ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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October 24, 2003

The Honorable Mark B. McClellan, MD, Ph.D
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857-0001

Dear Commissioner McClellan,

In the last six years, there has been a lot of attention paid to the safety of dietary supplements containing ephedra. While FDA has failed to exercise its authority and remove these unreasonably dangerous products from the market, state governments have started to act. Recently, California became the third state to ban the sale of dietary supplements containing ephedra. At the same time, dietary supplement companies are facing increasing litigation and difficulties getting insurance, and are moving away from marketing products containing ephedra. Thus, we are seeing fewer ephedra-containing supplements, and more "ephedra-free" formulations.

According to medical experts, some of the stimulant ingredients in these "ephedra-free" formulations may pose the same kinds of risks posed by ephedra. In fact, in a letter FDA sent to me in 2001, the agency said "synephrine, like the ephedrine alkaloids, is a sympathomimetic agent…[it] is often combined in products with other stimulants, including ephedrine alkaloids and caffeine …which increases the potential for adverse cardiovascular events."[1] In that letter, FDA said about another dietary supplement ingredient, yohimbine/yohimbe, that it "readily penetrates the central nervous system and has been shown to stimulate mood and motor activity, produce anxiety and tremors, and increase blood pressure and heart rate."[2]

I am concerned that the public is being exposed to another generation of dangerous stimulant products. In order to understand whether these products may indeed pose a risk, I ask that you answer the following questions:

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[1] Letter from Melinda K. Plaisier to Rep. Henry Waxman (July 11, 2001).
[2] Letter from Melinda K. Plaisier to Rep. Henry Waxman (July 11, 2001).

1. Is FDA aware of evidence that proves that synephrine is demonstrably safer than ephedrine? If so, please provide me with that evidence.

2. Is FDA aware of evidence that proves that other stimulant ingredients in dietary supplements, such as yohimbe/yohimbine, are demonstrably safer than ephedrine? If so, please provide me with that evidence.

3. Is FDA aware of evidence that proves that the combination of ingredients contained in "ephedra-free" formulations, or in any other dietary supplement that contains stimulant ingredients, can be used safely in combination with one another?

4. Is FDA concerned that dietary supplements that contain stimulants, or combination of stimulants, may pose particular risks to consumers because these products can increase heart rate, speed up metabolism, and may pose the potential for serious adverse events, including, but not limited to, myocardial infarction, stroke, and sudden death?

5. What steps is FDA planning to take to protect consumers from the growing use of potentially dangerous stimulants in dietary supplements?

Please respond to this letter by November 7, 2003. If you have any questions, please contact Sarah Despres of my staff at (202)225-5420.

Sincerely,

Henry A. Waxman
Ranking Minority Member