.fda.gov/>.

² FDA published nine interim final rules based upon the Guidance in response to notifications of health claims based on authoritative statements. 63 Fed. Reg. 34084, 34092, 34097, 34101, 34104, 34107, 34110, 34112, and 34115 (June 22, 1998). CHPA does not address the nine interim final rules themselves.

³ Guidance, note 1, *supra*.

⁴ *Id.*

⁵ The provision is as follows:

"The Secretary shall promulgate regulations authorizing [health] claims ... only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is *significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims*, that the claim is supported by such evidence."

Congress found this process to be seriously flawed because it failed to give sufficient weight to the authoritative statements of other government bodies with public health protection responsibility. The prime example cited by Congress was FDA's refusal from 1992 until 1996 to accept the Centers for Disease Control (CDC) determination about the relationship between folic acid and neural tube defects. Even though CDC was recognized for its authority and standing to issue scientific recommendations about public health matters, FDA would not accept the CDC folic acid/neural tube defect recommendation without a protracted rulemaking process. Congress said the process is "inefficient and fails adequately to benefit from the deliberative processes in which authoritative scientific bodies engage in issuing statements on matters of public health."⁶

To correct this problem, Congress developed an alternative mechanism intended to streamline and expedite health claims authorization. The alternative process gives proper weight to the authoritative statements of other federal science bodies such as CDC, without FDA reexamination of the underlying scientific evidence. Under the alternative system, codified in FDAMA, Congress permits health claims to be made based upon duly authorized statements from federal bodies other than FDA with public health responsibility, where FDA has been given premarket notification about the claim. The provision states that a health claim "shall be authorized and may be made" if:

"[A] scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers." 21 U.S.C. § 343(r)(3)(C).

A health claim that meets these criteria for an authoritative statement is presumptively valid under the statute. There is no basis for an independent FDA review of the science that has already been reviewed by another federal government science body. FDA reexamination of the claim under the NLEA significant scientific agreement standard would basically bootstrap the NLEA standard and procedure into the FDAMA procedure. It would mean that the agency could substitute its own judgment for the authoritative

⁶ Report of the Committee on Labor and Human Resources on S. 830 at 49 (July 1, 1997).

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statement of another federal government body, effectively gutting the FDAMA provision. This would produce a repetition of the problem represented by the folic acid situation, which the FDAMA provision was intended to correct.⁷

Under FDAMA, FDA has the ability to supersede an authoritative statement health claim if it independently issues a regulation "prohibiting or modifying the claim" under the significant scientific agreement standard of section 403(r)(B)(i). This is different, however, from FDA's ability to publish a health claim regulation based upon a health claim petition filed under the NLEA. The FDAMA provision cannot be read to permit FDA to approve a health claim based on an authoritative statement only where the agency would be prepared to approve an NLEA health claim petition under the significant scientific agreement standard. To do so would transform the authoritative statement health claims provision of FDAMA into a virtual clone of the NLEA health claims provision, nullifying the FDAMA provision.

The federal courts have also made clear that under the First Amendment commercial speech doctrine, FDA may not suppress health claims that are truthful and not misleading. In Pearson v. Shalala, the U. S. Court of Appeals held that health claims enjoy First Amendment commercial speech protection, and it rejected FDA's arguments that health claims are inherently misleading unless they are pre-approved by the agency based on a "significant scientific agreement" standard. No. 98-5043, slip op. (D.C. Cir., Jan. 15, 1999).⁸ It is clear under the Pearson decision that truthful claims based upon the authoritative statements of federal scientific bodies, including qualified statements concerning diet/disease relationships, not only must be authorized under FDAMA but are constitutionally protected under the First Amendment. To the extent that the FDA Guidance document would import the significant scientific agreement standard from the NLEA health claims provision into the authoritative statement health claims provision barring truthful and nonmisleading qualified claims, the Guidance document is invalid under Pearson v. Shalala, and should be revoked or revised.

In sum, FDA should not attempt to impose its authority over other government agencies charged with public health protection by defining an over-arching standard that it would administer to approve all health claims. At the most, FDA should only define its own approval standard for health claims based on applications submitted for FDA health

⁷ While CHPA maintains that the significant scientific agreement standard does not apply to authoritative statement health claims under § 343(r)(3)(C), the Association notes that the U.S. Court of Appeals for the D.C. Circuit recently invalidated four FDA health claims regulations for dietary supplements issued under § 343(r)(3)(B), on the grounds, in part, that FDA violated the Administrative Procedure Act by failing to define the standard. Pearson v. Shalala, No. 98-5043 (D.C. Cir., Jan. 15, 1999).

⁸ The court also found that the agency had failed to define "significant scientific agreement" and therefore violated the Administrative Procedure Act. Id. at 20.

claims regulations. The following section specifies those aspects of the proposed § 101.90 that should be amended to conform with CHPA's recommendations.

II. The Process for Approval of Health Claims Based on Statements from Authoritative Bodies

FDA proposed to add a new section to subpart E of § 101 (101 CFR 101) to provide for the use of health claims based on statements from authoritative bodies, in order to place dietary supplements on an equal footing with conventional foods with respect to health claims.

CHPA agrees with the basic approach of proposed § 101.9(a) – (b), including the following basic points:

1. Per FDA's proposal, proposed § 101.90(a) should apply to health claims based on authoritative statements that are "not authorized by FDA" (see page 3254 of the Federal Register proposal, middle column). Therefore, FDA should not attempt to define a preemptive approval standard.
2. The authoritative statement from a scientific body of the U.S. government with official responsibility for public health protection should be "currently in effect" [see proposed § 101.90(a)]. CHPA believes FDA should define the term "currently in effect" in the preamble to the Final Rule or in a guidance, stating that the term means that the statement from a sanctioned authoritative body, including FDA, represents the current published public policy of that agency on the specified health issue relating to, for example, dietary supplements and not a statement of an employee of the scientific body made in the individual capacity of the employee.

CHPA recognizes that this concept is found in proposed § 101.90(a)(4). However, the Association believes that the relevant concepts (i.e., "currently in effect," "published policy;" and "not a statement of an employee...in the individual capacity of the employee") should be consolidated in one place for the purposes of facilitating compliance policy.

3. The 120-day pre-notification process cited in proposed § 101.90(a)(2) should be regarded, as specified in the proposal, as a period of time during which FDA may notify the submitter that not all the information specified in proposed § 101.90 has been submitted. This should not be construed by the agency or any other party as an approval period for FDA's review of a health claim statement from another sanctioned authoritative body.

CHPA believes that this distinction, between FDA's approval of a health claim within a 120 day period and FDA's review as to whether all the information has been submitted for a health claim based on a statement from other authoritative bodies, should be made in the preamble and in any guidance that might be developed or revised in relation to this general issue.

4. The submission of a health claim based on a statement from an authoritative body should include, per proposed § 101.90(a)(2):
 - A notice of the claim [see proposed § 101.90(a)(2)(i)];
 - A copy of the statement [see proposed § 101.90(a)(2)(ii)];
 - A balanced presentation of the scientific literature [see proposed § 101.90(a)(2)(ii)];
 - The statement of the claim and dietary supplement in conformance with § 101.14(a)(5) and (c)(3) and sections 403(a) and 201(n) of the act [21 USC 343(a) and 21USC 321(n); see proposed § 101.90(a)(3)];
 - The statement of the claim in a manner that is an accurate presentation of the authoritative statement that is the subject of the submission, so that the public can comprehend the information and be able to understand the relative significance of such information in the context of a total daily diet [see proposed §101.90(a)(4)].

Finally, in terms of proposed §101.90(b) relating to FDA's ability to issue a regulation prohibiting or modifying a health claim, CHPA requests that FDA modify proposed §101.90(b) to specifically state that any prohibition or modification of a health claim based on a statement from another sanctioned authoritative body will first rely on the prohibition or modification of that statement by that sanctioned body, not by an action initiated by FDA prior to consideration of the statement by the other authoritative body. As stated in Section I of these remarks (see above), Congress found the pre-FDAMA system of FDA approval of health claims seriously flawed because it failed to give sufficient weight to the authoritative statement of other government bodies. We cited the prime example that led to Congress' concern as CDC's determination that folic acid can prevent neural tube defects. To permit in regulation, as found in proposed § 101.90(b), provisions that would allow FDA independently to supercede the public policy statements of other sanctioned authoritative bodies would to undermine the intent of Congress in this area.

Thus, FDA should specifically clarify that it will not "second guess" the public policy of another sanctioned authoritative body by undertaking a review of that body's policy that is "currently in effect." It should be the responsibility of the authoritative body that created the public policy statement supporting the health claim to revise its policy before FDA prohibits or modifies the health claim. Once that is done, then FDA has the legal authority to prohibit or mandate the claim. If the health claim has been originally

submitted for issuance of an FDA health claim regulation, then FDA would have the responsibility to prohibit or amend the health claim. Specifically, proposed § 101.90(b) should be amended as follows (i.e., the underlined language below represents language CHPA requests be added to the Final Rule):

Re: Proposed § 101.90 (b)

“(b) A claim submitted under the requirements of paragraph (a) of this section may be made until:

“(1.) Such time as FDA issues a regulation under the standard in § 101.14(c):

“(i) Prohibiting or modifying the claim and the regulation has become effective, providing that, if the claim is based on a statement from authoritative body other than FDA, that body has made a determination that its statement supporting the health claim should be modified or amended;

or

“(ii) Finding that the requirements of paragraph (a) of this section have not been met, including finding that the petitioner has not submitted all the information required by such clause and, if applicable, section (i) of this section has been met ; or

“(2) A District Court of the United States in an enforcement proceeding under chapter III of the act (21 USC 301-310) has determined that the requirements of paragraph (a) of this section has not been met.”

III. Summary

In summary, CHPA requests the following changes in concept and content of the agency's proposal to create the same standard and process for use on dietary supplements of health claims based on authoritative statements, as provided by section 403r(3)(c) of the act for conventional foods:

1. The Final Rule should reflect Congress' intent under FDAMA that there be an alternative mechanism to NLEA for health claims for dietary supplements, since the development of health claims has been shown to be susceptible to protracted rulemaking process (e.g., the health claim for folic acid and neural tube defects).
2. In order to streamline and expedite health claims development, FDA should not attempt to impose its authority over other government agencies charged with public health protection by defining an over-arching standard that it would administer to

approve all health claims. At the most, FDA should only define its own approval standard for health claims based on applications submitted for an FDA health claim regulation.

3. CHPA agrees with the basic approach of proposed § 101.9(a) – (b), but makes specific recommendations about the wording to reflect in the Final Rule a process that would facilitate and therefore not thwart health claims development, including:
 - Per FDA's proposal, proposed § 101.90(a) should apply to health claims based on authoritative statements that are "not authorized by FDA;" therefore, FDA should not attempt to define a preemptive approval standard;
 - CHPA recognizes that the concept of "currently in effect" is partially addressed in proposed § 101.90(a)(4); however, the Association believes that the relevant concepts (i.e., "currently in effect," published policy;" and "not a statement of an employee...in the individual capacity of the employee") should be consolidated in one place for the purposes of facilitating compliance policy;
 - CHPA believes that the distinction between FDA's approval of a health claim within a 120 day period and FDA's review as to whether all the information has been submitted for a health claim based on a statement from other sanctioned authoritative bodies should be made in the preamble and in any guidance that might be developed or revised in relation to this general issue;
 - CHPA agrees with the basic provisions of proposed § 101.90(a)(2);
 - CHPA requests that FDA modify proposed §101.90(b)i) and (ii) to specifically state that any prohibition or modification of a health claim based on a statement from another sanctioned authoritative body will first rely on the prohibition or modification of that statement by that sanctioned body, not by an action initiated by FDA prior to consideration of the statement by the other authoritative body as follows (new language underlined below):

“(b) A claim submitted under the requirements of paragraph (a) of this section may be made until:

“(1.) Such time as FDA issues a regulation under the standard in § 101.14(c):

“(i) Prohibiting or modifying the claim and the regulation has become effective, providing that, if the claim is based on a statement from authoritative body other than FDA, that body has made a determination that its statement supporting the health claim

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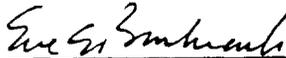
should be modified or amended;

or

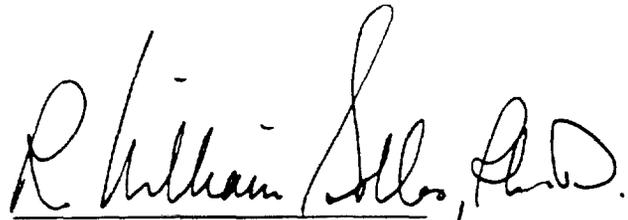
“(ii) Finding that the requirements of paragraph (a) of this section have not been met, including finding that the petitioner has not submitted all the information required by such clause and, if applicable, section (i) of this section has been met ;”

CHPA offers these comments in the spirit of cooperation with the agency in order to achieve the best possible final rule for the health benefit of consumers. Should you wish any clarification to these comments, please do not hesitate to reach either of us at CHPA (telephone number 202-429-9260).

Respectfully submitted on behalf of
the CHPA Dietary Supplement Strategic Planning Group
by:



Eve E. Bachrach, Esq.
Senior Vice President,
General Counsel and Secretary



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

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Consumer Healthcare Products Association (CHPA)

Representing producers of quality dietary supplements and nonprescription medicines

Founded 1881

**CHPA's Response to FDA's Questions (FR 64: 14178-14180, 1999)
for the
May 11, 1999 Public Meeting: Implementation of FDAMA § 303 & 304**

FDA's Questions	CHPA's Responses
<p>1. Re: The Scientific Basis for Claims</p>	
<p>a. What is an "authoritative statement"?</p>	<p><u>Per FDAMA</u>, an authoritative statement:</p> <ul style="list-style-type: none"> ▪ Is the <u>basis for a nutrient content claim</u> which characterizes the nutrient level [403(r)(2)] or a <u>health claim</u> about the relationship between a nutrient and a disease or health-related condition to which the claim refers [403(r)(3)]; ▪ Is intended to be the <u>basis for "streamlined procedures</u> available for the Secretary to <u>permit more scientifically sound nutrition information</u> to be provided to consumers through health and nutrient content claims (FDAMA, Joint Explanatory Statement of the <u>Committee of Conference</u>)¹ ▪ Is <u>published by a scientific body</u> of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions [403(r)(3)(C)(i)] ▪ Is intended by Congress to represent the consensus of the authoritative body such as NIH or CDC, or any of the "subsections of NAS" [see footnote #1 and 403(r)(3)(C)(i)] ▪ Is <u>currently in effect</u> [403(r)(3)(C)(i)] ▪ May apply to foods, including <u>conventional foods</u> and/or <u>dietary supplements</u> ▪ Does <u>not have to be in a form that is understood by the general public</u>, since it the claim derived from the authoritative statement that must be stated in a way that "enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet." [403(r)(3)(C)(iv)] ▪ Shall <u>not represent a statement of an employee</u> of the scientific body made in the individual capacity of the employee [403(r)(2)G(iv)] ▪ Is <u>based in part on a balanced representation of the scientific literature</u> and may include a bibliography of such literature (see endnote #1) <p>Re: Disclaimers: Although current law specifies much of the definition of an authoritative statement, the nature of an authoritative</p>

	<p>statement is not defined. That is, the authoritative statement is not stipulated to be phrased in absolute terms concerning the anticipated effect of ingestion of a specific level of a nutrient or the relationship between a nutrient and a health-related condition or disease. It may be that the statement is based on a pooled analysis or meta-analysis of the available information and that a definitive statement in absolute terms can not be made, yet because of the safety of the ingredient there is sufficient reason to indicate that, for example, the daily intake level of a particular ingredient should be raised in a specific target population. Under such circumstances, <u>it is therefore appropriate and sound public policy to permit the nutrient content or health claim in association with a disclaimer.</u> Furthermore, the US Court of Appeals in <u>Pearson v. Shalala</u> (D.C. Cir., No 98-5043, Jan 15, 1999) made clear that under the First Amendment FDA may not suppress truthful, nonmisleading claims. In the analogous situation of health claims regulations promulgated by FDA, the court declared that FDA may not prohibit a health claim where a disclaimer or other qualification concerning the diet/disease relationship can be provided to make the claim truthful and nonmisleading. The same legal principle applies to health claims based on authoritative statements.</p>
<p>b. Who decides if a particular statement is an "authoritative statement"?</p>	<p><u>The scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition.</u> However, in the process of reviewing a notification, FDA may make the confirmation that the submitted claim is based on an authentic authoritative statement from an accepted scientific body.</p>
<p>c. Is the "context" of a statement in the publication in which it appears relevant to that determination? If so, how?</p>	<p><u>Health and nutrient content claims must be truthful and not misleading. How this is achieved is fact dependent and should be determined during the pre-notification review of these claims.</u> For example, if an authoritative statement about a nutrient describes its benefit specifically in the context of a specific target population or in relation to the total daily diet, then the specific context should be reflected understandably in the claim submitted to FDA under the pre-notification procedure. <u>As such, the context would be taken into account as part of FDA's review of health claim or nutrient content claim submissions.</u> In any case, because the context cannot be predicted in each and every case, it is best not to stipulate the definition of "context" too narrowly. In some case, it may be appropriate in some case to provide a disclaimer with the health claim.</p>
<p>d. How does the significant scientific agreement standard apply to health claims based on authoritative statements?</p>	<p>Under 403(r)(B)(i), it states that "[T]he Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), <u>that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.</u>"</p> <p>As such, <u>significant scientific agreement does not apply to development</u></p>

	<p>of the authoritative statement. Congress specifically intended that the pre-notification claims procedure would be "streamlined procedures available for the Secretary to permit more scientifically sound nutrition information to be provided to consumers through health and nutrient content claims." FDA's delay of the CDC-based health claim for folic acid in reducing neural tube defects was a critical precipitating factor creating this provision of FDAMA. <u>Therefore, if the claim is the exact or even a reasonable representation of the authoritative statement, then FDA's inquiry is at an end.</u> If there is reasonable question as to whether the submitted claim is either misleading or inaccurate, then FDA can under the pre-notification procedures notify the sponsor of the claim that not all the information needed to support the claim has been submitted.</p> <p>FDA has no legal authority under FDAMA to apply a "significant scientific agreement" standard to health claims based upon authoritative statements. This would create the type of situation that would set FDA above another <u>"scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition,"</u> as this was not the intent of Congress.</p>
<p>2. Re: Existing Regulatory Requirements</p>	
<p>a. What requirements of 21 CFR 101.13 and part 101, subpart D should we apply to nutrient content claims based on authoritative statements?</p>	<p>In the context of broadening the development and use of health claims based on authoritative statements, the current requirements of 101.13 and part 101 subpart D should apply.</p>
<p>What requirements of 21 CFR 101.14 should we apply to health claims based on authoritative statements?</p>	<p>In the context of broadening the development and use of health claims based on authoritative statements, the current requirements of 101.14 should apply.</p>
<p>3. Procedural and Definitional Issues</p>	
<p>a. Which agencies should we identify as scientific bodies of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition under section 403(r)(2)(G)(i) and (r)(3)(C)(i) of the act?</p>	<p>Per FDMA: "<u>(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition</u> (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions"</p> <p>We concur with FDA's June 11, 1998 Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body in terms of the statement that: "FDA believes that other federal agencies may also qualify as appropriate sources for such authoritative statements. Along with NAS (or any of its subdivisions), the agency currently considers that the following federal scientific bodies may be sources of authoritative statements: the CDC, the NIH, and the Surgeon General within Department of Health and Human Services; and the Food and Nutrition Service, the Food Safety and Inspection Service, and the Agricultural</p>

	<p>Research Service within the Department of Agriculture.”</p> <p>Other agencies may also be identified by FDA and/or other interested parties, and should be included in the list of acceptable “scientific bodies.”</p>
<p>b. Should we provide by regulation that health claims based on authoritative statements may be used in the labeling of dietary supplements?</p>	<p><u>Yes</u>. Like conventional foods, dietary supplements are also foods by law.</p>
<p>c. What should we require that you submit with a notification of a health or nutrient content claim based on an authoritative statement?</p>	<p>Per FDAMA, a petitioner must submit:</p> <p>“(1) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied,</p> <p>“(2) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and</p> <p>“(3) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers.”</p> <p>In the Joint Explanatory Statement of FDAMA by the Committee of Conference, it also states: “As part of the submissions to the Secretary for health claims based on authoritative statements, a balanced representation of the scientific literature may include a bibliography of such literature.”</p> <p>Since health claims and nutrient content claims based on authoritative statements from “a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition,” it is expected that the authoritative statement would have been based on all available safety and benefit information relevant to the current authoritative statement. As such, the requirements for substantiation of the claim based on the authoritative statement should not be as extensive as those claims that are not based on authoritative statements from acceptable “scientific bodies of Government” [e.g., no requirement for “all information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance), per 21 CFR 101.70).</p>
<p>d. Should we require you to submit in a notification an analytical methodology for measuring the substance that is the subject of your submitted claim?</p>	<p>This is not required for conventional foods and should not be required for dietary supplements.</p>

<p>e. What is a balanced presentation of the scientific literature relating to the subject to which a claim refers that is required under section 403(r)(2)(G)(ii)(III) and (r)(3)(C)(ii)(III) of the act?</p>	<p>The FDA Guidance on Health Claims Based on an Authoritative Statement of a Scientific body of June 11, 1998 contains an explanation, which we believe is reasonable. FDA states that it regards a "balanced representation of the scientific literature" to call for compilation of a "bibliography of the scientific literature on the topic of the claim." In addition, the Guidance says that "a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement should be submitted."</p>
<p>f. Should FDA keep notifications confidential for 120 days after the date of their submission or should we place them in a public docket upon receipt?</p>	<p>Yes. This would give an incentive to petitioners to submit health claims. However, note that in 21 CFR 101.70 (Health Claims): "(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the petitioner, except that clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of: (1) Names and any information that would identify the person using the product; (2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution."</p>
<p>g. If a notification is incomplete or does not support a claim, should we respond to it by letter or by issuing a regulation, and what should be the legal effect of letters were we to use them?</p>	<p>FDA should respond to incomplete notification by letter with a follow-up notice in the Federal Register, similar to the approach taken for OTC Feedback Letters and OTC Monographs. The letter allows the agency flexibility and speed in responding to petitioners that promulgation of a regulation alone does not permit.</p> <p>The intent of FDAMA is "... enable the Secretary to act promptly to ban or modify a [nutrient content or health] claim under this paragraph"² As such, however, the letter should not have the standing of the follow-up regulation, but should serve as a warning that such a regulation would be forthcoming..</p>

ENDNOTES

1 FDAMA, Joint Explanatory Statement of the Committee of Conference:
 "Title III--Improving Regulation of Food;
 "Flexibility for regulations regarding claims (Sec. 301)

"The conference agreement clarifies the parameters within which the Secretary may use the interim final rulemaking authority established under this section. This authority enables the Secretary to make proposed regulations on claims effective upon publication, pending consideration of public comment and publication of a final regulation. The conferees' clarifying language emphasizes that this authority may be used when the Secretary determines that it is necessary to enable the Secretary to improve consumer access to important dietary information and to ban or modify a claim in a prompt fashion. The conferees' intent in creating this expedited rulemaking authority for health and nutrient content claims is that it be used primarily to expedite the review of petitions for health and nutrient content claims based on authoritative statements. Health and nutrient content claims (Secs. 303, 304)

"The conference agreement makes streamlined procedures available for the Secretary to permit more scientifically sound nutrition information to be provided to consumers through health and nutrient content claims. This process is triggered by authoritative statements of entities such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and the National Academy of Sciences (NAS). Although the provision specifically permits claims

to be made on the basis of a statement produced by subsidiaries of NAS, the conferees intend that the lack of similar language with respect to entities such as NIH and CDC be interpreted as a reflection of the desire of the conferees that statements issued by entities such as NIH and CDC reflect consensus within those institutions. The agreement makes minor modifications to the House provisions on health and nutrient content claims to expedite the process by which such claims are processed. As part of the submissions to the Secretary for health claims based on authoritative statements, a balanced representation of the scientific literature may include a bibliography of such literature."

2

TITLE III--IMPROVING REGULATION OF FOOD**SEC. 301. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.**

Section 403(r) (21 U.S.C. 343(r)) is amended by adding at the end the following:

"(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary--

"(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to--

"(i) enable consumers to develop and maintain healthy dietary practices;

"(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

"(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

"(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph."

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