ROUTING SLIP
GENERATED BY: HF-40
DATE: OCT 02, 2001

FDA CONTROL NUMBER: 01 4943 **TRACER #:** **OS #:**

DATE OF CORRESPONDENCE: 09/18/01 **DATE INTO FDA:** 10/02/01

TO: BERNARD A SCHWETZ HF-1

FROM: DOUG SAUNDERS, AFDO, ASSOCIATION OF FOOD AND DRUG OFFICIALS

SYNOPSIS: EXPRESSE CONCERNS OVER THE SAFETY OF EPHEDRA

LEAD OFFICE: HFA-305 **HOME OFFICE:** HF-40

CONTACT/PHONE#: MIKELE A BRYANT 301-827-4450

COPIES: GENERAL DISTRIBUTION
HF-40 INDYA P GORDON
HF-40 KRISTINE M MORAN
HF-40 ANNE B CRAWFORD
HFS-1
HF-1 BERNARD A SCHWETZ

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HFA-305	NECESSARY ACTION	

Association of Food and Drug Officials

2550 Kingston Road, Suite 311 York, PA 17402
Telephone (717)757-2888 · Fax (717)755-8089
E-Mail: afdo@afdo.org · Internet: www.afdo.org

September 18, 2001

Bernard Schwetz, D.V.M., Ph. D.
Acting Principal Deputy Commissioner
Food and Drug Administration
Room 14-71 (HF-1)
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Schwetz:

The Association of Food and Drug Officials (AFDO) has been a keen observer and active participant in addressing the safety concerns regarding products containing ephedrine, especially those labeled as dietary supplements. As you know, AFDO is a 105-year-old association, which represents federal, state, and local regulators and industry associates. We strive to advance uniform laws, regulations, and guidelines that result in efficient and less confusing regulation of foods, drugs, medical devices and other consumer products.

AFDO's membership has longstanding concerns with the public health risks associated with dietary supplement products containing ephedrine. In June 2001, AFDO considered and adopted the attached resolution at our annual conference in Atlanta, Georgia, urging the FDA to expedite a policy decision on this issue and to provide effective regulatory guidance in this difficult public health protection area. Considering the extensive documentation of serious adverse health effects associated with ephedrine-containing dietary supplement products and more recent developments, AFDO believes it is critical that FDA take action regarding products that contain ephedrine.

FDA has already effectively removed phenylpropanolamine, a compound with similar pharmacological effects and a partial metabolite of ephedrine, from the marketplace based on recommendations of its own Advisory Committee and a Yale University School of Medicine study linking the drug to strokes. Yet since 1994, more strokes associated with ephedrine containing dietary supplements have been reported to FDA's MedWatch than for the almost 30 year period phenylpropanolamine was on the market. AFDO believes ephedrine should be considered equally dangerous for the same reasons and evidence.

On September 9, 2001, the National Football League (NFL) announced it has added ephedra, a genus of herbs from which the dietary supplement ephedrine is extracted, to its list of banned substances.[1]

[1] Officials, Ephedra Take Hits by NFL. Latimes.com, September 9, 2001. wysiwyg://1/http://latimes.com/sports/la-000072934sep09.story

4943

The league based their decision on the available scientific evidence and the fact that three NFL players who died this year were found, on autopsy, to have ephedra in their systems. NFL league spokesman Greg Aiello, quoted in a Los Angeles Times article stated that "the purpose is to protect our players who operate in a very unique and stressful environment". Aiello also said "because of the research that's out there on ephedra, the commissioner [Paul Tagliabue] has reached the conclusion that it shouldn't be used by our players."

As evidenced by the previous paragraph, a non-healthcare professional, when presented with the evidence, concluded that ephedrine-containing dietary supplements promoted and marketed as "safe and natural" for uses such as weight loss, body building and increased energy, are dangerous. It has also been alleged that there are healthcare professionals who tout the safety of these products who are paid by industry to review the research, data, and FDA ephedra docket. AFDO believes that those healthcare professionals who have reviewed the research, data, and docket and who have concluded the products are dangerous, even when taken as directed, have not been financially linked to the industry.

Trustee J. Edward Hill, M.D., of The American Medical Association (AMA) stated, "Tobacco is the only product sold in America that kills when used as directed by the manufacturer." [2] Based upon the data and the statistics documented in the FDA docket on ephedrine adverse events reported, over 90% of the adverse events occurred when the products were taken as directed or at lesser doses. These statistics would seem to indicate that tobacco is no longer the only product that should be considered dangerous when used as directed by the manufacturer.

Another organization, the Public Citizen Health Research Group, very recently petitioned your agency via Secretary Thompson to ban the production and sale of dietary supplements containing ephedrine alkaloids. Their petition thoroughly and adequately addresses the data, statistics, research and science associated with our mutual concern regarding these products,[3] which further supports our urging that FDA expedite action on dietary supplements containing ephedrine.

We would like to thank you for the opportunity to provide you with our comments, and for your time and consideration of this request. It is in the interest of true public health safety that AFDO urges the FDA to act expeditiously.

Sincerely,

Doug Saunders

Doug Saunders
President
Association of Food and Drug Officials

Attachment

cc: AFDO Board of Directors
Cynthia Culmo

---

[2] AMA says FDA regulation of tobacco will save thousands of lives. March 16, 2001. http://www.ama-assn.org/ama/pub/article/2403-4355.html

[3] Petition to ban production and sale of dietary supplements containing ephedrine alkaloids. September 5, 2001. http://www.citizen.org/hrg/PUBLICATIONS/1590.htm

ASSOCIATION OF FOOD AND DRUG OFFICIALS

2001

RESOLUTION NUMBER TWO

Submitted by: Central Atlantic States Association of Food & Drug Officials

Date: May 18, 2001

Concerning: FDA Action on Herbal Products Containing Ephedrine.

Whereas, dietary supplements containing ephedrine alkaloids continue to be promoted for uses such as weight loss, body building, increased energy, and in some marketing programs as a safe and natural alternative to illicit street drugs, and

Whereas, the effects of these alkaloids are potentially powerful ones which can result in tremors, seizures, heart attacks and strokes, and

Whereas, the U.S. Food and Drug Administration (FDA) , on June 2, 1997, proposed a dosage limitation of 8 mg of ephedrine alkaloids per serving, and a duration of use of no more than 7 days, in an effort to reduce the risks associated with these products, and

Whereas, FDA subsequently withdrew these two proposed limitations in April 2000 and reopened the public comment period from August 10- September 30, 2000 to generate additional information regarding the safety of these products, and

Whereas, over seven months have passed since the comment period closed and nothing has issued from FDA on this matter, therefore be it

Resolved, that the Association of Food and Drug Officials (AFDO), express strong concern to FDA about the continued uncontrolled marketing of these potentially dangerous herbal products, and be it further

Resolved, that AFDO ask FDA to expedite its' policy decision on this issue and provide effective regulatory guidance in this difficult public health protection area.