



April 14, 2003

Mr. Anthony Curry
Center for Food Safety and Applied Nutrition (HFS)-306
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Dietary Supplements Containing Ephedrine Alkaloids; Reopening of the Comment Period — 21 CFR Part 111 [Docket No. 95N-0304], RIN 0910-AC51

Dear Mr. Curry:

I am writing on behalf of the Pharmaceutical Printed Literature Association (PPLA) with regard to FDA's request for comments on the proposed requirement for a warning statement on the product label of dietary supplements containing ephedrine alkaloids. Specifically, the PPLA endorses and applauds FDA for initiating decisive measures to protect consumers from a known and significant health risk via explicit labeling on dietary supplements containing ephedrine alkaloids. We further are well aware of the controversy surrounding continued sales of such products. We respectfully ask the Agency to take into consideration in its forthcoming rulemaking the specific comments that are outlined later in this document.

PPLA Background

The PPLA is a not-for-profit association chartered in 2001 to serve as the voice of pharmaceutical printed package information manufacturers, and provide a forum for members to promote and improve delivery of information for protection of patients. To do so, the PPLA works to support health care professionals, and advocates use of printed literature to legislative, regulatory and other decision-making bodies. Additionally, PPLA acts as an educational resource for strategic partners and the public.

As a young association, PPLA's core initial goal is to help the pharmaceutical industry help consumers benefit from existing and new drugs - a return on investment of billions of research and development dollars - by taking those drugs as prescribed, with instructions, precautions and risk data clearly understood. The desired outcome is a win-win-win situation: consumers enjoy better health, the healthcare system operates at lower total cost, and drug manufacturers report higher sales.

As a result of the evolution of the Food, Drug and Cosmetic Act of 1938, the carefully regulated content of printed literature provided by pharmaceutical manufacturers has been the primary means for communicating to physicians and pharmacists how and when patients should take drugs correctly, and how to avoid mistakes. But despite this history, there is still no guarantee that patients will get accurate information directly from the manufacturer each time they have a prescription filled. And today, consumers are playing an increasing role in identifying medications and specifically requesting that their doctors write prescriptions for one drug instead of another.

This trend has already caused liability concerns in at least one state, New Jersey, where the state's supreme court has abolished the "learned intermediary" defense for pharmaceutical manufacturers who engage in DTC advertising. One of the functions of the PPLA, therefore, is to offer input to FDA, Congress, and other governmental agencies on how to provide reliable, detailed and controlled information for healthcare professionals and consumers in the age of direct-to-consumer and Internet information. Our members have extensive expertise in developing inserts, outserts and labeling used by physicians, pharmacists and patients to ensure that drug products are prescribed, dispensed and consumer properly. We stand ready to assist FDA in all efforts to promote wellness through information sharing.

PPLA Specific Comments

The PPLA respectfully requests that FDA consider the following comments in preparing the final rule.

1. The PPLA takes no position with regard to dietary supplements containing ephedrine alkaloids remaining on the market.
2. The PPLA endorses the language proposed for warning labels, and applauds FDA for taking this step toward explicit and comprehensible printed labeling.
3. Should FDA determine that continued sales of such products are allowed, the PPLA urges the Agency to require extensive labeling in all printed literature to accompany these products. The PPLA advocates a requirement for patient package inserts (PPIs) containing the FDA proposed warning label, as well as known adverse events associated with ephedrine alkaloids.
4. If helpful to the Agency, the PPLA will share its resources with FDA to develop appropriate labeling.

Conclusions

Given the significant and well-documented threat to public safety posed by dietary supplements containing ephedrine alkaloids, the PPLA maintains that it is appropriate and necessary to implement a broader labeling program for these products. The public is far more likely to heed health warnings about these products if they also receive more information through a PPI about documented adverse events. The public has a right to be as informed as possible about the dangers associated with these products. The PPI, as an existing format for communicating recorded adverse events to consumers, is the best medium in our view for optimizing the public's awareness of, and response to, the potentially lethal consequences of inappropriate use of dietary supplements containing ephedrine alkaloids.

Sincerely,

Peter G. Mayberry
Executive Director