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AUDREY I PHEFFER
Assemblywoman 23rd District

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

Dock number: 95N-0304

Dear Sir or Madam:

This letter is in response to the Food and Drug Administration's (FDA) recent proposal to place warning labels on herbal supplement bottles containing ephedra. Although this proposal advances somewhat the important goal of alerting consumers to the danger of ephedra, it fails to adequately address the risks posed by this herb.

In 1997, the FDA evaluated the need for warning labels on ephedra, but determined labels were unwarranted. The unfortunate death of Baltimore Orioles pitcher Steve Bechler has reawakened the public to the threat posed by ephedra. Public outcry is now prompting the more responsible segments of industry to stop marketing products containing ephedra, as well as calling for legislative action to protect consumers. I urge you to take steps to ban ephedra.

The following are examples of action taken by business and governments that illustrate the growing consensus that a ban is necessary:

- The 7-Eleven Corporation and EAS (a major dietary supplement supplier) are ending sales of products containing ephedra;
- Twinlab Corporation (a major herbal supplement manufacturer based on Long Island) will stop all sales of products containing ephedra because of "escalating insurance costs and regulatory uncertainties";
- Major League Baseball has banned ephedra use in minor league divisions, following an established ban by the International Olympic Committee, the National Football League, and the National Collegiate Athletic Association;
- Canada, the United Kingdom, and Germany all prohibit sales of ephedra;
- Suffolk County, New York, has banned the sale of ephedra-containing products to both children and adults;
- The Army and Air Force military exchanges have removed ephedra-related products from military commissary shelves worldwide; and
- The American Medical Association (AMA) has called for the removal of ephedra-containing products from the marketplace.

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A report published in the *Annals of Internal Medicine* stated that although ephedra products make up less than one percent of all dietary supplement sales, these products account for 64 percent of adverse events associated with dietary supplements. The FDA "white paper" on ephedra stated that "even if a very costly, definitive large randomized clinical trial could be funded, it might be unethical to carry it out, given the risks suspected from ephedra and the likelihood that its health benefits are modest at best."

In 2002, after an investigation by the Justice Department regarding the truthfulness of Metabolife's statements that the company had never received any adverse health reports, Metabolife turned over 13,000 "adverse event reports" to the FDA. After an analysis of the reports, the House Committee on Government Reform concluded that there were 2,000 reports of significant reactions, including three deaths, 20 heart attacks, 24 strokes, 40 seizures, 465 episodes of chest pains, and 966 reports of heart rhythm disturbances. This is some indication that the health risks posed by ephedra products are greater than the current evidence would suggest.

To address the dangers of ephedra to consumers, I have introduced bill A. 6921 in the New York State Assembly. The purpose of this bill is to ban the sale of supplements that contain ephedra in New York State except for the drugs under FDA supervision and if a person has a prescription. Although a statewide ban would effectively remove the ephedra supplement threat from store shelves, the most effective method would be a nationwide ban.

It is imperative that the FDA take significantly stronger action than a warning label. The FDA must remove this deadly herb from the reach of consumers. Under the Federal Food Drug and Cosmetic Act, the FDA has the power to ban the production and sale of dietary supplements that "pose an imminent hazard to public health or safety." The time is now for the FDA to wield its power and ban ephedra.

Sincerely,

Audrey I. Pheffer, Chair
Assembly Consumer Affairs and Protection Committee

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