PIPER & MARBURY
L.L.P.
1200 NINETEENTH STREET, N.W.
WASHINGTON, D.C. 20036-2430
202-861-3900
FAX: 202-223-2085

BALTIMORE
NEW YORK
PHILADELPHIA
EASTON

ANTHONY L. YOUNG
(202) 861-3882
FAX: (202) 223-2085
Ayoung@pipermar.com

April 5, 1999

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

Re: Docket No. 98N-0826 Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements

Dear Sir:

Please accept for filing the enclosed comments of the American Herbal Products Association on the Administration's proposal regarding the use on dietary supplements of health calims based on authoritative statements.

Respectfully submitted,

Anthony L. Young
Counsel for the
American Herbal Products Association

ALY/jek
Enclosure

98N-0826

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Docket No. 98N--0826

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE AMERICAN HERBAL PRODUCTS ASSOCIATION

Proposed Regulations on the Use on

Dietary Supplements of Health Claims Based

On Authoritative Statements

April 5, 1999

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry, which is comprised of domestic and foreign companies doing business as importers, growers, processors, manufacturers, and distributors of herbs and other botanical products. AHPA serves its members by promoting the responsible commerce of dietary supplements which contain herbs or botanicals and which are used to enhance health and quality of life.

AHPA supports the proposal to permit the use on dietary supplements of Nutrition Labeling and Education Act (NLEA) health claims based on authoritative statements under the notification procedures of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Pub.L. 105-115. AHPA notes, however, that all of the Administration's NLEA and FDAMA implementing regulations must be re-evaluated to consider the mandate and decision of the United States Court of Appeals for the District of Columbia decision in *Pearson and Shaw v. Shalala,* 1999 U.S. App. LEXIS 464 (Jan. 15, 1999). In addition, AHPA wishes to make the following points:

- FDAMA applies to dietary supplements and the proposed regulations specifically referring to dietary supplements provide symmetry to the food and dietary supplement regulatory scheme.
- Dietary supplements are entitled to make health claims so long as such claims conform with the requirements of DSHEA's structure function provision and do not make any prohibited "disease" claims.
- Authoritative statements from scientific bodies of governments outside the United States are appropriate as whole or partial substantiation for structure function claims.

A. It is AHPA's position that FDAMA applies to dietary supplements and that the proposed regulations, while providing symmetry within the food and dietary supplement labeling regulations, are not necessary to extend FDAMA to dietary supplements. FDAMA authorizes the use of health claims for foods

and dietary supplements based on authoritative statements published by a scientific body of the U.S. government about "the relationship between a nutrient and a disease or health-related condition" to which the claim refers. Under FDAMA, such claims do not require approval by the Administration, but must still be authorized. Manufacturers or distributors must: (1) notify the Administration at least 120 days in advance of marketing a product with the prospective health claim; (2) demonstrate that the claim is based on an authoritative statement of a United States government scientific body with official responsibility for public health protection or research directly relating to human nutrition; and (3) submit a balanced presentation of the scientific information substantiating the claim. Once a manufacturer takes those steps, the claim can be made unless the Administration, within the 120-day period, issues an interim final regulation prohibiting the claim or successfully brings a lawsuit against the company in court. The Administration's proposed regulations describe how to fully notify the Administration of a proposed claim.

B. AHPA is the principal trade association of the botanical products industry. In the main, botanical products used traditionally for their health maintenance qualities do not meet the definition of nutrient insofar as that term is described by the Administration's NLEA--implementing regulations. 21 C.F.R. § 101.14. Specifically, herbal botanicals are rarely RDI/DRV nutrients (21 C.F.R. § 101.14(b)(2)) and often do not contribute "taste, aroma, or nutritive value, or any other [food] technical effect" to food (collectively, "nutrients"). 21 C.F.R. § 101.14(b)(3)(i). Accordingly, and depending on the particular botanical at issue, FDAMA's authoritative statement provision may not be available to the herbal products industry as a vehicle for making NLEA health claims. This failure, of both NLEA and the Administration's NLEA--implementing regulations, to address health claims for herbs, was one of the motivating factors behind the Dietary Supplement Health and Education Act of 1994 (DSHEA).

DSHEA compensates for NLEA's narrow application to nutrients by exempting dietary supplements from the requirements for a health claim regulation if certain conditions are met. 21 U.S.C. § 343(r)(6). For

dietary ingredients (21 U.S.C. § 321(ff)), DSHEA allows statements of nutritional support (structure and/or function claims) to be made, consistent with NLEA's health claims regulation requirement, if the statements do not claim to diagnose, mitigate, treat, cure, or prevent a disease. This includes statements regarding the structural or functional effect of such dietary ingredients on the body. Thus, under DSHEA, there is no bar to relating these structural or functional effects to health-related conditions, those natural conditions that are not diseases or a class of diseases.

Statements that relate matters of structure and function to health-related conditions such as sleeplessness, pre-menstrual syndrome, functional effects of menopause, elevated cholesterol, overweight, age-related prebsbyopia, and fatigue, to name a few, are allowed under DSHEA because these are merely conditions and not diseases. The AHPA position on this issue is spelled out in detail in its September 28, 1998, Comments on Proposed Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body filed in Docket No. 98N-0044 (copy enclosed herewith).

C. Because FDAMA's authoritative statement health claims provision is limited by its terms to "a scientific body of the United States government with official responsibility for public health protection or research," its application to herbal botanicals that have been used as traditional medicines is further limited by the failure of United States government bodies to address such products. Instead, the main source of such statements is from similar government bodies in foreign countries. AHPA's position is that the "authoritative statements" of such bodies are wholly appropriate as substantiation for herbal supplement structure/function claims, including those which address health related conditions. Moreover, where an herbal supplement meets the nutrient requirement of NLEA, AHPA believes it would be in the public interest for the Administration to give fair consideration to such authoritative statements as has been proposed in material time and extent regulations regarding over-the-counter drug products.

CONCLUSION

In accordance with the foregoing, AHPA supports the Administration's proposed regulations on the use on dietary supplements of health claims based on authoritative statements so long as they conform in all respects to the decision in *Pearson and Shaw v. Shalala*, 1999 U.S. App. LEXIS 464 (Jan. 15, 1999). In this regard, AHPA urges the Administration to conform previously promulgated NLEA–implementing regulations to this decision as well.

Respectfully submitted,

Gregory O. Gray
Vice President & Acting President
American Herbal Products Association
8484 Georgia Avenue
Suite 370
Silver Spring, MD 20910
(301) 588-1171

Of Counsel:

Anthony L. Young
Piper & Marbury, L.L.P.
1200 Nineteenth Street, N.W.
Washington, D.C. 20036
(202) 861-3900

Docket No. 98N-0044

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE AMERICAN HERBAL PRODUCTS ASSOCIATION

Proposed Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body

September 25, 1998

The American Herbal Products Association ("AHPA") is the national trade association and voice of the herbal products industry, which is comprised of domestic and foreign companies doing business as importers, growers, processors, manufacturers, and distributors of herbs and other botanical products. AHPA serves its members by promoting the responsible commerce of dietary supplements which contain herbs or botanicals and which are used to enhance health and quality of life.

INTRODUCTION

Almost four years ago, Congress enacted the Dietary Supplement Health and Education Act of 1994 ("DSHEA") as amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"). (Pub. L. No. 103-417, 108 Stat. 4324 (codified in scattered sections of 21 U.S.C.)). AHPA was a principal DSHEA supporter. For the first time, dietary supplements were defined (21 U.S.C. § 321(ff)) and manufacturers were permitted by Section 6 of DSHEA to make statements related to their structural or functional effect on the body, without causing such products to be deemed drugs under the law. DSHEA § 6, 21 U.S.C. § 343(r)(6). Herbal supplements are a principal component of the dietary supplement definition as products intended for ingestion which contain "an herb or other botanical" or "a concentrate, metabolite, constituent, extract, or combination of" an herb or other botanical. 21 U.S.C. § 321(ff)(1)(C), (F).

Under Section 6 of DSHEA, dietary supplements may now make substantiated label and labeling claims about how their consumption affects structure or function in humans, or general well-being. Such a statement or claim may:

- describe a benefit related to a classical nutrient deficiency disease if it discloses the prevalence of such disease in the United States,
- "describe[ ] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,"

- "characterize[ ] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or functions," or
- "describe[ ] general well-being from consumption of a nutrient or dietary ingredient."

It is AHPA's position that the Proposed Regulations published in the Federal Register of April 29, 1998 (63 Fed. Reg. 23624) on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body significantly undermine the very section of DSHEA they seek to implement, and are, in many respects, unlawful. Because they are contrary to law and the findings Congress made when it enacted DSHEA,[1] these proposed regulations should be withdrawn.

I. THE PROPOSED EXPANSION OF THE DISEASE DEFINITION UNLAWFULLY RESTRICTS STRUCTURE/FUNCTION CLAIMS AUTHORIZED BY THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994

A. DSHEA's Section 6 sets forth the conditions under which "a statement for a dietary supplement may be made." 21 U.S.C. § 343(r)(6). For purposes of the proposed regulations, three of these conditions are relevant because, when taken together, they evidence a Congressional decision to permit substantiated structure/function claims on dietary supplement labels and labeling, so long as no drug claim is made.

First, Congress limited structure/function claims as follows:

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1 In Section 2 of DSHEA, Congress made fifteen findings (DSHEA § 2, 21 U.S.C. § 321 note). Three of those findings are relevant to the proposed regulations:

(2) the importance of nutrition and the benefits of dietary supplements to health promotion . . .;

(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers.

> (A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient. [21 U.S.C. § 343(r)(6)(A).]

Second, when such a statement is made, Congress directed that the statement must contain a disclaimer, "prominently displayed and in boldface type," as follows:

> "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." [21 U.S.C. § 343(r)(6)(C).][2]

Third, Congress reiterated in DSHEA's Section 6 what the required disclaimer boldly and prominently states, that a "statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6).

It is AHPA's position that Congress, by requiring the disclaimer and reiterating what may not be claimed, placed all the constraints upon dietary supplements that it deemed to be appropriate with respect to statements regarding structure/function. In short, Congress has said structure/function claims, but not disease claims, may be made for dietary supplements.

These Section 6 provisions also evidence a Congressional understanding that the Section created a tension between structure/function claims and drug claims. The Congressional prescription to relieve this tension was to require a disclaimer that advises consumers that the statement has not been evaluated by the FDA and that the product is not intended for use as a drug. This legislatively mandated interplay

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[2] Regulations regarding placement of the disclaimer on labels and labeling are set forth at 21 C.F.R. § 101.93(b)-(e).

between structure/function claims and the required disclaimer, standing alone, should be enough to show that the Administration's proposal, which seeks to redefine disease to encompass structure/function statements, is inconsistent and contrary to DSHEA.

B. Congress not only carefully defined what marketers of dietary supplements may and may not do with respect to structure/function claims, and required a disclaimer, Congress also modified the FFDCA definition of drug (21 U.S.C. § 321(g)(1)) to assure that structure/function claims made under Section 6 of DSHEA do not cause products to be deemed drugs. In enacting DSHEA, Congress added the following language to the drug definition:

> A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement. [21 U.S.C. § 321(g)(1)(D).]

It is AHPA's position that this is an unequivocal directive from Congress to those who interpret and enforce the FFDCA that structure/function claims for dietary supplements are not to be deemed by FDA to be drug claims as they had been in the past.[3] The direction is unequivocal because clause (C) of the FFDCA's drug definition is that section which otherwise makes products drugs if they are "articles (other than food) intended to affect the structure or any function of the body of man or other animals * * *." 21 U.S.C. § 321(g)(1)(C). When read against this provision, the Administration's proposal to expand the definition of disease to include structure/function claims is, in AHPA's view, an act of defiance in contravention of Congress' DSHEA mandate.

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3 Prior to DSHEA, FDA successfully argued that structure/function claims for non-nutritive food supplements caused the products to be drugs. *Nutrilab v. Schweicker*, 713 F.2d 335 (7th Cir. 1983).

C. When DSHEA was passed, regulations promulgated by the Administration under the Nutrition Labeling and Education Act of 1990 ("NLEA") defined "disease or health-related condition" as follows:

> (6) *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to § 101.14 or § 101.70). [21 C.F.R. § 101.14(a)(6).]

These regulations were promulgated in 1993, adopted in early 1994 (59 Fed. Reg. 395 (Jan. 4, 1994)), and amended later that year (59 Fed. Reg. 15050 (Mar. 31, 1994)) to implement NLEA's health claims provision. 21 U.S.C. § 343(r)(1)(B).

The Administration's pre-existing NLEA disease definition is significant because DSHEA's Section 6 is directly related to NLEA. "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dept. of Treasury*, 489 U.S. 803, 809 (1989). DSHEA Section 6 was added as a sixth section to 21 U.S.C. § 343(r), the codification of NLEA, to create conditions under which a statement of nutritional support (structure/function claim) may be made "for purposes of paragraph (r)(1)(B)". Accordingly, while there is no direct legislative history on the point,[4] it is plainly apparent that the pre-existing disease definition set forth in FDA's NLEA-implementing regulations represents the most appropriate and likely candidate to

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[4] DSHEA's "entire legislative history" is expressed in the Statement of Agreement of its chief sponsors which is set forth at 140 Cong. Rec. S14801 (daily ed. Oct. 7, 1994) and 140 Cong. Rec. H11179 (daily ed. Oct. 6, 1994). The Statement of Agreement makes no reference to structure/function claims.

serve as a baseline for the Congressional understanding of this important term. On its face, the relevant part of this definition limits the definition of disease to body damage and dysfunction resulting from such damage.[5]

The Administration's proposed new disease definitions significantly expand upon the NLEA-implementing definition by replacing it with the following:

> "* * * any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements, that are characteristic of a disease) * * *." [Proposed 21 C.F.R. §§ 101.14(a)(6) and 101.93(g)(1).]

These proposed definitions stand DSHEA's Section 6 on its head. By defining disease to include "any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body," the Administration is going exactly where Congress has directed it not to go, i.e., to make a statement regarding how a dietary supplement is intended to "affect the structure or <u>any</u> function of the body of man * * *" (21 U.S.C. § 321(g)(1)(C) (emphasis added)) into drug claims.

Congress did not limit Section 6 to "normal" or "abnormal" functions. Instead, Congress gave these sections the broadest possible scope to include "the structure or function in humans" (21 U.S.C. § 343(r)(6)(A)) and "structure or any function of the body of man" (21 U.S.C. § 321(g)(1)(C)). By expanding the definition of disease, the Administration seeks to do indirectly what Congress has

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5 With respect to nutrient deficiency diseases, Congress carried forward the Administration's determination that classic nutrient deficiency diseases should be exempt from DSHEA's disease claim prohibition. 21 U.S.C. § 343(r)(6)(A).

unequivocally said it cannot do directly – cause structure/function claims to be drug claims. On this point, DSHEA is clear on its face and the Administration's proposed expanded and enlarged disease definition is simply not lawful. It is a basic tenet of administrative law that "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, *reh'g denied*, 468 U.S. 1227 (1984). Thus, where an agency defines a term in its regulations that violates the clear language of the controlling statute, the agency interpretation cannot stand. *See, e.g., ADA v. Shalala*, 3 F.3d 445 (D.C. Cir. 1993).

II. THE PROPOSED DISEASE DEFINITION INCLUSION OF CLAIMS REGARDING EFFECTS ON "NATURAL STATE CONSEQUENCES"AND "ABNORMALITIES" IS ALSO CONTRARY TO LAW

As discussed in Part I of these comments, under the FFDCA, as amended by NLEA and DSHEA, dietary supplements are explicitly permitted to make substantiated statements related to product structural/functional effects and health-related conditions. By defining disease claims to include "effect[s] on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body" (Proposed 21 C.F.R. § 101.93(g)(iii)), the Administration has proceeded both unlawfully to expand the definition of disease and to propose a vague, variable, and unenforceable symptoms prohibition.

First, NLEA permits a claim that "characterizes the relationship of any nutrient * * * to a disease or a health-related condition * * *" so long as a health claim regulation is in effect. 21 U.S.C. § 343(r)(1)(B). "For purposes of paragraph (r)(1)(B)," however, Section 6 of DSHEA allows a substantiated structure/function statement for a dietary supplement to be made so long as the conditions of Section 6 are

met, including that the statement "not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases * * *." 21 U.S.C. § 343(r)(6). Significantly, this prohibition on disease claims does not extend to the relationship of a dietary ingredient to "health-related conditions." It is therefore clear that Congress, by permitting structure/function claims for purposes of NLEA's health claims provision, has determined to allow structure/function claims for health-related conditions and not for diseases. Moreover, because Section 6 of DSHEA applies to both dietary ingredients and nutrients, Congress has expanded the kinds of dietary supplements that can make such claims.[6]

Second, DSHEA amends the FFDCA drug definition to include the provision that:

> A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. [21 U.S.C. § 321(g)(1).]

Because a structure/function claim regarding a health-related condition falls squarely within this provision, Congress has directed FDA not to classify dietary supplements as drugs solely on the basis of such claims. As discussed previously, this direction is reiterated in the next and final sentence of 21 U.S.C. § 321(g)(1). Accordingly, a dietary supplement may make a structure/function claim under Section 6 of DSHEA regarding a health-related condition.

Proposed 21 C.F.R. § 101.93(g)(2)(iii) would classify any claim, "explicitly or implicitly, that the product . . . [h]as an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals as constituting an abnormality of the body." Under this definition, the otherwise normal consequence of a natural state is to be classified as an "abnormality" if it is so "recognized" by "health care professionals" or "consumers." Once again, the Administration is

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6 NLEA's health claims provision applies only to nutrients. 21 U.S.C. § 343(r)(1).

attempting to do indirectly by word play what Congress has said it may not do at all. Normal consequences of natural states are obviously not diseases. Indeed, they are best defined as "health-related conditions," and certainly they are not "natural state abnormalities" because there is nothing abnormal whatsoever about natural state consequences. Because structure/function claims regarding health-related conditions are specifically authorized by DSHEA, this portion of the Administration's proposal should be withdrawn. *See, e.g.*, *Public Employees Retirement System of Ohio v. Betts*, 492 U.S. 158, 171 (1989) ("no deference is due to agency interpretations at odds with the plain language of the statute itself.").

Several structure/function claim examples presented in the proposal relate to natural states and are addressed below. It is AHPA's position that structure/function claims related to such states are authorized by DSHEA as structure/function claims regarding health-related conditions or are otherwise lawful claims for dietary supplements. None are drug claims. Moreover, as will appear below, at least some health care professionals take the same position.

- Alleviates constipation. According to Stedman's Medical Dictionary, constipation is "a condition in which bowel movements are infrequent or incomplete." Stedman's Medical Dictionary 386 (26th ed. 1995). The National Institute on Aging ("NIA") notes specifically that constipation is "not a disease."[7]

- Improves urine flow in men over 50 years old (benign prostatic hypertrophy). According to NIA, benign prostatic hypertrophy ("BPH"), enlargement of the prostate, is a "condition [that] is common in older men."[8] NIA states "[m]ore than half of men in their 60's have BPH. Among men in their 70's and 80's, the figure may go as high as 90 percent." *Id.* Indeed, according to the National Kidney and Urologic Diseases Information Clearinghouse ("NKUDIC"), "prostate enlargement is as common a part of aging as

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7 NIA AgePage: Constipation (visited Sept. 23, 1998) <http://www.nih.gov/nia/health/pubpub/const.htm>.

8 NIA AgePage: Prostate Problems (visited Sept. 23, 1998) <http://www.nih.gov/nia/health/pubpub/prostate.htm>.

gray hair."[9] Plainly, this is a condition and not a disease. Moreover, AHPA notes that the claim "for men over 50 years old," which the Administration characterizes as not a disease claim because there is no recognizable abnormality (AHPA agrees), is just the kind of meaningless claim that Congress sought to make unnecessary by enacting DSHEA.

- Premenstrual Syndrome. This syndrome, associated with over 150 symptoms, is associated with a normal body function, menstruation.[10] Women's Health America, Inc. notes that "[n]early 40% of all women of childbearing age suffer from PMS symptoms." *Id.* Accordingly, this syndrome, essentially a collection of symptoms associated with a normal function, is in no way a "disease" and is best described as a collection of health-related conditions.

- Aging-related "abnormalities." Only if the "abnormality" is a disease should it be regulated as a disease (e.g., Alzheimer's disease). The NIA states slowing of sexual response is "part of the normal aging process."[11] Similarly, NIA states presbyopia "is a normal process that happens over a lifetime."[12] Finally, with respect to hot flashes and their causal condition, menopause, the Administration itself has stated in FDA Consumer, that "[d]espite its sometimes annoying, peripheral problems, more than ever before menopause is now seen as a natural process, not a disease."[13]

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9 NKUDIC, *Prostate Enlargement: Benign Prostatic Hyperplasia*, NIH Pub. No. 91-3012 (Sept. 1991).

10 Women's Health America, Inc., *Premenstrual Syndrome FAQ: What is PMS?* (visited Sept. 23, 1998) <http://www.womenshealth.com/wha.htm/#pmsfaq>.

11 NIA AgePage: Sexuality in Later Life (visited Sept. 3, 1998) <http://www.nih.gov/nia/health/pubpub/sexual.htm>.

12 NIA AgePage: Aging and Your Eyes (visited Sept. 3, 1998) <http://www.nih.gov/nia/health/pubpub/eyes.htm>.

13 Sheryl Weinstein, *New Attitudes Towards Menopause*, FDA Consumer (Mar. 1997) <http://www.fda.gov/fdac/features/1997/297_meno.html>.

III. OTHER DISEASE CLAIM EXAMPLES PROVIDED IN THE ADMINISTRATION'S PREAMBLE TO THE PROPOSED RULE UNLAWFULLY RESTRICT DSHEA'S STRUCTURE/FUNCTION CLAIM PROVISION AND DEMONSTRATE THE NEED FOR FDA TO RECOGNIZE DSHEA'S IMPACT ON STRUCTURE/FUNCTION CLAIMS DEEMED BY OTC DRUG REGULATIONS TO BE DRUG CLAIMS

Other examples of claims that the Administration has set out in the preamble to these proposed regulations evidence the Administration's inability to implement the letter of DSHEA. These claims are discussed below.

- "Decreases the effects of alcohol intoxication," 63 Fed. Reg. at 23626: While alcoholism is widely recognized as a disease, simple alcohol intoxication is a condition and not a disease. It is a self-induced condition caused by drinking alcohol.

- "Lowers cholesterol" (hypercholesterolemia), 63 Fed. Reg. at 23626: The claim "lowers cholesterol" is functional only. While hypercholesterolemia may be an abnormally large amount of cholesterol in the blood, amounts below abnormal may certainly be referenced in dietary supplement labeling. Moreover, the functional effect of lowering cholesterol is plainly a structure/function claim. DSHEA's response to the Administration's concern that this claim may cause consumers to "believe" the product is a drug, is to require the Section 6 disclaimer.

- "Relieves headache" (migraine or tension headache), 63 Fed. Reg. at 23626: With respect to tension headache, this condition, by its terms, is simply the result of tension, anxiety, or contraction of the scalp muscles. It is not a disease but a consequence of daily life.

Many of the claims identified by the Administration as prohibited drug claims, as well as those identified as acceptable structure/function claims, show that the Administration is not yet prepared to address the letter of DSHEA and is instead mired in pre-DSHEA interpretations of the food and drug definitions. Nowhere is this more apparent than in the Administration's statement that "[a] claim that did not

identify a specific drug, drug action, or therapy (e.g., "use as a part of your weight loss plan") would not constitute a disease claim under this criterion." 63 Fed. Reg. at 23627. The criterion in this instance is an "impl[ication] that a dietary supplement has an effect on disease by claiming that the effect of the dietary supplement is the same as that of a recognized drug or disease therapy." *Id.* In this case, the Administration must be referring to drugs for weight control. But weight loss or weight control are classic structure/function claims. Lowering weight is not disease management unless it is done to treat obesity, just as lowering cholesterol is not disease management unless it is done to treat hypercholesterolemia.

Weight control is a drug claim in the over-the-counter (OTC) drug regulatory scheme. (21 C.F.R. § 310.546). The Administration's inability to recognize that it is also a structure/function claim for a dietary supplement demonstrates that DSHEA's mandate is being ignored. DSHEA created a new class of products – dietary supplements which may make structure/function claims. This legislation effectively amended the OTC Drug Product Review as it otherwise had been applied by the Administration to dietary supplements.

Set forth below are those OTC drug product claims which AHPA has identified as wholly appropriate as structure/function claims for dietary supplements, if substantiated.

LIST

Antacids (21 C.F.R. § 331.30)	"[R]elief of . . . heartburn" "[R]elief of . . . sour stomach" "[R]elief of . . . acid indigestion" "[R]elief of . . . upset stomach associated with these symptoms"
Antiflatulents (Antigas) (21 C.F.R. § 332.30)	"Alleviates . . . the symptoms referred to as gas" "Alleviates . . . bloating" "Alleviates . . . pressure" "Alleviates . . . fullness" "Alleviates . . . stuffed feeling"

Antiemetics (21 C.F.R. § 336.50)	"For the prevention and treatment of the nausea, vomiting, or dizziness associated with motion . . . ."
Nighttime sleepaids (21 C.F.R. § 338.50)	"Helps you . . . fall asleep if you have difficulty falling asleep." "For relief of occasional sleeplessness." "Helps to reduce difficulty falling asleep."
Stimulants (Alertness aids) (21 C.F.R. §340.50)	"Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness."
Daytime sedatives (21 C.F.R. § 310.519)	"[O]ccasional simple nervous tension," "nervous irritability," "nervous tension headache," "simple nervousness due to common every day overwork and fatigue," "a relaxed feeling," "calming down and relaxing," "gently soothe away the tension," "calmative," "resolving that irritability that ruins your day," "helps you relax," "restlessness," "when you're under occasional stress . . . helps you work relaxed."
Aphrodisiacs (21 C.F.R. § 310.528)	"[A]rouses or increases sexual desire and improves sexual performance," "helps restore sexual vigor, potency, and performance," "improves performance, staying power, and sexual potency," "builds virility and sexual potency."
Products for relief of symptoms of benign prostatic hypertrophy (21 C.F.R. § 310.532)	"To relieve the symptoms of benign prostatic hypertrophy, e.g., urinary urgency and frequency, excessive urinating at night, and delayed urination."
Anticholinergics (21 C.F.R. § 310.533)	"[R]elieve excessive secretions of the nose and eyes"
Products for certain uses (21 C.F.R. § 310.545)	Nasal decongestant Expectorant Bronchodilator Digestive aid Laxative Stool softener Weight control Menstrual

Products for the treatment and/or prevention of nocturnal leg muscle cramps (21 C.F.R. § 310.546)	"[T]reatment and/or prevention of nocturnal leg muscle cramps, i.e., a condition of localized pain in the lower extremities usually occurring in middle life and beyond with no regular pattern concerning time or severity."

The FFDCA, as amended by DSHEA, provides an excellent framework for OTC drugs and dietary supplements making structure/function claims to co-exist. OTC drugs may call themselves drugs and are characterized by standardized label text, active ingredients, and cautions, all of which are established, albeit somewhat slowly, by monograph. OTC drugs are required to be listed, 21 C.F.R. Part 207, and imprinted, 21 C.F.R. Part 206.

In comparison, dietary supplements making structure/function claims are denominated as dietary supplements, have Supplement Facts on the label, and bear a Section 6 disclaimer. They are easy to differentiate. And this is exactly the situation the Administration sought to ensure when DSHEA was enacted – that the Section 6 disclaimer would provide consumers a clear way to identify those products making structure/function claims that are FDA-approved and those that are not. In this fashion, consumers are in no way misled. Manufacturers can select the appropriate category for their product, drug or dietary supplement, and market that product in accord with the applicable provisions of the FFDCA.

IV. AHPA INCORPORATES BY REFERENCE THE COMMENTS OF OTHER TRADE ASSOCIATIONS TO THE EXTENT THAT SUCH COMMENTS ARE NOT INCONSISTENT WITH ITS OWN

Other trade associations of the dietary supplement industry have also filed comments on the proposed regulations discussed herein. In particular, AHPA has had the opportunity to review the comments of the Council for Responsible Nutrition (CRN). To the extent CRN's comments are not

inconsistent with AHPA's comments herein, AHPA incorporates them by reference as if they were set forth as part of these comments. Similarly, while AHPA has not had the opportunity to review the comments of the National Nutrition Foods Association, the Utah Natural Products Alliance, the American Herbal Pharmacopoeia, and Nutralite Division of Amway, Inc., any legal analysis contained therein is also incorporated herein by reference to the extent it is not inconsistent with or contradictory to the comments made herein.

V. CONCLUSION

In conclusion, on the basis of the foregoing, AHPA respectfully requests the withdrawal of the proposed rule on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body.

Respectfully submitted,

Anthony L. Young

Anthony L. Young
Janice L. Weiner
Piper & Marbury, L.L.P.
1200 Nineteenth Street, N.W.
Washington, D.C. 20036
(202) 861-3900
Counsel for the American Herbal Products Association

Mr. Jeffrey Morrison
President
American Herbal Products Association
8484 Georgia Avenue
Suite 370
Silver Spring, MD 20910
(301) 588-1171

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