



State of New Jersey

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April 11, 2003

Mark B. McClellan, M.D., Ph.D.
Commissioner, Food and Drug Administration
Docketing Management Branch (HFA-305)
5630 Fischers Lane, Room 1061
Rockville, Maryland 20852

Re: **21 CFR 111, Docket No. 95N-0304**

Dear Commissioner McClellan:

Please consider this letter as the comment of New Jersey Acting Attorney General Peter C. Harvey and Commissioner of Health and Senior Services Clifton R. Lacy, M.D., in response to your proposed rule at 21 CFR 111, dietary supplements containing ephedrine alkaloids. Acting Attorney General Harvey and Commissioner Lacy urge the Food and Drug Administration ("FDA") to ban the sale of dietary supplements containing ephedrine alkaloids. This view has recently been expressed by the American Medical Association in testimony before the United States Congress and by others. Further, by the FDA's own calculation, there have been approximately 17,000 adverse events related to ephedrine alkaloids reported to the FDA. Thus, the marginal benefits, if any, of the consumption of dietary supplements containing ephedrine alkaloid products are clearly far outweighed by the substantial risks and apparent harms to consumers of these products.

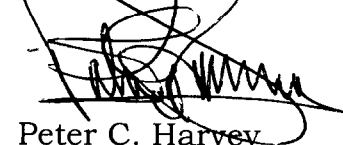
In addition, the use of dietary supplements containing ephedrine alkaloids has been associated with adverse medical effects in individuals such as death, myocardial infarction, cardiac arrhythmia, myocarditis, hypertension, stroke and seizures. Therefore, even if the FDA believes that further studies are required, the

95N-0304

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sale of such products should be banned pending the completion of all such studies. In that way, consumers will be adequately protected until the completion of these studies.

Respectfully submitted,



Peter C. Harvey
Acting Attorney General



Clifton R. Lacy, M.D.
Commissioner
Health and Senior Services

amc

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