

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

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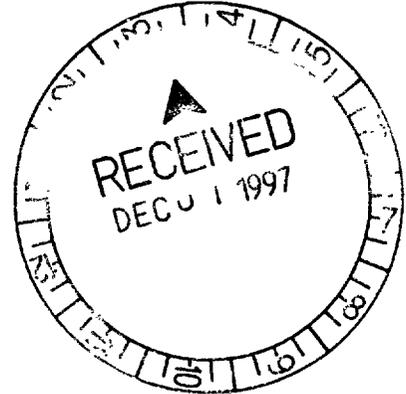
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United States Senate

WASHINGTON, DC 20510-0802

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June 11, 1997



David A. Kessler, M.D., Commissioner
Food and Drug Administration
5600 Fishers Lane
Room 14-71
Rockville, MD 20857

Dear Dr. Kessler:

I am writing with regard to the Food and Drug Administration's (FDA) proposed rule imposing strict controls on the use of ephedrine in dietary supplements. I commend the FDA for taking this action.

It is my understanding that in just the last three years, ephedrine has been implicated in over 800 health problems -- including heart attacks and strokes -- and has been associated with about two dozen deaths. One of those deaths was a constituent of mine.

About a year ago, Ms. [redacted] informed me that her 24-year old son died from taking a product containing ephedrine. Since then, she has been working to make more people aware of the dangers of this product, and the FDA's proposed regulations are an important step.

Please keep me informed of any further action taken by the FDA on this matter. And, if you wish to contact Ms. [redacted] directly, she can be reached at [redacted]

Sincerely,

Joe Biden
Joseph R. Biden, Jr.
United States Senator

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Ms. [REDACTED]
[REDACTED]

Dear Ms. [REDACTED]:

This is in response to Senator Joseph Biden's letter of June 11, 1997, on your behalf, regarding the dietary supplement, ephedrine. Please accept our sympathies on the death of your son.

Dietary supplements are regulated under the food provisions of the Federal Food, Drug and Cosmetic Act (the Act), as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA), and the Fair Packaging and Labeling Act. The term "dietary supplement" is defined in section 201 (ff) of the Act, and means a product (other than tobacco) intended to supplement the diet that contains one or more of certain dietary ingredients, such as a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of the preceding ingredients.

For several years, the FDA has been concerned with the safety of products that contain sources of ephedrine alkaloids. On April 10, 1996, FDA released a public statement warning consumers not to purchase or consume ephedrine-containing dietary supplements with labels that often portray the products as alternatives to illegal street drugs because these products pose significant health risks. This statement was partly in response to the death of a twenty year old man who died after ingestion of "Ultimate Xphoria - A 100% Herbal Alternative Supplement with Vitamin C." A medical examiner's report stated that the cause of death was "cardiac arrhythmia due to synergistic effect of ephedrine, pseudoephedrine, phenylpropanolamine, and caffeine." At the same time, FDA added ephedrine-containing dietary supplements as topics on its information hotline and World Wide Web site.

Dietary supplements do not have to be submitted to the Food and Drug Administration (FDA) for premarket review or approval. Moreover, manufacturers are not required to register their products with FDA and generally do not have to notify FDA of

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the type or composition of the products that they market. If, however, the consumption of large amounts of a diet supplement may be unsafe, FDA may consider action to correct an unsafe condition under section 402 of the Act. Under section 402(f) of the Act, a dietary supplement may contain dietary ingredients that do not present "a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested in labeling, under ordinary conditions of use." Burden of proof requirements for regulation of dietary supplements differ from those for other products such as food additives or drugs. Section 402 (f) requires that "the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis." For FDA to take regulatory action against a dietary supplement or ingredients contained in dietary supplements, there must be substantial evidence that these products are unsafe, using the previous definition and burden of proof requirements. This is a high standard of proof and it takes time and resources to develop the evidence necessary for the Agency to engage in regulatory action to ensure that marketed dietary supplements can be safely used.

On June 4, 1997, the FDA published a proposed rule in the Federal Register which proposed safety measures for ephedrine dietary supplements by limiting the amount of ephedrine alkaloids in products and requiring labeling and marketing measures that give adequate warning and information to consumers. The rule also articulates FDA's policy that products marketed as alternatives to illicit street drugs are drugs, not dietary supplements. These products are intended to be used to affect the structure and function of the body and are not intended to supplement the diet. The FDA is allowing a 75-day comment period on the rule.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Melinda K. Plaisier
Deputy Associate Commissioner
for Legislative Affairs

cc: The Honorable Joseph Biden
United States Senate
Washington, D.C. 20510

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