

**Before the  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

<b>In re: Proposed Rule on</b>	)	
<b>Dietary Supplement Products</b>	)	<b>Docket No. 95N-0304</b>
<b>Containing Ephedrine Alkaloids</b>	)	
	)	
	)	

**JOINT COMMENTS OF  
AMERICAN NUTRITIONAL CORPORATION, INC.;  
LIFE EXTENSION FOUNDATION BUYERS CLUB, INC.;  
JULIAN M. WHITAKER, M.D.;  
LIFE ENHANCEMENT PRODUCTS, INC.;  
VITAMIN RESEARCH PRODUCTS, INC.;  
LIFE PRIORITY, INC.; and  
DURK PEARSON AND SANDY SHAW**

American Nutritional Corporation, Inc.; Life Extension Foundation Buyers Club, Inc.; Julian M. Whitaker, M.D.; Life Enhancement Products, Inc.; Vitamin Research Products, Inc.; Life Priority, Inc.; and Durk Pearson and Sandy Shaw (collectively, “Joint Commenters”), by counsel and in response to the notice seeking additional comments published in the Federal Register, 68 Fed. Reg. 10417 (March 5, 2003), hereby submit these comments for FDA’s consideration.

**I. BACKGROUND OF COMMENTERS**

*American Nutritional Corporation, Inc.* American Nutritional Corporation, Inc. (“ANC”) is a private-label contract manufacturer of dietary supplement products. ANC was officially incorporated in 1988 and reorganized under the laws of the state of Nevada in 1992. ANC is in the business of manufacturing and selling several dietary supplement products as well as other nutritional food products, including several ephedra-containing

dietary supplements for its private label customers. None of the dietary supplements sold by ANC for human consumption contains more than 25 mg of ephedrine alkaloids per serving. A majority of ANC's ephedra-containing products contain caffeine. Those products do not contain caffeine in excess of 80 mg per serving.

***Life Extension Foundation Buyers Club, Inc.*** The Life Extension Foundation Buyers Club, Inc. ("Life Extension") is a for-profit organization with a long-range goal of extending the healthy human lifespan. Life Extension was officially incorporated in 1980, but the founders have been involved in anti-aging research since the 1960s. Life Extension funds scientific research aimed at extending the healthy human lifespan and publishes a monthly magazine, ***Life Extension Magazine***. Life Extension is also engaged in the business of manufacturing, marketing, distributing, and selling over 400 pharmaceutical grade dietary supplements for human and companion animal consumption. Two of the dietary supplements sold by Life Extension for human consumption contain ephedrine alkaloids. One of the dietary supplements sold by Life Extension for human consumption contains 20 mg of ephedrine alkaloids per serving. That product, a tea, contains no caffeine. The other product sold by Life Extension contains 8 mg of ephedrine alkaloids per serving and 8 mg of caffeine per serving.

***Julian M. Whitaker, M.D.*** Julian M. Whitaker, M.D. is a physician licensed to practice medicine in the states of California and Washington. He was graduated from Dartmouth College in 1966 with a B.S. degree and from Emory University in 1970 with an M.D. degree. He received additional training in surgery as a resident at the University of California Medical School. From 1975 to 1976 he worked as a physician at the Pritikin Institute in California. Since that time he has been the Clinical Director of the

Whitaker Wellness Institute in Newport Beach, California. He is the author of eight books, including: *Reversing Heart Disease* (1985), *Reversing Diabetes* (1987), *Reversing Health Risk* (1989), *Natural Healing* (1994), and *What Your Doctor Won't Tell You About Bypass* (1995). He is also the author of a widely read monthly newsletter: *Health & Healing*. Dr. Whitaker's newsletter was recognized by *Time Magazine* as one of the top-ten newsletters in the country. Dr. Whitaker believes that ephedrine alkaloids in amounts not greater than 25 mg/serving; 90 mg day provide a useful weight loss option for those, including certain of his patients, who are healthy but overweight. Dr. Whitaker wants to continue recommending such ephedra-containing supplements to his patients in appropriate medical circumstances.

*Life Enhancement Products, Inc.* Life Enhancement Products, Inc. is engaged in the business of manufacturing, distributing, and selling nearly 200 dietary supplements for human consumption. The company, which began doing business in 1995, manufactures about 95% of its own products. Life Enhancement Products markets and sells products in over 80 countries. The company also publishes a monthly magazine, *Life Enhancement*. One of the dietary supplements sold by Life Enhancement for human consumption contains not in excess of 20 mg of ephedrine alkaloids from ephedra herb per serving. That product, a tea, contains no caffeine. Ephedra teas have been consumed safely in China for over five thousand years to date and in the United States (known variously as Mormon Tea) for over one hundred years. Life Enhancement fears that FDA will make a hasty generalization and impose either its present proposed warning label or an outright ban on ephedra sale that will prevent the sale not only of dietary supplements containing unsafe per serving amounts of ephedrine in excess of 25

mg but also of dietary supplement teas containing safe ephedra with naturally occurring ephedrine alkaloids not in excess of 20 mg per serving.

***Vitamin Research Products, Inc.*** Vitamin Research Products, Inc. (“VRP”) is engaged in the business of manufacturing, marketing, distributing and selling approximately 500 pharmaceutical grade dietary supplements for human consumption worldwide. VRP was incorporated in 1979 and reorganized under the laws of the State of Nevada in 1995. VRP manufactures about 95% of its own products and distributes them directly to consumers, health food stores and health care practitioners. None of the five ephedrine-containing dietary supplements sold by VRP for human consumption contains more than 20 mg of ephedrine alkaloids per serving. Two of VRPs ephedra-containing products contain caffeine.

***Life Priority, Inc.*** Life Priority, Inc. (“Life Priority”) is engaged in the business of distributing and selling several dietary supplement products for human consumption. Life Priority was officially incorporated in 1995. One of the dietary supplements sold by Life Priority for human consumption contains 20 mg of ephedrine alkaloids per serving. That product, a tea, contains no caffeine.

***Durk Pearson and Sandy Shaw.*** Pearson and Shaw are scientists, maintaining residences in Nevada and California. They are authors of three best-selling books on aging and age-related diseases. Their latest book, ***Freedom of Informed Choice: FDA v. Nutrient Supplements***, discusses FDA’s censorship of truthful and nonmisleading speech on the labels and in the labeling of dietary supplements. They design dietary supplement formulations and license them to small manufacturing and retailing companies. Pearson and Shaw design dietary supplements that contain whole ground ephedra herb, not

synthetic ephedrine. One of the dietary supplements licensed for Pearson and Shaw for human consumption contains 20 mg of ephedrine alkaloids per serving. That product, a tea, contains no caffeine. Adoption of the Proposed Rule would have an adverse economic impact on Pearson and Shaw.

## **II. INTRODUCTION**

Since its inception in 1906, FDA's mission has been to promote and protect the public health by guarding against unsafe and ineffective foods and drugs. To achieve that objective, FDA must make unbiased decisions based on sound scientific evidence. Political pressure for action against products in the market should not obscure or override sound scientific judgment on the appropriate course for regulating those products. A large body of well-designed scientific studies supports the role of ephedra and ephedrine in helping to reduce weight. That evidence reveals ephedrine in per serving amounts not above 25 mg and per daily dose amounts not above 90 mg to be safe in healthy, and in healthy but overweight, populations. The United States is experiencing an overweight and obesity epidemic. Overweight status increases the risk of diabetes, heart disease, and cancer. Ephedrine alkaloids are an important tool in the fight against overweight status and should remain on the market in safe dose amounts, with appropriate label warnings and use instructions.

As the Baylor University report appended hereto confirms, there simply is no sound scientific evidence establishing a causal nexus in the general healthy adult population between the use of ephedrine alkaloids not above 25 mg per dose (maximum of 90 mg per day) and adverse reactions reported to FDA. Moreover, the agency should not make the hasty and unscientific generalization that synthetic ephedrine is

indistinguishable from naturally occurring ephedra herb, when ephedra herb has been safely consumed in ephedra teas by the Chinese for over 5,000 years and by American Mormons for over 100 years. Finally, the agency should not ignore the strong evidence that baseball player Steve Bechler died not from ephedra but from heat exhaustion (specifically, dehydration and exercise-induced hyperthermia), as the second Baylor University report appended hereto confirms.

The Joint Commenters rely in pertinent part on two scientific reports prepared by the scientists at Baylor University's Center for Exercise, Nutrition & Preventive Health Research ("CENPHR"). The first report has previously been filed as CENPHR's Comments to FDA in response to the agency's call for comments on the new evidence.<sup>1</sup> The second<sup>2</sup> is a scientific evaluation prepared by CENPHR's Richard Kreider, Ph.D. and Mike Greenwood, Ph.D.<sup>3</sup> on the causes of Steve Bechler's tragic, untimely demise. Both scientific evaluations confirm that ephedrine alkaloids, in reasonable dose amounts, are safe and useful supplements to the daily diet of healthy adults when used as directed.

The Joint Commenters agree with FDA that a warning statement on ephedrine-containing products is warranted. They find the warning statement proposed by FDA, however, misleading to the public. The warning statement as now written will misinform consumers into believing that ephedrine alkaloids not above 25 mg per dose and not above 90 mg per day are a threat to the lives of healthy individuals when, in the worst case, they may be a contributing factor to adverse reactions in unhealthy individuals. Herein the Joint Commenters offer an alternative disclaimer to the one proposed by FDA.

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<sup>1</sup> Attached herein as Exhibit 1.

<sup>2</sup> Attached herein as Exhibit 2.

<sup>3</sup> The curriculum vitae of Drs. Kreider and Greenwood are attached herein as Exhibit 3.

The Joint Commenters' alternative accurately reflects scientific data on known risks and appropriately warns the public of those risks. It is based upon, and is thus substantially similar to, the warning FDA has prescribed for ephedrine and pseudoephedrine-containing over-the-counter drugs.

The Joint Commenters respectfully urge FDA to avoid making any hasty generalizations about ephedrine alkaloids that will restrict public access to appropriately labeled ephedrine alkaloid supplements in safe dose amounts. They urge FDA to avoid taking action without sound scientific proof of any causal nexus between ephedrine alkaloids and reported adverse events. Such hasty generalizations may well lead overweight individuals, who currently use ephedrine alkaloid-containing supplements and who cannot afford, tolerate, or endure other therapies, to abuse over-the-counter, higher dose ephedrine and pseudoephedrine drugs (designed principally as bronchodilators and nasal decongestants<sup>4</sup>) to achieve desired weight loss effects. Instead, the agency should restrict its actions to those that are scientifically warranted based on sound evidence, keeping ephedrine alkaloid-containing dietary supplements available but at an appropriate maximum ephedrine alkaloid dose level (i.e., a maximum of 25 mg/dose and 90 mg/day) and with an appropriate disclaimer (recommended herein below). That latter course the Joint Commenters recommend below.

### **III. SUMMARY OF OVERWEIGHT HEALTH EPIDEMIC**

Overweight and obesity are direct and substantial threats to the health of an already great and increasing number of Americans. One in five Americans is obese, and

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<sup>4</sup> See 21 C.F.R. §§ 341.16; 341.20.

three in five Americans are either overweight or obese.<sup>5</sup> Obesity and overweight are known risk factors for chronic diseases, including heart disease, diabetes, high blood pressure, stroke and some forms of cancer.<sup>6</sup> According to the National Institute of Health's National Heart, Lung and Blood Institute, approximately 280,000 American adults die each year due to obesity related illnesses.<sup>7</sup> Not surprisingly, associated health care costs have increased with the rise in overweight status. In 1995 alone the direct cost of preventive, diagnostic and treatment services for overweight and obese individuals totaled over fifty-one billion dollars.<sup>8</sup>

Obviously, overweight and obesity present serious economic problems and risks to Americans. In light of the present overweight and obesity epidemic, useful, safe and inexpensive tools in the fight against overweight and obesity, including ephedra, in reasonable doses, must continue to be available. The best approach for FDA, therefore, is to keep ephedrine alkaloid-containing supplements available but prohibit ephedrine alkaloid amounts per serving above 25 mg and prohibit daily dose amounts above 90 mg while fully informing consumers of the health risks associated with product abuse and product use by certain at-risk populations.

#### IV. ARGUMENT

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<sup>5</sup> See Strum, R. The effects of obesity, smoking, and problem drinking on chronic medical problems and health care costs. 21 *Health Affairs* 245-53 (2002); Strum, R., Wells, K.B. Obesity contribute as much to morbidity as poverty or smoking? 15 *Pub. Health* 229-95 (2001).

<sup>6</sup> See <http://www.niddk.nih.gov/> (visited March 26, 2003).

<sup>7</sup> See <http://www.niddk.nih.gov/health/nutrit/pubs/unders.htm> (visited March 26, 2003).

<sup>8</sup> See Wolf, A.M., Colditz, G.A. Current estimates of the economic cost of obesity in the United States. 6 *Obes. Res.* 51S-209S (1998).

## **A. LACK OF SOUND SCIENTIFIC EVIDENCE**

FDA has not established that a causal nexus exists between the symptoms reported to be due to ephedrine alkaloid consumption in the Adverse Events Reports (“AER”) and the ephedrine alkaloids consumed. To the extent adverse events are known to have occurred in people taking ephedrine alkaloid-containing dietary supplements, FDA has not determined in any instance that ephedrine alkaloids alone (in any particular amount) were the actual causative factors. Other potential causes, such as pre-existing ailments, abusive overdoses, use/abuse of other drugs, or environmental factors, have not been ruled out scientifically. Thus, reliance on the AERs (even as manipulated by the agency) is a mistaken, unscientific exercise because it lacks proof of causality essential to employ any scientific method of analysis.

### **1. The AERs are Unscientific**

FDA recognized the weaknesses of the Special Nutritional Adverse Event Monitoring System (“SNAEMS”) and removed it in August of 2002. FDA then stated:

Data from the Special Nutritional Adverse Event Monitoring System website for dietary supplements has not been added to or updated since 1999, and the website has now been removed. The information previously available on dietary supplement adverse event reports on this website was very limited and was provided in a manner that made it difficult for users to appropriately interpret the adverse events.

It seems clear that FDA’s primary basis for the Proposed Rule has been repudiated, not only by several scientists and commenters<sup>9</sup>, but indeed by the agency itself.

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<sup>9</sup> See Center for Exercise, Nutrition & Preventive Health Research Comment, EC-26 at 3 (attached as 1); C2253; C2092; C1864; and C2253.

Upon realization that the AERs did not establish a causal relationship between consumption of ephedrine alkaloids and the adverse events reported, the National Institute of Health Office of Dietary Supplements, the National Center for Complementary and Alternative Medicine and the Agency for Healthcare Research and Quality commissioned the RAND Corporation to conduct a comprehensive ephedra study (“RAND Report”).<sup>10</sup> The RAND scientists reviewed fifty-nine scientific articles, over 1,000 AERs and 18,502 cases in the Metabolife files.<sup>11</sup> The scope of their study included: (1) ephedra alkaloids and ephedrine-containing dietary supplements’ effect on short-term weight loss; (2) ephedra alkaloids and ephedrine-containing dietary supplements’ effect on immediate athletic performance; and (3) safety issues associated with consumption of ephedra alkaloids and ephedrine-containing dietary supplements.<sup>12</sup> The RAND Report concluded that “the majority of case reports are insufficiently documented to make an informed judgment about a relationship between the use of ephedrine or ephedra-containing dietary supplements and the adverse event in question.”<sup>13</sup> The scientists were unable to find any causal connection between consumption of ephedrine alkaloids and the adverse events reported to FDA or in the clinical trials they studied. Instead the RAND Report instructs FDA that additional research must be performed to determine with reasonable certainty whether ephedrine is the causative factor in any reported

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<sup>10</sup> See Shekelle, P., Morton, S., Maglione, M., et al. Ephedra and ephedrine for weight loss and athletic performance enhancement: clinical efficacy and side effects. Evidence Report/Technology Assessment No. 76. AHRQ Publication No. 03-E022. Rockville, MD: Agency for Healthcare Research and Quality. February 2003.

<sup>11</sup> See *id.*, at v.

<sup>12</sup> See *id.*, at vi.

adverse event or whether other potential causes are truly responsible. The RAND Report states:

In order to assess a causal relationship between ephedra or ephedrine consumption and serious adverse events, a hypothesis-testing study is needed. Continued analysis of case reports cannot substitute for a properly designed study to assess causality.<sup>14</sup>

In short, there is presently no reliable scientific data linking use of ephedrine alkaloids taken as directed with the adverse events reported to FDA.

## **2. Herbal Ephedrine-Containing Dietary Supplements Are Safer Than Synthetic Ephedrine Products**

Herbal ephedra, in the form of the ground herb (rather than a rapidly soluble extract), like that found in the tea sold by the Joint Commenters, has a natural time release mechanism when consumed as an iced tea. One's risk of adverse reaction due to consumption of ephedrine alkaloids depends on the rate of release of the ephedrine alkaloids into the blood stream. Synthetic ephedrine and ephedra extract products contain concentrated amounts of ephedrine alkaloids that enter the blood stream at a faster rate than the diluted amount of ephedrine alkaloids contained in whole ground herbal ephedra teas. It is this slower rate of release that makes herbal ephedra teas less likely to be abused and safer. No proof exists that herbal ephedra tea is a causative factor in any adverse event reported to FDA.

## **B. LEGAL FLAWS**

FDA must act rationally, based on sound scientific evidence. It must rely on scientifically valid empirical data on causation between adverse events and consumption of ephedrine alkaloids before it can meet its statutory burden under 21 U.S.C. § 342(f) to

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<sup>13</sup> Id.

remove a dietary supplement from the market or to restrict supplement access. Likewise, FDA must not mislead the public by requiring use of warning statements that propound to the general population a level, degree, or nature of harm in excess of that which may reasonably be expected to occur. Because it has not met its burden of proof under 21 U.S.C. § 342(f) and because its present warning statements would mislead healthy and healthy but overweight Americans into believing ephedrine alkaloid-containing dietary supplements in no greater than 25 mg/serving; 90 mg/day amounts to be unsafe, the Proposed Rule is arbitrary and capricious, contrary to law, and thus in violation of the APA, 5 U.S.C. § 706.

Moreover, FDA's warning statement violates the First Amendment. Under apposite precedent, the warning statement must be reasonable to comply with First Amendment strictures on FDA regulation of commercial speech. The warning is unreasonably burdensome because it is not backed by requisite proof of causality and it deviates materially from the less burdensome yet fully adequate warning prescribed by FDA for higher dose over-the-counter ephedrine and pseudoephedrine-containing drugs.

**1. Daily Dose Amounts of Ephedrine at or Below 90 mg Have Not Been Shown to Pose a Risk of Harm to the General Healthy Population**

FDA has failed to prove by a preponderance of the evidence that all ephedrine-containing dietary supplements are harmful to the general healthy population. The evidence fails to show that ephedrine alkaloid-containing supplements contain poisonous or deleterious ingredients that may render them injurious to health when used as directed. The evidence fails to show that the label recommendations and ordinary use of products

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<sup>14</sup> Id. at xvii.

containing ephedrine alkaloids in amounts not in excess of 25 mg/serving; 90 mg/day create a significant or unreasonable risk of illness or injury.

The Proposed Rule thus violates the FDCA because FDA has failed to demonstrate that dietary supplements with ephedrine alkaloids not in excess of 25 mg/serving; 90 mg/day contain any poisonous or deleterious substance that would render the products injurious to health when used as directed.<sup>15</sup> In order to render a product injurious to the public health, FDA must show that there is a reasonable possibility of harm due to adulterated or poisonous substances.<sup>16</sup> FDA has not made that showing. The agency has not demonstrated that ephedrine alkaloids are the causative agents for any adverse events reported to the agency.<sup>17</sup>

DSHEA mandates that FDA prove by a preponderance of the evidence that a dietary supplement is adulterated.<sup>18</sup> That is a high standard to meet. It requires that FDA prove that illness or injury is likely to occur if the products are used in accordance with the conditions for use prescribed. FDA has provided no scientific substantiation, however, that amounts of ephedrine alkaloids not in excess of 25 mg/serving; 90 mg/day are injurious to the public health.

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<sup>15</sup> The botanical sources of ephedrine alkaloids (i.e., Ma huang, Ephedra, and Chinese Ephedra) are not dietary supplements when they are in herbal tea and not for a special dietary use or for supplement to the daily diet. 21 U.S.C. § 321(ff). Those botanical sources of ephedrine alkaloids are subject only to the adulterated foods standard.

<sup>16</sup> See U.S. v. 2,116 Boxes of Boned Beef Weighing Approximately 154,121 Pounds, 516 F. Supp. 321 (D.C., Kan., 1981), aff'd 725 F.2d 1481, certiorari denied, 469 U.S. 825.

<sup>17</sup> By its own admission FDA acknowledged that AERs offer no meaningful link between taking ephedrine-containing dietary supplements suffering an adverse event. In August of 2002, FDA removed the Special Nutritional Adverse Event Monitoring System (“SNAEMS”) because the information provided on the website “was very limited and was provided in a manner that made it difficult for users to appropriately interpret the adverse events.” See Center for Exercise, Nutrition & Preventive Health Research Comment, EC-26 (attached herein as Exhibit 1).

<sup>18</sup> See 21 U.S.C. § 342(f).

Upon reopening the comment period for the Proposed Rule, FDA stated that “new scientific evidence has come to light concerning health risks associated with the use of dietary supplements containing ephedrine alkaloids.”<sup>19</sup> The evidence since 1997 demonstrates that when properly used in amounts not in excess of 25 mg/serving; 90 mg/day, ephedrine alkaloids present very few health risks. FDA either relies on faulty evidence or mischaracterizes the state of the scientific evidence. For instance, FDA cites a study published by Stephen Bent in the *Annals of Internal Medicine*, wherein Bent et al. argue that ephedra-containing dietary supplements account for less than 1% of the market for herbal supplements, yet they are associated with 64% of adverse event reports for dietary supplements.<sup>20</sup> However, ephedrine alkaloid-containing dietary supplements make up a lion’s share of the dietary supplement market. According to SPINS, Inc. (the same consulting firm that provided Bent et al. with empirical data), ephedrine alkaloid-containing dietary supplements comprise 60% of all dietary supplements sold in the United States, not 1%.<sup>21</sup> There is thus no multi-fold risk of adverse events with use of ephedrine-alkaloid containing dietary supplements. In fact, there is neither more nor less occurrence of adverse events from ephedrine alkaloid-containing products per market share than with other dietary supplements.

The untimely demise of Steve Bechler is also cited as further proof of ephedrine risk. Based on the evidence, however, Steve Bechler’s death cannot reliably be attributed to ephedrine alkaloids and could have been prevented. The Baltimore Oriole’s pitcher suffered from numerous health conditions, including a prior history of heat illness,

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<sup>19</sup> 68 Fed. Reg. 10417 (March 5, 2003).

<sup>20</sup> See Bent, S., et al. The relative safety of ephedra compared with other herbal products. 138 *Annals of Int. Med.* 468-472 (March 18, 2003).

hypertension, and liver disease.<sup>22</sup> Compounding those health conditions, Bechler was obese, dehydrated, suffered from over-exertion, and had not eaten properly.<sup>23</sup> Based on the coroner's report, Bechler had consumed only 30 mg of ephedrine. Drs. Kreider and Greenwood of Baylor University's CENPHR evaluated the coroner's report and concluded the following:

- Mr. Bechler's history of prior heat illness/episodes (including a possible episode on the day prior to his collapse) markedly increased his risk of subsequent heat illness events...It is our view that this prior history was a significant contributor to the death of Mr. Bechler.<sup>24</sup>
- There is simply no scientific basis to indicate that these levels of ephedrine in the blood represent a toxic level or ephedrine toxicity.<sup>25</sup>
- There is simply no scientific data supporting Dr. Perper's contention that ingesting 30 mg of ephedra alkaloids could cause an increase in heart rate, blood pressure, metabolism, or energy expenditure to explain a 1-2 °F increase in core temperature and therefore served as a "significant" contributor to the onset of heat stroke.<sup>26</sup>

In the final analysis, Drs. Kreider and Greenwood conclude that there is no causal nexus between Bechler's consumption of ephedrine alkaloids and his death. They conclude that "dietary supplementation of 30 mg of ephedra did not significantly contribute to the tragic heat stroke death of Mr. Bechler."<sup>27</sup> Rather, the best evidence reveals Steve Bechler to have died from heat exhaustion (dehydration and exercise-induced hyperthermia).

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<sup>21</sup> Attached herein as Exhibit 4.

<sup>22</sup> See Center for Exercise, Nutrition & Preventive Health Research, The Alleged Role of Ephedra in the Death of a Professional Baseball Player, (<http://www3.baylor.edu/HHPR/ESNL/EphedraStatement.htm>), February 21, 2003 (attached herein as Exhibit 5); see also Kreider, R and Greenwood, M. Evaluation of the Scientific Merit of the Medical Examiner Report of Steven Bechler. (attached herein as Exhibit 2) Pg. 4 (March 24, 2003).

<sup>23</sup> See id.

<sup>24</sup> Kreider, R and Greenwood, M. Evaluation of the Scientific Merit of the Medical Examiner Report of Steven Bechler. (attached herein as 2) Pg. 7 (March 24, 2003).

<sup>25</sup> Id. at 11.

<sup>26</sup> Id.

<sup>27</sup> Id. at 12.

## 2. FDA Has Failed to Prove that 25 mg/dose; 90 mg/day of Ephedrine Alkaloids Is Unsafe.

FDA has failed to prove by a preponderance of the evidence that consumption of ephedrine alkaloids in amounts not greater than 25 mg per dose/ 90 mg per day creates a significant or unreasonable risk of illness or injury. A significant body of scientific evidence reveals ephedrine alkaloids safe when used as directed at amounts well above FDA's limits in the Proposed Rule.<sup>28</sup> In fact, FDA admitted that the side effects reported in the studies on ephedrine alkaloids were not as severe as those presented in the AERs.<sup>29</sup>

Drs. Kreider and Greenwood at CENPHR reviewed the current scientific studies on ephedrine and concluded that “there is no evidence from clinical studies that ephedrine supplementation increases peak heart rate, peak blood pressure, or increases the prevalence of cardiac arrhythmias in comparison to subjects taking placebos. Further, there is no evidence that short-term ephedra supplementation causes a marked increase in resting heart rate, blood pressure, or cardiovascular function as is commonly described in media reports.”<sup>30</sup>

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<sup>28</sup> See Astrup, A., et al. The effect and safety of an ephedrine caffeine compound compared to ephedrine, caffeine and placebo in obese subjects. 16 Int. J. Obesity 269-77 (1992). Astrup, A., et al. Thermogenic synergism between ephedrine and caffeine in healthy volunteers. 40 Metabolism. 323-29 (1991). Filozof, C., et al. The effect of ephedrine plus caffeine after a 4-week portion-controlled diet. 1 at the Int. Cong. Obes., Sao Paulo, Brazil, 2002. Pasquali, R., et al. A controlled trial using ephedrine in the treatment of obesity. 9 Int. J. Obesity 93-8 (1985). Pasquali, R., et al. Effects of chronic administration of ephedrine during very low calorie diets on energy expenditure, protein metabolism and hormone levels in obese patients. 82 Clinical Sci. 85-92 (1992).

<sup>29</sup> See 62 Fed. Reg. at 30688-30689.

<sup>30</sup> Center for Exercise, Nutrition & Preventive Health Research Comment, EC-26 at 2, citing Boozer, C., et al. Herbal ephedra/caffeine for weight loss: a 6-month randomized safety and efficacy trial. 26 Int J Obes Relat Metab Disord 593-604 (2002); Kalman, D., et al. An acute clinical trial evaluating the cardiovascular effects of an herbal ephedra - caffeine weight loss product in healthy overweight adults. 26 Int J Obes 1363-1366 (2002).

Indeed, consumption of 90 mg of ephedrine alkaloids per day appears safe for healthy adults.<sup>31</sup> The Joint Commenters are recommending a single dose maximum of 25 mg and a daily intake maximum of 90 mg of ephedrine alkaloids for ephedrine-containing dietary supplements. Those figures are well below the actual levels at which adverse events have been documented in healthy adults.

### **3. FDA Has Failed to Prove That Its 7 Day Limit Is Scientifically Valid and Supported**

FDA has failed to prove by a preponderance of the evidence that consumption of ephedrine alkaloids in amounts not in excess of 25 mg/serving; 90 mg/day for more than seven consecutive days creates a significant or unreasonable risk of illness or injury. The scientific literature does not support FDA's conclusion that ephedrine is *per se* unsafe if consumed for more than seven consecutive days.<sup>32</sup> Numerous studies have evaluated ephedrine consumption for several weeks on end or even consecutive months finding ephedrine alkaloids well-tolerated.<sup>33</sup> In addition to those studies, the scientists at CENPHR reported in their Comments that a recent study on supplementation of

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<sup>31</sup> See Kreider, R and Greenwood, M. Evaluation of the Scientific Merit of the Medical Examiner Report of Steven Bechler (attached herein as Exhibit 2) Pg. 11 (March 24, 2003), citing Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects. (2003). Available at: <http://www.fda.gov/bbs/topics/NEWS/ephedra/summary.html>.

<sup>32</sup> See Astrup, A., et al. The effect and safety of an ephedrine caffeine compound compared to ephedrine, caffeine and placebo in obese subjects. 16 Int. J. Obesity 269-77 (1992). Filozof, C., et al. The effect of ephedrine plus caffeine after a 4-week portion-controlled diet. 1 at the Int. Cong. Obes., Sao Paolo, Brazil, 2002. Greenway, F. L. The safety and efficacy of pharmaceutical and herbal caffeine and ephedrine use as a weight loss agent. 2 Obes Rev 199-211. (2001). Pasquali, R., et al. A controlled trial using ephedrine in the treatment of obesity. 9 Int. J. Obesity 93-8 (1985). Pasquali, R., et al. Effects of chronic administration of ephedrine during very low calorie diets on energy expenditure, protein metabolism and hormone levels in obese patients. 82 Clinical Sci. 85-92 (1992).

<sup>33</sup> See id.

ephedrine/caffeine (20 mg/day of ephedrine and 200 mg/day of caffeine) with an 11 month duration yielded not a single side effect.<sup>34</sup>

#### **4. FDA Has Failed to Prove a Significant or Unreasonable Risk of Illness or Injury**

FDA has failed to prove by a preponderance of the evidence that consumption of ephedrine alkaloids in amounts equal to or below 25 mg/serving; 90 mg/day creates a significant or unreasonable risk of illness or injury. FDA's assertion that ephedrine alkaloids, in combination with caffeine, create a significant or unreasonable risk of injury is unsupported by sound scientific data. Numerous studies have shown that consumption of ephedrine plus caffeine products for six months results in significant weight loss with minimal side effects.<sup>35</sup> Moreover, by the eighth week of treatment, the number of symptoms for ephedrine plus caffeine was substantially the same as the number for the placebo group.<sup>36</sup> The scientists at CENPHR concur. In their Comments, the scientists at CENPHR cite a 2002 NIH study conducted by Dr. Boozer, wherein Dr. Boozer and his colleagues concluded that "herbal ephedra/caffeine supplementation, when used as directed by overweight men and women in combination with healthy diet and exercise habits, may be beneficial for weight reduction without significantly increased risk of

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<sup>34</sup> See Center for Exercise, Nutrition & Preventive Health Research Comment, EC-26 at 2, citing Filozof, C., et al. The effect of ephedrine plus caffeine after a 4-week portion-controlled diet, 1 at the Int. Cong. Obes., Sao Paulo, Brazil, 2002.

<sup>35</sup> See Astrup, A., et al. The effect and safety of an ephedrine caffeine compound compared to ephedrine, caffeine and placebo in obese subjects, 16 Int. J. Obesity 269-77 (1992) (Side effects were limited to dizziness, headache, tremor, depressed mood, euphoria, insomnia, postural hypotension, palpitation, and tachycardia.); see also, Dulla, A.G. & Miller, D.S., , Dulla, A.G. & Miller, D.S., The thermogenic properties of ephedrine/methylxanthina mixtures: human studies, 10 Int. J. Obesity 467-81 (1986); Filozof, C., et al. The effect of ephedrine plus caffeine after a 4-week portion-controlled diet, 1 at the Int. Cong. Obes., Sao Paulo, Brazil, 2002.

<sup>36</sup> There were three incidences of symptoms in both the ephedrine plus caffeine group and the placebo group. Id.

adverse events.”<sup>37</sup> Based in part on the Boozer study, the scientists at CENPHR conclude that “claims suggesting that ephedrine/caffeine supplementation significantly increases thermal load is not supported by the available literature.”<sup>38</sup> Thus, the combination of herbal ephedra and caffeine does not cause significant or unreasonable risk of illness or injury.

In its Proposed Rule, FDA recommends a lengthy and inaccurate warning statement for dietary supplements containing ephedrine alkaloids:

**WARNING: *Contains ephedrine alkaloids. Heart attack, stroke, seizure, and death have been reported after consumption of ephedrine alkaloids.*** Not for pregnant or breastfeeding women or persons under 18. Risk of injury can increase with dose or if used during strenuous exercise or with other products containing stimulants (including caffeine). Do not use with certain medications or if you have certain health conditions. Stop use and contact a doctor if side effects occur. See more information[...].

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<sup>37</sup> Center for Exercise, Nutrition & Preventive Health Research Comment, EC-26 at 2, citing Boozer, C, et al. Herbal ephedra for weight loss: a 6-month randomized safety and efficacy trial. 26 Int. J. Obes. Relat. Metab. Disord. 2002 (attached herein as Exhibit 1).

<sup>38</sup> Id.

**This product contains ephedrine alkaloids, which can have potentially dangerous effects on the heart and central nervous system.**

- **Do not use with**
  - ✓ a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping a MAOI drug;
  - ✓ certain drugs for depression; psychiatric, or emotional conditions;
  - ✓ drugs for Parkinson's disease;
  - ✓ drugs for obesity or weight control;
  - ✓ methyldopa.
  
- **Contact a doctor before using this product if you have or ever had**
  - ✓ heart disease, high blood pressure, thyroid disease, seizure, diabetes, depression, or other mental, emotional or behavioral conditions, glaucoma, or difficulty urinating due to prostate enlargement.
  
- **Stop use and contact a doctor immediately if these side-effects occur**
  - ✓ dizziness, severe headache, rapid and/or irregular heartbeat, chest pain, shortness of breath, nausea, loss of consciousness, or changes in emotions or behavior (such as depression, hallucinations or severe mood swings).
  
- **Your risks of serious side-effects from this product can increase**
  - ✓ with increased dose, frequency, or duration of use;
  - ✓ if you take it with other dietary supplements containing ephedrine alkaloids (such as ephedra, ma hang, Side cord folia);
  - ✓ if you take it with additional products containing stimulants, such as caffeinated beverages and foods (including dietary supplements containing guarana, kola nut, mate, yohirobine/yohimine, Citrus aurantium);
  - ✓ if you take it with medications containing synephrine, phenylephrine, ephedrine, pseudoephedrine or phenylpropanolamine;
  - ✓ if you use it before or during strenuous exercise.

That warning statement is misleading to the public. It misleads the public in the following specific respects.

(1) The statement, "heart attack, stroke, seizure, and death have been reported after consumption of ephedrine alkaloids," is unscientific with regard to dietary supplements containing no more than 25 mg/dose; 90 mg/day of ephedrine alkaloids.

There is no statistically significant scientific evidence proving that ephedrine alkaloids in supplements equal to or below those dose amounts causes (or increases the risk of) heart

attack, stroke, seizure, and death in the healthy general population.<sup>39</sup> The fact that ephedrine-containing OTC products do not include this warning, despite up to 150 mg ephedrine/240 mg pseudoephedrine per daily dose, may cause supplement users to shift to the OTCs on the mistaken view that the OTCs are safer.

(2) The statement, “Risk of injury can increase with dose or if used during strenuous exercise or with other products containing stimulants (including caffeine),” is unscientific with regard to dietary supplements containing no more than 25 mg/dose; 90 mg/day of ephedrine alkaloids. There is no statistically significant scientific evidence of an increased risk of injury with dose, if not exceeding the maximum 25 mg/dose; 90 mg/day recommended herein. There is no statistically significant scientific evidence that within the 25 mg/dose; 90 mg/day limit, there is any increased risk of injury associated with strenuous exercise.<sup>40</sup> There is no statistically significant scientific evidence of an increased risk of injury when combining ephedrine alkaloids at no greater than 25 mg/dose; 90 mg/day with caffeine.<sup>41</sup> Moreover, the proposed language does not appear in the OTC warning statement, a statement applied to products containing as much as 150 mg ephedrine/ 240 mg pseudoephedrine per daily dose.

(3) The statement, “contact a doctor before using if you have or ever had...depression, other mental, emotional or behavioral conditions...,” is unscientific with regard to dietary supplements containing no more than 25 mg/dose; 90 mg/day of ephedrine alkaloids. There is no statistically significant scientific evidence (and nothing in the RAND Report) that there are any adverse reactions caused by ephedrine alkaloids

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<sup>39</sup> See Kreider, R and Greenwood, M. Evaluation of the Scientific Merit of the Medical Examiner Report of Steven Bechler. (attached herein as Exhibit 2) Pg. 11 (March 24, 2003).

<sup>40</sup> See id.

within those dose and day limits in people who have depression, other mental, emotional or behavioral conditions. Moreover, the terms “mental, emotional, or behavioral conditions” are so inexact as to make it extremely difficult, if not impossible, for a consumer to know just who falls in this excluded class. It thus confuses and misleads rather than edifies. Moreover, the proposed language does not appear in the OTC warning statement, a statement applied to products containing as much as 150 mg ephedrine/ 240 mg pseudoephedrine per daily dose.

(4) The statement, “Stop use and contact a doctor immediately, if these side-effects occur...nausea...” is unscientific with regard to dietary supplements containing no more than 25 mg/dose; 90 mg/day of ephedrine alkaloids. There is no statistically significant scientific evidence that the symptom of “nausea” is indicative of serious harm. By contrast, in the OTC ephedrine/pseudoephedrine warning, if “nausea *persists or becomes worse*” (emphasis added) physician contact is implored. Nausea in and of itself (not persistent or worsening) is not indicative of serious harm.

(5) The statement, “Your risks of serious side-effects from this product can increase with increased dose, frequency, or duration of use;...if you take it with additional products containing stimulants, such as caffeinated beverages and foods (including dietary supplements containing guarana, kola nut, mate,...Citrus aurantium);...if you use it before or during strenuous exercise,” is unscientific with regard to dietary supplements containing no more than 25 mg/dose; 90 mg/day of ephedrine alkaloids. There is no statistically significant scientific evidence that risks of serious side effects can increase with consumption of ephedrine alkaloids in amounts not

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<sup>41</sup> See id.

exceeding 25 mg/dose; 90 mg/day. There is no statistically significant scientific evidence that risks of serious side effects can increase if you take ephedrine alkaloids with caffeinated beverages and foods containing guarana, kola nut, or Citrus aurantium if consumption of ephedrine alkaloids does not exceed 25 mg/dose; 90 mg/day.<sup>42</sup> There is no statistically significant scientific evidence that risks of serious side effects can increase if you take ephedrine alkaloids before or during strenuous exercise if consumption of ephedrine alkaloid consumption does not exceed 25 mg/dose; 90 mg/day.<sup>43</sup>

The FDA's proposed warning statement is inaccurate and incapable of scientific substantiation. There are possible side effects when taking products that contain ephedrine alkaloids, but millions of people safely and successfully take ephedrine products every day. The warning statement is not an accurate reflection of the actual risks associated with ephedrine alkaloid consumption. The side effects listed in the warning statement occur only in rare circumstances, and no causal connection has been medically established between those serious side effects and ephedrine alkaloid consumption in the healthy adult population (when consumption levels do not exceed 25 mg/dose; 90 mg/day).<sup>44</sup>

## **5. The Proposed Rule Violates the APA**

FDA must not promulgate any rule or regulation that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.<sup>45</sup> An agency rule is deemed arbitrary and capricious if the agency ignored or failed to evaluate rationally the evidence

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<sup>42</sup> See id.

<sup>43</sup> See id.

<sup>44</sup> See Center for Exercise, Nutrition & Preventive Health Research Comment, EC-26 at 4 (attached herein as Exhibit 1).

<sup>45</sup> See 5 U.S.C. § 706(2)(A) (2003).

before it.<sup>46</sup> FDA's explanation of its Proposed Rule is not supported by the scientific evidence. In fact, the evidence supports the conclusion that ephedrine alkaloid-containing dietary supplements are safe in amounts not in excess of 25 mg/serving; 90 mg/day, when used as appropriately directed. FDA has approved the use of ephedrine-containing OTCs at a **150 mg** daily dose maximum (and pseudoephedrine-containing OTCs at a 240 mg daily dose maximum), fully **60 mg** higher than the dietary supplement ephedrine alkaloid daily dose maximums proposed by the Joint Commenters, yet FDA has approved a less onerous warning statement for the higher ephedrine-containing OTC products.<sup>47</sup>

Concerning the warning statements, there is no logical, legal, or scientific justification for FDA's disparate treatment of ephedrine-containing OTCs and ephedrine-containing dietary supplements. In fact, ephedrine and pseudoephedrine-containing OTC products with higher amounts of ephedrine alkaloids intended for relief of disease symptomology (including asthmatic conditions, as well as those of colds, flus and allergies) would clearly appear to warrant a more stringent warning statement than dietary supplements containing ephedrine alkaloids in amounts no greater than 25 mg/dose; 90 mg day. Thus, FDA's warning statement for ephedrine-containing dietary supplements is arbitrary and capricious, in light of its disparate treatment of the potentially more dangerous ephedrine and pseudoephedrine-containing OTCs.

Ephedrine-containing dietary supplements typically do not contain ephedrine alkaloids at OTC dose levels and are intended for use by the general healthy adult

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<sup>46</sup> See Motor Vehicle Manufacturer's Assoc. of the United States, Inc. v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983); see also, New York Council, Assoc. of Civilian Technicians v. Federal Labor Relations Auth., 757 F.2d 502 (2d Cir. 1985), certiorari denied, 474 U.S. 846 (1985).

population. Hence, the warning statement for ephedrine-containing dietary supplements should be no more onerous or stringent than the warning statement approved for ephedrine and pseudoephedrine-containing OTC products. The Joint Commenters thus propose that the agency adopt substantially the same warning for dietary supplements as it has for ephedrine/pseudoephedrine-containing OTC products.

## **6. The Proposed Rule Violates the First Amendment to the U.S. Constitution**

The U.S. Supreme Court has long recognized that commercial speech disclaimers must be reasonable because unreasonable and burdensome disclaimers offend the First Amendment by chilling the speech of others who would otherwise communicate the same (or a substantially similar) commercial message.<sup>48</sup> FDA has adopted one warning statement for ephedrine and pseudoephedrine-containing OTC products but proposes a different, more onerous warning statement for lower daily dose ephedrine alkaloid-containing dietary supplement products. The agency has not offered any scientific evidence that the different warning statements are justified. Ephedrine and pseudoephedrine-containing OTCs contain higher amounts of ephedrine alkaloids (up to 150 mg of ephedrine or 240 mg of pseudoephedrine).<sup>49</sup> The most common ephedrine-containing dietary supplements, and those of and recommended by the Joint Commenters, have daily dose amounts of no more than 90 mg. Hence, the warning statement for ephedrine-containing dietary supplements should not be more stringent than

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<sup>47</sup> See 21 U.S.C. § 341.76 (2003); 21 U.S.C. § 341.80 (2003).

<sup>48</sup> See *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 651 (1985) (where the Supreme Court recognizes the risk of a chilling effect on commercial speech if government mandated disclaimers are unreasonable).

<sup>49</sup> See 21 U.S.C. § 341.80 (2003).

the warning statements approved for ephedrine and pseudoephedrine-containing OTC products.

Disparate treatment of OTCs and dietary supplements, requiring dietary supplements to have a different, more severe (and more frightening) warning statement without a sound scientific justification, offends the First Amendment to the U.S. Constitution because it unduly burdens the speech of dietary supplement makers and distributors (via a disparate, lengthier, and more frightening warning than those required on OTCs).<sup>50</sup> The presence of the OTC warning reveals an obvious, less burdensome and less restrictive alternative to the FDA's proposed warning statement for ephedrine-containing dietary supplements. As such, failure to adopt the less burdensome warning recommended below by the Joint Commenters, which is closely patterned after the OTC warning statement, violates the First Amendment.<sup>51</sup>

If the agency adopts the language of the warning statement in the proposed rule, it will compel all manufacturers of ephedrine alkaloid-containing dietary supplements to place an inaccurate and misleading warning statement on their labels.<sup>52</sup> It is well established that the First Amendment protects not only the right to speak but also the right to refrain from speaking.<sup>53</sup> If FDA adopts its proposed warning statement, it will be infringing upon the Joint Commenters' First Amendment rights by insisting that they convey a message regarding the safety of their products that is expressly contrary to the

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<sup>50</sup> See Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 651 (1985)

<sup>51</sup> See Thompson v. Western States Medical Center, 535 U.S. 357, 373-4 (2002).

<sup>52</sup> See 68 Fed. Reg. 10417, 10419 (March 5, 2003).

<sup>53</sup> See West Virginia State Bd. of Ed. v. Barnette, 319 U.S. 624, 633 (1943).

scientific evidence. The U.S. Supreme Court has held that such government compulsion “contravenes core First Amendment values.”<sup>54</sup>

## V. RECOMMENDED DISCLAIMER

Due to the possibility of misuse, which may lead to serious adverse events, an accurate, nonmisleading disclaimer should be placed on the labels and in the labeling of dietary supplements containing ephedrine alkaloids. FDA has not established the existence of any sound scientific evidence that ephedrine alkaloids in amounts not exceeding 25 mg/dose; 90 mg/day cause any of the adverse events reported to the agency. The Joint Commenters recommend the following disclaimer (in lieu of FDA’s recommended version) for all dietary supplements that limit ephedrine alkaloids to 25 mg/dose; 90 mg/day. A disclaimer similar to this one is presently used on ephedrine and pseudoephedrine-containing over-the-counter drugs:

**INTENTIONAL ABUSE OF THIS PRODUCT CAN BE HARMFUL OR FATAL. WARNING:** Contains ephedrine alkaloids. **Do not use** if you are taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. **Do not use** if you are pregnant or lactating or under 18 years of age. **Do not use** if you are using a non-prescription or prescription drug (such as some asthma, cold, flu, or allergy medicines) that contains ephedrine, pseudoephedrine, or phenylpropanolamine. **Ask a doctor before use if you have** heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to enlarged prostate gland, or are taking a weight loss drug. **When using this product** some users may experience nervousness, tremor, sleeplessness, nausea, or loss of appetite. **Stop use and ask a doctor if** nervousness, tremor, sleeplessness or nausea persist or become worse. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions: Do not exceed 25 mg ephedra alkaloids per serving. Do not**

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<sup>54</sup> Pacific Gas & Elec. Co. v. Public Utilities Comm’n, 475 U.S. 1, 16 n.2 (1986); see also, Paulsen v. County of Nassau, 925 F.2d 65, 68 (2d Cir. 1991).

**exceed one serving every 4 hours. Do not exceed 90 mg ephedra alkaloids in 24 hours.**

## **VI. CONCLUSION**

The Joint Commenters have shown that the Proposed Rule lacks a scientific foundation in empirically valid data. They have shown that the agency has not met its burden of proof under 21 U.S.C. § 343(f) (the adulteration standard for dietary supplements) to justify removing ephedrine alkaloid-containing dietary supplements from the market or to justify the Proposed Rule. The Joint Commenters have shown that the Proposed Rule is arbitrary and capricious, contrary to law, and violates the First Amendment, and the Joint Commenters have offered FDA a scientifically valid alternative in the form of a 25 mg/serving; 90 mg/day ephedrine alkaloid limit and a reasonable disclaimer substantially indistinguishable from the one now used on

ephedrine and pseudoephedrine-containing over-the-counter drugs. To ensure compliance with all applicable law and to protect the public health, the Joint Commenters urge FDA to adopt the alternative to its Proposed Rule that they recommend herein.

Respectfully submitted,

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