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Docket Management Branch  
Food & Drug Administration  
5630 Fishers Lane room 1061  
Rockville MD 20852

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ref: **Docket No. 00N-1200**  
*public comment on supplements containing ephedrine*

Since 1992 I have been active in efforts to control ephedrine's availability. As a member of Missouri's *Eastern Regional Council on Alcohol and Drug Abuse* I spoke in November 1994 to the special FDA committee which looked at problems caused by ephedrine and related issues of concern to asthmatics. As a member, and chair, of the *Missouri Advisory Council on Alcohol and Drug Abuse* I have continued to track this problem and attack misuse of ephedrine. I have accumulated pounds of documents, magazine and newspaper articles, product samples and journal pieces concerning ephedrine. While I am not a medical doctor or chemist, I have studied the impact this substance causes on those who consume ephedrine -- and our communities.

I ask the FDA to **scrap** the proposed restrictions on the **Availability Of Dietary Supplements Containing Ephedrine Alkaloids**: I urge the FDA to classify ephedrine in all guises as a drug and enact a ban on the use of ephedrine except in a limited number of low-dose products available only with a doctor's prescription.

As the adverse event reports included in the 1997 and 2000 register notices show, ephedrine kills people. (A number of fatal occurrences were also related at the November 1994 FDA session.) The substance also induces dangerous, sometimes chronic, damage to the heart, kidneys and other organs and systems in a substantial number of those who consume the product.

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Banning ephedrine from all non-prescription uses will eliminate virtually all of the deaths and damage caused by this substance.

Allow me to expand on a few of the reasons why I do not feel the proposed restrictions will reduce the toll ephedrine inflicts:

**1. Those who market ephedrine have found ways around existing state and federal efforts to limit the substance's availability.**

When Missouri and other states banned single-ingredient formulations, manufacturers added secondary active ingredients. When prohibitions regarding marketing ephedrine products as diet aids emerged, names changed -- from *Mini Thin* to *Mini Two-Way Action*, in one example -- while packaging colors and displays remained the same.

I see no reason to believe companies which have skirted the intent of every previous effort to control ephedrine won't look for roads around any new rule.

**2. Dosage suggestions on packaging aren't heeded.**

As I learned back in the early 1990's, most people who consume ephedrine take many, many more pills than the label recommends. In 1992 I heard from one young man who was taking forty to fifty 25 mg tablets each day to stay alert while he worked full time and attended school. While at a south St. Louis County, Missouri shopping mall in December 1999 I heard the clerk at a *Metabolife* display tell a potential customer that he knew of people who took "eight or nine" tablets a day -- way beyond the package's suggested dose -- "with no problems."

**3. A lower dose amount will simply sell more units of ephedrine.**

People accustomed to a certain "buzz" will just keep taking ephedrine until they get the result they desire. Instead of taking one 25 mg serving they'll take three or four 8 mg servings.

**4. Most consumers do not understand what ephedrine is, despite current packaging requirements.**

Most of those I talk to who are taking "herbal" or "weight loss" products never imagined that the active ingredient they take is also a key component of methamphetamine. And, manufacturers disguise the current warning labels with small type and obscure language. (Enclosed is a sample of a liquid ephedrine product sold at a gas station near my work. To even see the warnings -- printed in sub-four point type -- you must buy the package and peel open the label. I don't think many people read those warnings.)

The *Missouri Advisory Council on Alcohol and Drug Abuse* is developing a **Fact Sheet** for the public with the headline...

**Ma Huang = Ephedra = Ephedrine = Speed = Death**

We feel we must get that blunt to get the attention of people taking these products.

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**5. There is a growing danger of people ingesting large amounts of ephedrine as they unknowingly mix various products containing the compound.**

A bodybuilder concerned about their weight may take "herbal" weight loss products, then pop **ECA stack** pills before their workout, followed by an energy bar or sports drinks which also contain ephedrine. The total dose could easily exceed 50 mg without the consumer being aware of the danger.

In the early 1990's in my community ephedrine was sold at gas stations, convenience stores and truck stops. Teens and truckers bought most of the products. Today products containing ephedrine are still at the *7-Eleven* and truck stops, but, even more is available at health food stores, national chain stores such as *Oscor*, *Walgreens*, *Wal Mart* and *K Mart*, at grocers as well as at kiosks in virtually every shopping mall. The proliferation of this drug must be stopped.

Ephedrine hurts and kills people. It is in the best interest of our nation to ban all non-prescription uses of this substance before it does more harm. This will save lives, and, save taxpayers money.

Act decisively. Do not compromise and enact further, minor restrictions on ephedrine which will be sidestepped by this growing, dangerous industry. Ban ephedrine's use except in a controlled number of prescription products.

Respectfully Submitted,



Glenn M. Koenen

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