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JOHN E. TIEDI

August 7, 2003

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

Re: Docket No. 95N-0304
Dietary Supplements Containing Ephedrine Alkaloids

Dear Dr. McClellan:

I have a copy of the letter written by Congressman Dan Burton to you on May 19, 2003. Mr. Burton's letter contains material misrepresentations.

The Dietary Supplement Health and Education Act ("DSHEA") has provided a number of felons (such as Michael Ellis of Metabolife International and Robert Occhifinto of NVE, Inc.) and other unscrupulous individuals with the opportunity to sell snake oil to the obese, diseased and desperate consumers. Many dietary supplement companies offer products that don't work and/or are very dangerous. I have spent the last seven (7) years litigating cases against the dietary supplement manufacturers. What I have learned would cause you to immediately ban ephedra-based products and fight for the amendments suggested by Senator Durbin to the Dietary Supplement Health and Education Act.

Specifically with regard to Mr. Burton's letter, there are certain points that must be made. My contact with the FDA revealed no bias against herbal dietary supplement companies. I witnessed several investigations of consumer complaints of ephedra based products that were handled objectively. The FDA's attempts to evaluate the safety of ephedra were reasonable and conducted in a fair and scientific manner. Mr. Burton's criticisms of the FDA have been motivated by political donations. Mr. Burton has taken large financial donations from Metabolife International and other companies that manufacture ephedra-based products. Mr. Burton has taken large financial donations from other companies which have engaged in fraudulent conduct (Cytodyne Technologies, Inc. - recently hit with a \$12.5 million verdict for consumer fraud in

The Honorable Mark McClellan, M.D.

August 7, 2003

Page 2

California; and Muscletech Research and Development, Inc. – a company currently subject to a fraud inquiry by the Attorney General of the State of Missouri).

As a physician, you know that ephedrine is a sympathomimetic amine. You know that ephedrine is an arrhythmogenic drug and cardiovascular stimulant that has caused thousands of injuries and hundreds of deaths. Nevertheless, Mr. Burton has falsely claimed that such dietary supplements are safe. Mr. Burton has used his contacts at the General Accounting Office to harass the FDA and provide unconscionably supportive opinions on the Metabolife adverse event reports, which now greatly exceed the 14,000 claimed by Metabolife International.

The clinical trials referenced in Mr. Burton's letter do not establish that ephedra is safe for public use. Some of these trials are under investigation for fraud and negligence. I am enclosing a copy of the Missouri Attorney General's complaint against Muscletech Research and Development, Inc. I am also enclosing a copy of Judge Styn's \$12.5 million verdict against Cytodyne Technologies, Inc.

Ephedra has devastated many lives. Political influence and money have kept ephedra in the marketplace while causing deaths, heart attacks, strokes, seizures, psychoses and other debilitating adverse events, all suffered by the citizens the FDA is supposed to protect.

You have the power and opportunity to stop the injuries. Simply declare that the ephedra/caffeine combination is a "new drug" pursuant to the Food, Drug and Cosmetic Act. You thereby shift the burden to Metabolife and other companies to prove the safety and efficacy of their products. Otherwise, expect more body bags courtesy of the FDA and the dietary supplement industry.

Very truly yours,

MOORE, WINTER, SKEBBA & McLENNAN, L.L.P.



John E. Tiedt

JET:bjm

cc: Senator Richard Durbin
Congressman Dan Burton
Congressman Henry Waxman
Congresswoman Susan Davis
Heidi Cuda, Fox 11 News L.A.
Guy Gugliotta, Washington Post