

April 17, 2008

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
Parklawn Bldg., Mail Code: HF-1
5600 Fishers Lane
Rockville, Maryland 20856

**Re: Citizen Petition Requesting FDA to Treat Weight Loss
Claims for Dietary Supplements as Disease Claims**

Dear Dr. von Eschenbach:

On behalf of the American Dietetic Association, The Obesity Society, Shaping America's Health, and GlaxoSmithKline Consumer Healthcare, LP ("GSK") (hereafter "petitioners"),¹ we are herewith submitting the attached citizen petition pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"). In this petition, we respectfully request the Food and Drug Administration ("FDA") to determine that claims that a dietary supplement promotes, assists, or otherwise helps in weight loss are "disease claims" under Section 403(r)(6) of the FDCA. As described below, we believe that expeditious action by FDA on this petition would help address an urgent public health problem confronting Americans who are overweight.

I. Scientific Reports and Epidemiological Studies During the Past Decade Establish That Being Overweight Is a Significant Risk Factor for Serious Chronic Diseases

Recent estimates indicate that approximately 127 million American adults are overweight and the numbers are growing each year. At the same time, the number of children and adolescents in the country who are overweight has risen dramatically in the recent past. In 2004, 66% of adults were obese or overweight, while 17% of children and adolescents were overweight. These figures are quite troubling because, as the population of Americans who are overweight increases annually, so does the number of individuals who are at increased risk of developing serious diseases, including type 2 diabetes, cardiovascular disease, cancer, and obesity.

¹ The American Dietetic Association -- the nation's largest organization of food and nutrition professionals -- serves the public by promoting optimal nutrition, health and well-being. The Obesity Society is the leading scientific society dedicated to the study of obesity and is committed to keeping the medical community and public informed of new advances. Shaping America's Health (SAH) was founded by the American Diabetes Association to reverse obesity trends and overweight issues facing individuals, families, and communities. The mission of SAH is to prevent and treat excess weight and obesity, and to facilitate a better understanding of weight management. GSK has provided unrestricted grants to the American Dietetic Association, The Obesity Society, and SAH in support of the missions of these organizations.

The link between the condition of being overweight and an increased risk of disease has been recognized by the National Institutes of Health ("NIH"), Centers for Disease Control ("CDC"), and the Surgeon General. Indeed, a substantial body of scientific evidence has been published over the past decade which confirms that being "overweight" – as opposed to being obese – is an independent and significant risk factor for many diseases and other medical conditions. Many of these studies are summarized in the attached petition, and the scientific papers are included in an addendum to the petition.

In addition, we are including, with this petition, an expert report from five top scientists who have focused on the relationship between weight gain and disease. To ensure that the scientific bases underlying this petition are principled and sound, GSK convened a panel of these researchers and clinicians in May 2006 to review the scientific literature and evaluate the relationship between being overweight and the risk of developing serious chronic diseases. Their report confirms that there is a strong relationship between the state of being overweight and an increased risk of disease.

II. Overweight Americans Are Being Diverted from Effective Ways to Lose Weight by Exaggerated and Unsubstantiated Claims Accompanying Weight Loss Supplements

During the past decade, it has also become clear that consumers understand the health risks associated with being overweight. A major consumer research survey recently completed by the University of Connecticut, with support from GSK, found that most overweight individuals (94%) understand that being overweight increases their risk of disease. That study also found that many overweight individuals are relying on dietary supplements to lose weight and thereby reduce that risk. That reliance is based on the mistaken belief by almost two-thirds of consumers that supplements have been approved by FDA as safe and effective products.

In the wake of this confusion, many supplement manufacturers are claiming with little, if any, substantiation that their products are clinically proven to help overweight individuals lose weight safely and quickly. In connection with such claims, supplement manufacturers capitalize on the fact that their products are available without a prescription and present a "natural solution" that is less demanding than special diets and increased physical activity. Yet, during the past few years, several independent teams of investigators (including scientists from NIH) have reviewed the purported evidence underlying claims accompanying weight loss supplements, and all have concluded that there is little, if any, evidence to indicate that any of these products actually work.

In recognition of these problems, both FDA and the Federal Trade Commission ("FTC") have pursued enforcement actions and other measures against supplement companies. While these initiatives have caused certain firms to stop making unsubstantiated statements about weight loss supplements, others have not. Moreover, still other companies have sprung up to make similar, but not identical, claims that also cannot be substantiated. As a result, despite the laudable efforts of FDA and the FTC to stem the tide of misleading claims made for weight loss

supplements, many overweight Americans are being lured into using supplements for which little or no scientific evidence exists to demonstrate that they actually work.

III. The FDA Must Find That Weight Loss Claims Are "Disease Claims" Under Its Existing Regulations and on the Basis of Substantial Legal Precedent

The FDA must now address this problem under Section 403(r)(6) of the FDCA. 21 U.S.C. § 343(r)(6). That provision prohibits manufacturers of dietary supplements from making claims that their products may be used to diagnose, mitigate, treat, cure or prevent a disease ("disease claims"). In 2000, FDA promulgated regulations that established ten separate and independent criteria for determining when a particular claim about a dietary supplement is an impermissible disease claim. 21 C.F.R. § 101.93. If a claim meets any one of these criteria, FDA must determine that the statement constitutes a disease claim.

Under these regulations, FDA has consistently indicated that supplement manufacturers may not claim that a product "*prevents or treats abnormal or unhealthy conditions or clinical measurements that are . . . markers of, or risk factors for, diseases*" (emphases added). Thus, during the past decade, FDA has repeatedly objected to claims by supplement manufacturers that their products reduce high cholesterol levels, high blood glucose, and high blood pressure because such statements imply treatment of a disease. Given the wealth of information linking an increased risk of disease with the condition of overweight, FDA must reach the same conclusion about claims that a supplement will reduce high weight levels.

To be sure, in January 2000, FDA allowed supplement manufacturers to make weight loss claims. That determination, however, was based on FDA's finding that the condition of being overweight is not a disease and, therefore, such statements could not be treated as disease claims under two different criteria in FDA's regulations. We are *not* asking FDA to reverse that position by finding that overweight is a disease. Rather, in light of the scientific information that has emerged since 2000 about the risks of being overweight, we are petitioning FDA to determine that weight loss claims are disease claims because they suggest treatment of an unhealthy condition that is a risk factor for disease.

IV. Conclusion

In closing, we believe that the actions requested in this petition would substantially advance the public health by requiring manufacturers of weight loss supplements to obtain FDA review of their claims before rushing to market. Such manufacturers might, for example, seek to obtain FDA clearance of their claims through the qualified health claims process. Under that regulatory scheme, FDA may review claims that the risk of developing a disease would be reduced through the intake of a substance in the supplement. The FDA may only allow for such statements, however, on the basis of credible scientific evidence. Accordingly, by taking the actions requested in this petition, FDA would protect millions of Americans who are currently relying on unproven and ineffective dietary supplements to lose weight.

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Thank you for your consideration of this petition.

Sincerely,



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