



July, 29 2008

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

RE: Docket No. FDA-2008-P-0248. Citizen Petition Requesting FDA to Treat Weight Loss Claims for Dietary Supplements as Disease Claims.

The Council for Responsible Nutrition (CRN)¹ appreciates this opportunity to provide FDA with comments regarding the Citizen Petition requesting the Food and Drug Administration (FDA) to treat weight loss claims for dietary supplements as disease claims recently submitted on April 17, 2008.² Appropriate and adequately substantiated weight loss claims for dietary supplements and conventional foods are legitimate structure/function claims, not disease claims. FDA has already carefully considered this matter in 2000, and nothing provided by the petitioners warrants a reversal of that position. CRN opposes this petition, and we urge the FDA to deny the petitioners' request.

This petition is without merit for four primary reasons:

¹ The Council for Responsible Nutrition (CRN) is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. Our 65+ manufacturers and supplier members agree to adhere to voluntary guidelines for manufacturing, labeling and marketing and CRN's Code of Ethics.

² On April 17, 2008 the American Dietetic Association, The Obesity Society, Shaping America's Health and Glaxosmithkline Consumer Healthcare jointly submitted a petition to the FDA requesting the Agency determine that dietary supplements bearing claims that they promote, assist, or otherwise help in weight loss are "disease claims" under Section 403(r)(6) of the FD&C Act. 21 U.S.C. § 343(r)(6).

(1) FDA correctly decided in 2000 that weight loss claims (as opposed to claims to treat obesity) are appropriately structure/function claims under the Dietary Supplement Health and Education Act of 1994 (DSHEA) based on the intended use of these products; marketers promote these products, and consumers overwhelmingly turn to various weight loss products (including conventional foods, dietary supplements and other weight loss plans, programs and equipment), for cosmetic reasons and immediate health benefits such as feeling better and having more energy, not primarily to manage their risk of disease.

(2) The condition of being “overweight” has not been established by the petitioners as a validated modifiable risk factor for, or surrogate endpoint for, disease. FDA has historically held petitions for health claims to a high threshold -- a standard the petitioners have failed to meet -- to demonstrate that modification of the risk factor results in a direct and quantifiable reduction of risk of a specific disease; mere associations of the risk factor with disease risk is insufficient to support a health claim.

(3) Contrary to the petitioners’ assertions, if FDA were to grant this petition, it would result in sweeping implications for weight-related claims for the entire category of “food,” and create a slippery slope for other structure/function claims that would essentially “disease-ify” many health conditions not currently considered to be diseases or surrogate endpoints for disease. This would cripple the dietary supplement category as envisioned by Congress with the passage of DSHEA.

(4) To the extent that unsubstantiated or misleading claims are being made for weight loss products (and indeed any FDA-regulated products), the petitioners’ concerns can and should be addressed through increased enforcement of existing laws and regulations by both FDA and the Federal Trade Commission (FTC). Many dietary ingredients are well-substantiated for weight loss, and a few outrageous examples of claims that already violate both FDA and FTC requirements for the substantiation of labeling and advertising do not justify removal of weight loss claims from the structure/function category altogether.

Background

Before elaborating on legal basis for CRN’s position with respect to the petition, it is important to call attention to the realities that should be acknowledged by the requests in this petition. The petitioners request that weight loss be re-classified as a disease claim, requiring FDA approval as a health claim, and simultaneously argue that none of the existing dietary ingredients making weight loss claims should satisfy the requirements of a health claim. Such a request, if granted, would in effect concede market exclusivity to a single company for its over-

the-counter (OTC) weight loss drug product. With the support of three non-profit organizations, GlaxoSmithKline (GSK) is essentially asking FDA to eliminate the claims for dietary supplement weight loss products that compete with its nonprescription drug alli[®]. Since the OTC introduction of alli[®] a year ago, the product has become a \$100 million revenue stream to GSK, one that would grow even more if dietary supplement options for weight management were eliminated.

As will be demonstrated below, if FDA were to make weight loss a disease claim and then hold dietary supplement weight loss claims to the “significant scientific agreement (SSA)” standard, it would likely lead to removal of many (if not all) weight loss claims made by dietary supplements -- not because they fail to possess reasonable scientific evidence to substantiate their weight loss claims, but because of the high bar that FDA has created for the SSA standard. The Center for Food Safety and Applied Nutrition (CFSAN) has previously declared that global indicators not related to any one specific disease are not recognizable modifiable risk factors for disease. alli[®] came to the consumer healthcare market through an “Rx-to-OTC switch” petition evaluated by CDER thus avoiding that scrutiny. In fact, one wonders if alli[®] was not a drug, but rather a dietary supplement, if GSK could demonstrate significant scientific agreement to the satisfaction of CFSAN as to the reduction of risk of a specific disease associated with its product, i.e., could alli[®] on its packaging claim that its ingestion results in the reduction of risk for a specific disease, such as cancer?

CRN now turns to its legal arguments:

- 1. FDA correctly decided in 2000 that weight loss claims (as opposed to claims to treat obesity) are appropriately structure/function claims under DSHEA based on the intended use of these products; marketers promote these products, and consumers overwhelmingly turn to various weight loss products (including conventional foods,**

dietary supplements and other weight loss plans, programs and equipment), for cosmetic reasons and for immediate health benefits such as feeling better and having more energy, not primarily to manage their risk of disease.

The question petitioners seek to re-open, namely whether weight loss is a structure/function claim³ or a disease claim⁴ was correctly decided in 2000. At that time, FDA issued regulations intended to clarify the types of structure/function claims that can be made for dietary supplements and specifically concluded that “weight loss claims are properly considered structure/function claims”.⁵ In the final rule on structure/function claims for dietary supplements, FDA concluded that overweight (any amount above one’s ideal body weight but not obese) is not a disease, and that weight loss claims for dietary supplements are legitimate structure/function claims and not disease claims. The Agency made clear that weight loss products can be used by consumers experiencing a variety of degrees of overweight, that overweight is not a disease state per se, and thus, weight loss claims cannot be viewed as treatment or disease claims.⁶ To CRN’s knowledge, this position has not changed within FDA, and the petitioners do not assert that overweight is a disease itself. (The claim that it is instead a validated modifiable risk factor for disease will be addressed in section 2 below). Rather, overweight is related in observational studies to so many conditions that it may best be understood as a factor affecting the general structure and function of the body and therefore

³ See 21 U.S.C. §434(r)(6)(A).

⁴ The term “disease claim,” as used in the petition, refers to 21 USC §343(r)(6), which generally prohibits the use of claims that “claim to diagnose, mitigate, treat, cure or prevent a specific disease . . .” in connection with dietary supplements. However, the FD&C Act, as modified by the NLEA, expressly permits certain kinds of disease claims called “health claims” for foods including dietary supplements, which describe the relationship between a nutrient and a disease or health related condition,” provided these claims are specifically permitted by the agency. See 21 U.S.C. §343(r)(3)..

⁵ 21 CFR §101.93 Federal Register: January 6, 2000 (Volume 65, Number 4) page 1027.

⁶ Id.

altering a person's overall susceptibility to a variety of conditions and diseases. This does not establish overweight as a disease itself or as a surrogate marker for any specific disease.

The National Institutes of Health (NIH) document on the health risks of being overweight, cited repeatedly by petitioners, makes mention not only of coronary heart disease, stroke, various cancers, and diabetes, but also includes sleep apnea, osteoarthritis, gallbladder disease, and complications of pregnancy as conditions that may be related to overweight.⁷ The broad scope of conditions potentially affected suggests that overweight may broadly impair normal functioning of the body, not that overweight is a disease itself or surrogate marker for any particular disease. Moreover, these conclusions are based on observational data from studies comparing populations with ideal body weight vs. populations that are overweight to demonstrate associations between risk for these health conditions and the degree of overweight.⁸

The petitioners further contend that consumers use or incorporate weight loss products in their daily diets *solely or primarily* to manage their risk of disease. This argument is flawed on two levels. First it supplants the statutory standard of "intended use" of a product with a consumer perception standard. The Food, Drug & Cosmetic Act (FD&C Act), as amended, determines the classification of a product based on its "intended use" as demonstrated by the

⁷ National Institute of Diabetes and Digestive and Kidney Diseases. Do you know the health risks of being overweight? (Accessed January 3, 2008, at http://win.niddk.nih.gov/publications/health_risks.htm); Centers for Disease Control and Prevention. Overweight and Obesity.

⁸ CRN has repeatedly advocated that FDA should give more weight to such observational data in evaluating new health claims (see, e.g., CRN Comments on CFSAN/Office of Nutrition, Labeling and Dietary Supplements *Evidence-Based Review System for the Scientific Evaluation of Health Claims* Draft Guidance, submitted August 29, 2007). However, the agency has stated its position that observational data alone are not sufficient on which to base a health claim; rather the agency has asserted that observational data are useful for hypothesis generating, but not for hypothesis proving. (see CFSAN/Office of Nutrition, Labeling and Dietary Supplements *Evidence-Based Review System for the Scientific Evaluation of Health Claims* Draft Guidance (July 2007)). While CRN disagrees with this conclusion as to the proper weight that should be given to observational data, that is the standard by which FDA must evaluate this petition unless it is prepared to revise its thinking around the use of observational data more generally. Thus, FDA cannot now rely on the NIH/NIDDK without simultaneously revising its views on the influence accorded to observational data in the context of other health claims.

claims made by the manufacturer or marketer of the product.⁹ Thus, the appropriate inquiry is whether the manufacturer who markets the particular dietary supplement is doing so for the intended use of reducing disease risk, or for other non-disease related purposes. Even the very ingredients that petitioners later identify as illustrating the alleged excesses of the weight loss category do not make claims for reducing one’s risk of diabetes or cutting one’s risk of heart disease from the use of the products (*see, e.g.*, “weight loss,” “burn fat and calories,” “effective weight control,” “metabolize fat, convert protein into muscle,” “development of lean body mass,” and “fires up your fat-burning engine”). As the claims made for the products amply demonstrate, the manufacturers overwhelmingly promote these weight loss products for weight loss itself, and for the cosmetic and appearance-related results as well as immediate health benefits such as feeling better or having more energy. The manufacturers’ intended use, regardless of consumers’ general perceptions about the possible residual benefits of weight-loss or weight control, is not about disease risk reduction.

Moreover, even if one were to accept that consumer motivations rather than manufacturer’s intent should govern, the petitioners have not established that reduction of disease is the *primary* motivation for consumers who use dietary supplements for weight loss. That assertion is based on a single survey sponsored and presented by the petitioners¹⁰ and provides insight into consumers’ perceived benefits of weight loss, not their motivation for seeking to lose weight or to use these products. According to other sources of consumer research, more consumers cite appearance than disease prevention as the reason for their use of weight

⁹ A dietary supplement means a product “intended to supplement the diet...” 21 U.S.C. §321(ff).

¹⁰ Data from *The Landmark Survey* –Center for Survey and Research Analysis, University of Connecticut, Center for Weight Loss, University of Pennsylvania; cited in the citizen’s petition, pg. 11

loss products (60% vs. 42%, respectively).¹¹ Not only do consumers turn to weight loss products primarily for cosmetic reasons and immediate health benefits, the degree and extent of weight loss desired varies tremendously, depending on circumstances and personal preferences. Indeed, in its 2000 final rule, FDA recognized this fact by stating, “FDA believes that it is commonly understood that ‘weight loss plans’ relate to a broad range of overweight statuses. Therefore, weight loss plans are not so narrowly associated with disease treatment that a reference to use as part of a weight loss plan should be considered a disease claim”.¹² With this comment, FDA alluded to the fact that consumers use or incorporate weight loss products for many reasons other than to manage their risk of disease. This contradicts the petitioners’ unsupported assertion that the condition of overweight is primarily a marker of disease risk and is so perceived by consumers. According to the petitioners, even “The Landmark Survey” supported by one of the petitioners, found that only 43% of consumers who had attempted to lose weight said the primary benefit they hoped to gain was to improve their health.¹³

For contextual purposes, consider the consumer who may be a few pounds over his or her ideal body weight, or who may even be at or below his or her ideal body weight. In both situations, the consumer may be interested in losing a few pounds, perhaps to fit into a different clothing size or improve appearance (before a beach vacation, in anticipation of a wedding, class reunion, or other public event, etc.). In neither case should they be classified as “diseased,” and in neither case is disease prevention the consumer’s primary motivation for weight loss.

¹¹ 2006 NMI Health and Wellness Trends Report (HWTR). Natural Marketing Institute.

¹² 21 CFR §101.93(g)(2)(vi) Federal Register: January 6, 2000 (Volume 65, Number 4).

¹³ Data from *The Landmark Survey* –Center for Survey and Research Analysis, University of Connecticut, Center for Weight Loss, University of Pennsylvania; cited in the citizen’s petition pg. 11

The FDA correctly decided in 2000 that weight loss is properly considered a structure/function claim and petitioners' arguments to the contrary should not now persuade FDA to reverse that decision.¹⁴

- 2. The condition of “overweight” has not been established by the petitioners as a validated modifiable risk factor for, or surrogate endpoint for, disease. FDA has historically held petitions for health claims to a high threshold -- a standard the petitioners have failed to meet -- to demonstrate that altering a risk factor results in a direct and quantifiable reduction of risk of a specific disease; mere associations of the risk factor with disease risk is insufficient to support a health claim.**

Acknowledging FDA's stated position that weight loss is not a disease claim, the petitioners claim that the condition of overweight is actually a risk factor for chronic disease and therefore request FDA to designate “weight loss” claims as "disease claims" under Section 403(r)(6) of the FD&C Act). 21 U.S.C. § 343(r)(6). Doing so, according to the petitioners, would require manufacturers of dietary supplements to obtain an FDA approved health claim prior to marketing products claiming to support weight loss. Therefore, in order for FDA to grant the petitioners' request, it must determine that overweight is a validated modifiable risk factor or surrogate endpoint for chronic disease. FDA has not determined this, and the petitioners provide little credible scientific evidence in this petition to establish overweight as a validated modifiable risk factor for disease. Certainly, there are insufficient data to satisfy the high threshold FDA has established in its evaluation of other health claim petitions to the agency.

¹⁴ Petitioners separately argue that their request does not seek to reverse prior FDA decisions but rather only to articulate a new interpretation of the criteria announced in 21 CFR §101.93. Regardless of how it is portrayed, the result the petitioners seek is a reversal of the previous decision clearly articulated by FDA in January 2000, namely, in order to remove weight loss as a permissible structure/function claim for dietary supplements and to require pre-market approval for these claims. Such a reversal would constitute a substantive change demanding full notice and comment rulemaking.

In its recently released Draft Guidance, *Evidence-Based Review System for the Scientific Evaluation of Health Claims*,¹⁵ the Agency lists the following examples as surrogate endpoints currently accepted by the NIH and/or FDA:

(1) serum low-density lipoprotein (LDL) cholesterol concentration, total serum cholesterol concentration, and blood pressure for cardiovascular disease; (2) bone mineral density for osteoporosis; (3) adenomatous colon polyps for colon cancer; and (4) elevated blood sugar concentrations and insulin resistance for type 2 diabetes.

The condition of overweight is not listed among these examples. Also missing from this list are many other risk factors for which there are substantial data, but that FDA does not consider validated modifiable risk factors or surrogate endpoints, including high serum homocysteine for cardiovascular disease, low macular pigment density for age-related macular degeneration (AMD), and cartilage degeneration for osteoarthritis (OA). In a letter of denial in response to a qualified health claim petition for lutein and AMD risk, FDA concluded that macular pigment "...is not recognized as a surrogate endpoint for risk of AMD or cataracts...,"¹⁶ citing a lack of intervention data that establishes a causal link between low macular pigment levels and AMD risk or that demonstrates that higher macular pigment lowers AMD risk. In a similar letter in response to a qualified health claim petition for glucosamine and chondroitin sulfate and OA risk, FDA concluded that cartilage degeneration is not a recognized modifiable risk factor for OA,¹⁷ again citing, among other issues, a lack of intervention data establishing causality between

¹⁵ CFSAN/Office of Nutrition, Labeling and Dietary Supplements *Evidence-Based Review System for the Scientific Evaluation of Health Claims* Draft Guidance (July 2007).

¹⁶ CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements, Qualified Health Claims: Letter of Denial - Xangold® Lutein Esters, Lutein, or Zeaxanthin and Reduced Risk of Age-related Macular Degeneration or Cataract Formation (Docket No. 2004Q-0180) December 19, 2005.

¹⁷ CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements, Letter Regarding the Relationship Between the Consumption of Glucosamine and/or Chondroitin Sulfate and a Reduced Risk of: Osteoarthritis; Osteoarthritis-related Joint Pain, Joint Tenderness, and Joint Swelling; Joint Degeneration; and Cartilage Deterioration (Docket No. 2004P-0059) October 7, 2004; CFSAN/Office of Nutritional Products, Labeling, and

cartilage degeneration and OA risk. FDA also considered whether joint degeneration could be considered a modifiable risk factor for OA, and concluded that the term is too global or general because joint degeneration is associated with several diseases. This same rationale applies even more so to the condition of overweight, which can be associated with a myriad of diseases, but not to any one specific disease.

The petitioners incorrectly and repeatedly refer to high serum cholesterol and high blood pressure in a failed attempt to equate these two conditions with overweight in terms of their relevance to disease risk. FDA has ruled these are validated modifiable risk factors or surrogate markers for disease, and thus, product claims which state or imply lowering of cholesterol or blood pressure are disease claims or health claims requiring FDA approval. This conclusion is based on human intervention data which shows that modulation of these risk factors directly and independently affects the risk of cardiovascular disease. Health claims for dietary fiber,¹⁸ phytosterols¹⁹ and sodium²⁰ have been approved by the Agency on this basis. While the petitioners cite a vast evidence base of epidemiological data which shows an association between adiposity and conditions of overweight and increased risk for various chronic diseases, they fail to provide data that demonstrates that weight loss per se for the average adult results in a quantifiable, direct and independent reduction in risk for any one chronic disease. In other

Dietary Supplements CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements, Letter Regarding the Relationship Between the Consumption of Crystalline Glucosamine Sulfate and a Reduced Risk of Osteoarthritis (Docket No. 2004P-0060) October 7, 2004.

¹⁸ 21 CFR § 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

¹⁹ 21 CFR § 101.83 Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD).

²⁰ 21 CFR § 101.74 Health claims: sodium and hypertension.

words, the petitioners fail to meet FDA’s criteria for establishing a marker as a validated modifiable risk factor or surrogate endpoint for disease.

Body weight, like countless other metabolic measures, is variable and can be influenced by individual genetics, decisions relating to the selection of foods and other environmental and lifestyle factors such as exercise. Body weight, like antioxidant status or immune function, can be optimized, and optimization is very likely to have health benefits as a direct result of improving the overall structure and function of the body. However, claims relating to such benefits are not health claims (or disease claims) as defined by the 1990 Nutrition Labeling and Education Act (NLEA). Instead, modification of body weight falls squarely within the scope of structure/function claims. Thus, FDA should not re-classify weight loss as a disease claim.

- 3. The petitioners’ request would result in sweeping implications for weight-related claims for the entire category of “food,” and would, at the same time, create a slippery slope for other structure/function claims that would essentially “disease-ify” many health conditions that are not currently considered to be diseases or surrogate risk factors for disease. This would cripple the dietary supplement category as envisioned by Congress with the passage of DSHEA.**

A. If implemented, the petition would have an impact on both dietary supplements and conventional foods.

Despite the petitioners’ brief (two sentence) attempt to remove conventional foods from being impacted by this petition, by their own rationale, they have not succeeded.²¹ The petitioners repeatedly reference, and attempt to interpret, Congress’ intent behind NLEA, through which Congress authorized FDA to promulgate regulations for health claims. According to FDA, health claims are, “...statements about substance/disease relationships... FDA has

²¹ The petition states that it would not “preclude manufacturers from making fully substantiated claims that their products ‘help to maintain healthy weight that is already within normal range.’ This petition also would not apply to conventional foods that may assist the general population in controlling weight.” (*see* page 2 of Petition).

defined the term ‘substance’ by regulation as a *specific food or component of food* (emphasis added). An authorized health claim may be used on both conventional foods and dietary supplements”.²² However, NLEA applies equally to all “food” products, a statutory category of which dietary supplements are only one part.

If, as the petitioners contend, weight loss claims are “disease claims” and products bearing such claims must petition FDA for a health claim approval under NLEA, then conventional foods as well as dietary supplements would necessarily be affected. In this case, products ranging from meal replacement beverages and bars to cereals and frozen dinners would be required to receive FDA approval prior to making weight loss claims. The petitioners attempt to deny this logical extension of their position by claiming that such foods are intended to “maintain weight” through calorie control, and thus are not subject to the petition. In fact, such food products are among the products most commonly purchased by consumers for “weight loss” and outperform dietary supplement products in terms of total volume and sales (\$5.4 billion vs. \$1.7 billion, respectively in 2006).²³ To officially exempt conventional foods from being affected by this petition if it were to move forward, would require amending the FD&C Act.

Many conventional foods are offered specifically for weight loss, and the weight loss claims for such foods cannot be treated separately from weight loss claims for dietary supplements. The 2002 FTC report on weight loss advertising²⁴ included discussion of

²² U. S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Special Nutritionals Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements December 22, 1999.

²³ Figures include combined sales for liquid meal replacements, low-carb foods, nutrition bars (foods) vs. sales for weight loss supplements for 2006. 2007 – 2008 Sport Nutrition and Weight-Loss Report. *Nutrition Business Journal*.

²⁴ Weight Loss Advertising: An Analysis of Current Trends. A Federal Trade Commission staff report. September 2002 <http://www.ftc.gov/bcp/reports/weightloss.pdf>.

numerous advertisements for dietary supplements but also included 48 advertisements for meal replacements and other conventional foods. A brief examination of today's supermarket shelves reveals numerous products specifically labeled and promoted for weight loss – not as the petitioners suggest merely for weight maintenance. Slim-Fast[®] product labels assert that “Slim-Fast[®] is a **proven** approach to weight loss” and urge consumers to visit a website “for **FREE** weight loss support.” The Slim-Fast[®] website says the products are “designed for weight loss” and encourages women to take the challenge to “lose up to 24 lbs. in 12 weeks.”²⁵ General Mills' fiber bars under the Curves[®] brand invite consumers to “take it off and keep it off” and the related website assures women that “losing weight tastes great.”²⁶ The National Dairy Council[®] asserts that three servings of dairy products every day helps with weight loss,²⁷ although a recent comprehensive review questions the evidence for such an effect.²⁸ FDA could not, as the petitioners suggest, restrict weight loss claims for dietary supplements while ignoring direct or implied weight loss claims for conventional foods.

The petitioners' vain attempt to exclude conventional foods, and especially foods for “weight management” as opposed to “weight loss,” from the requested action should be seen as nothing more than an attempt to isolate and eliminate claims for dietary supplements that are in most competition with alli[®] while not disturbing conventional foods that are likewise promoted for weight loss but do not directly compete with this product. There is no rationale for selectively targeting dietary supplement weight loss claims and not implicating weight loss claims for conventional foods, as suggested by the petitioners. The scope of the petitioners' argument

²⁵ See <http://www.slimfast.com/>.

²⁶ <http://www.curvesfoods.com/>.

²⁷ <http://www.nationaldairycouncil.org/nationaldairycouncil/healthyweight>.

²⁸ Lanou AJ, Barnard ND. Dairy and weight loss hypothesis: an evaluation of the clinical trials. *Nutr Rev*. 2008 May;66(5):272-9.

relates to the general condition of overweight and thus would have to apply to both product categories equally, if the argument were accepted at all.

B. Petitioners' request to reclassify weight-loss as a disease claim would lead to other structure/function claims being similarly re-classified and would thwart the intent of DSHEA.

The petitioners are essentially asking FDA to adopt as the criteria that any claim is a disease claim if the intended use of the product “treats an unhealthy condition that can be a risk factor for disease,” when construed in its broadest context. If dietary supplements making weight loss claims are reclassified as making disease claims, what is the fate of exercise equipment that makes similar weight loss claims? Are weights and treadmills to be classified as medical devices? The petitioners' zeal to rein in the most outrageous of weight loss claims (a goal shared by CRN and all responsible marketers of dietary supplements) would in fact create a slippery slope with widespread implications.

Under this expansive view of what is a disease claim, even items like household soap (long recognized as a cosmetic) could be reclassified as a drug. Consider that soap (not anti-microbial soap, but plain ol' soap) “treats” an unhealthy condition (dirty, unwashed skin) that can be a risk factor for disease (topical infections). Thus, to the extent that using soap to remove dirt can reduce the risk of infection, under petitioners' logic it would treat a risk factor for disease and would necessarily require FDA approval – even if the advertiser never makes this claim, but consumers routinely understand that one of the effects of washing with soap is not only cleaner hands, but a decreased risk of infection. While this example may seem extreme, it is easy to see how this logic could be applied to many other structure/function claims for dietary supplements, in effect turning common health statements into diseases. Health statements that form the basis for structure/function claims would be “disease-ified,” and the ability to make

these claims would be diminished. Congress enacted DSHEA in 1994 to provide consumers with access to accurate information; to assure consumers of access to dietary supplements and to establish a vibrant marketplace for these products. The petitioner's request would unravel that clear direction of Congress.

Moreover, the petitioners assert that once overweight is reclassified as a disease claim, the appropriate standard for the review of weight loss claims for dietary supplement products would be the statutory requirement of significant scientific agreement.²⁹ FDA has elaborated on this standard, saying, "The standard of scientific validity for a health claim includes two components: 1) that the totality of the publicly available evidence supports the substance/disease relationship that is the subject of the claim, and 2) that there is significant scientific agreement among qualified experts that the relationship is valid."³⁰ One wonders if alli[®] was a dietary ingredient instead of a drug approved through an amended new drug application (also referred to as an "Rx-to-OTC switch petition"), could it demonstrate to FDA's satisfaction that there is significant scientific agreement that the product is effective for reducing the risk of the myriad of diseases that the petitioners' link to overweight (not just that it helps its users to lose weight) -- or alternatively, that all products that can demonstrate weight loss effects are entitled to use the disease reduction claims that they reduced consumers' risk for a variety of chronic diseases.

- 4. To the extent that unsubstantiated or misleading claims are being made for weight loss products (and indeed, any FDA-regulated products), the petitioners' concerns can and should be addressed through increased enforcement of existing laws and regulations by both FDA and the FTC. Many dietary ingredients are well-substantiated for weight loss, and a few outrageous examples of claims that already violate both FDA and FTC requirements for the substantiation of labeling and**

²⁹ 21 U.S.C. §343(r)(3)(B)(i).

³⁰ CFSAN/Office of Special Nutritionals, *Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, Guidance for Industry (Dec. 22, 1999).

advertising do not justify removal of weight loss claims from the structure/function category altogether.

The petitioners' complaints are really about outrageous claims for weight loss that cannot be substantiated by the marketers who make these claims. These complaints are more appropriately addressed through additional enforcement, not reversal of FDA's existing policies. Unsupported claims for FDA-regulated products also have been reported to the Agency for "improved memory", "increased sex drive", "reduction of menstrual symptoms", "increased strength and muscle mass" and "maintaining digestive health". Would the petitioners likewise seek to disease-ify all these conditions in order to address the unsubstantiated claims in these areas? Existing laws and regulations already make it illegal to promote dietary supplements for intended uses -- either in labeling or advertising -- that are not substantiated with adequate and credible evidence. Regulators possess adequate authority and should enforce existing laws and regulations.³¹ Increased enforcement of these requirements does not require any change in policy by FDA.

Under DSHEA and the FD&C Act, FDA has adequate authority to take action against products misbranded with unsubstantiated claims. The FD&C Act specifically provides that the manufacturer of a dietary supplement must have substantiation for claims and that they be truthful and not misleading.³² Moreover, the law requires that a manufacturer must notify the FDA within 30 days of first marketing a dietary supplement with such structure/function claims, allowing the agency the opportunity to review the claim and to notify the company if it believes

³¹ The same Federal register Notice that petitioners now seek to reverse states that "section 402(r)(6)(B) of the FD&C Act clearly states that manufacturers must have substantiation to show that the statements that they make under section 403(r)(6) of the act are truthful and not misleading. This indicates that manufacturers must be prepared to demonstrate to the court that they have support for each claim." 65 Fed. Reg. at 1032.

³² 21 U.S.C. §343(r)(6)(B).

the claim is not a valid structure/function claim.³³ Similarly, the FTC under the FTC Act has adequate authority to take action against deceptive, untruthful or misleading advertisements.³⁴ In fact, in 2004, the FTC launched “Operation Big Fat Lie,” a nation-wide law enforcement sweep against companies making false weight-loss claims in national advertisements. That was one of several efforts on the part of the FTC to stop deceptive advertising and provide refunds to consumers harmed by unscrupulous weight loss advertisers; to encourage media outlets not to carry advertisements containing bogus weight loss claims; and to educate consumers to be on their guard against companies promising miraculous weight loss without diet or exercise.³⁵ Both agencies work collaboratively to enforce these laws for both the dietary supplement and conventional food industries. Both possess and frequently utilize the authority to pursue criminal charges against offenders as well as to seek redress for consumers, disgorgement of profits and (in the case of FDA) product seizures.

CRN acknowledges that there is a small segment of both the dietary supplement and food industries whose products are associated with unsubstantiated weight loss claims. CRN encourages, on an ongoing basis, rigorous enforcement of the law by both FDA and FTC, and urges its members and the industry as a whole to engage in self-regulatory behavior with respect to advertising and labeling claims. Beginning in 2007, CRN has provided an unrestricted three-year grant totaling nearly \$500,000 to the National Advertising Division (NAD) of the Better Business Bureau to help support increased monitoring and adjudication of cases involving

³³ Id. At §343(r)(6)(C).

³⁴ The FTC’s authority derives from Section 5 of the FTC Act. In addition, dietary supplements have traditionally been regulated under Sections 12 and 15, which prohibit false advertisements, defined as those that are “misleading in a material respect,” for foods, drugs, devices or cosmetics.

³⁵ <http://www.ftc.gov/opa/2004/11/bigfatliesweep.shtm>.

dietary supplement advertising.³⁶ Under this program, CRN has already brought ten competitive challenges against marketers of dietary supplements, including several against weight loss products. We believe that inadequate enforcement is a problem of resources, not regulatory authority or legislation. CRN has for some time lobbied Congress for more funding for FDA, and will continue to do so, on behalf of its members and the Agency.³⁷

Reversing the appropriate decision that was reached by FDA in 2000 would unfairly penalize responsible dietary supplement and food companies that market their products using well substantiated claims which properly promote the use of their products in the context of an overall weight loss plan. The current laws and regulations require that all claims, not just weight loss claims, must be substantiated by credible scientific evidence. Both FDA and FTC have adequate authority to enforce these laws and regulations, and the action requested by this petition would not in any way enhance the Agencies' ability to take action against misleading claims.

Conclusion

In conclusion, CRN urges FDA to deny this petition on the grounds that FDA correctly determined in 2000 that weight loss claims are appropriately classified as structure/function claims, and the petitioners have not provided justification to reverse that decision. Overweight has not been established as a validated modifiable risk factor or surrogate endpoint for disease, and even the petitioner's own product would be hard pressed to meet the standard it seeks to hold dietary supplements to in order to demonstrate that weight loss associated with the use of its product directly impacts a person's risk of the diseases it cites. Moreover, if FDA were to grant

³⁶ CRN, *NAD Initiative to Expand Review of Dietary Supplement Advertising*, CRN press release dated October 18, 2006, http://www.crnusa.org/PR06_CRN_NAD091806.html and www.nadreview.org.

³⁷ CRN is an active member in the Alliance for a Stronger FDA, an education and advocacy group dedicated to increasing the appropriated resources available to FDA <http://www.strengthenfda.org/>

petitioners' request, that decision would apply to all foods that make weight loss claims, not just dietary supplements. Finally, FDA and FTC already have adequate authority to enforce existing laws and regulations. The petitioners' arguments are unsupported and therefore should not be accepted with respect to either dietary supplements or conventional foods intended to assist consumers in achieving weight loss.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven M. Mister". The signature is written in a cursive style with a large, stylized initial "S".

Steven M. Mister
President & CEO