

April 7, 2003

The Dockets Management Branch
(HFA – 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Dietary Supplements Containing Ephedrine Alkaloids;
Reopening of the Comment Period (95N-0304)**

To Whom It May Concern:

The Office of Advocacy respectfully submits the following comments on the Food and Drug Administration's (FDA) proposed rule entitled, "Dietary Supplements Containing Ephedrine Alkaloids; Reopening of the Comment Period" which was published in the *Federal Register* on March 5, 2003.¹ Because the Office of Advocacy is an independent entity within the U.S. Small Business Administration (SBA), the views expressed by the Chief Counsel do not necessarily reflect the views of the SBA, or the Administration. The Chief Counsel for Advocacy participates in rulemakings and other agency actions when he deems it necessary to ensure proper representation of small business interests. In addition to these responsibilities, the Chief Counsel monitors agencies' compliance with the Regulatory Flexibility Act (RFA), and works with Federal agencies to ensure that their rulemakings demonstrate an analysis of the impacts that their decisions will have on small businesses.²

Introduction

One of the Administration's goals has been to lessen the regulatory burden on small businesses. U.S. Department of Health and Human Services Secretary, Tommy Thompson, has taken up this issue by voicing his support for reducing regulatory burden in his agency's rulemakings. The Office of Management and Budget has also supported reducing the impact of regulatory burden on small businesses through various mechanisms, including the use of a science-based approach to measuring a rule's impact on small entities.

¹ 68 Fed. Reg. 10417 (March 5, 2003).

² Pub. L. No. 96-354, 94 Stat. 1164 (1981). (Codified as amended at 5 U.S.C. §§ 601-612).

Advocacy appreciates the FDA's effort to educate consumers on the potential risks of using dietary supplements containing ephedrine alkaloids. Advocacy's comments are not critical of the public policy behind the regulation. Rather, Advocacy requests that the FDA balance the need for the regulation with its likely effect on small businesses through the use of a science-based regulatory approach. This request is warranted because the majority of the industry is comprised of small businesses and the science behind the regulation continues to be unsettled. Advocacy commends the FDA for its continued efforts to obtain scientific evidence on the health risks associated with the use of dietary supplements containing ephedrine alkaloids. Advocacy welcomes the opportunity to help the FDA assess potential impacts of the proposed rule on small businesses and is confident that the FDA will take steps prior to finalizing the rule to minimize adverse effects on small businesses.

On February 3, 1998, Advocacy filed comments based on the FDA's Notice of Proposed Rulemaking (NPRM)³ on this issue and many of Advocacy's concerns remain valid today.

A. In the June 1997 NPRM, the FDA concluded that the proposed rule would have a significant impact on a substantial number of small entities.

In its June 1997 NPRM, the FDA concluded that the proposed rule would have a significant impact on a substantial number of small entities. Pursuant to the RFA, the FDA appropriately prepared an Initial Regulatory Flexibility Analysis (IRFA). At the time, Advocacy faulted the adequacy of the IRFA because, among other things, it failed to properly assess the rule's affect on small businesses and it relied on questionable scientific evidence.

Advocacy recommends that the FDA revisit the issue of small business impact as it undergoes the current rulemaking process. If the regulation of dietary supplements was likely to have a significant effect on a substantial number of small entities in 1997, the same situation is likely to exist today. Pursuant to the RFA, in order to determine the impact of a regulation, an agency must make a reasonable effort to identify the type and number of entities likely to be affected by the regulation. This is especially important in this instance as the rulemaking will not only affect the manufacturers of the ephedrine alkaloid products, but the distributors and retailers as well.

The FDA will not be able to obtain meaningful public input on the rule's impact on the industry by reopening the comment period for only thirty (30) days. Further, the March 5, 2003, proposed rule narrowly seeks input on the FDA's authority to regulate products containing ephedrine alkaloids, the appropriateness of the proposed warning label, and any new evidence on the health risks associated with ingesting products containing ephedrine alkaloids. Why not obtain the information necessary to ascertain the economic impact of the rule at the same time? Advocacy believes that the FDA can obtain useful information on the number of entities affected by opening a dialogue with industry

³ 62 Fed. Reg. 30,678 (June 4, 1997).

associations and others through greater use of agency outreach. This will help to foster small business participation in the rulemaking and minimize the potential for judicial review based on RFA issues.

Advocacy also recommends that the FDA consider reasonable alternatives to the rule in an effort to reduce the burden on small businesses. This will provide small businesses with the flexibility necessary to minimize the economic impact of the rule. For example, the FDA may consider lengthening the time required for small businesses to comply with the regulation or extending the time for any recordkeeping or reporting mandates required by the rule.

B. The warning label suggested by the FDA in the proposed rule may adversely impact small businesses.

It should be noted that Advocacy has discussed the proposed warning label with various small businesses. The small business representatives agree that there is a need for a warning label on products that contain ephedrine alkaloids. However, the proposed rule provides that a warning label will appear on the principal display panel of the product. Advocacy is concerned that such a prominently displayed warning label may result in a significant economic impact on small businesses. Small business representatives question whether the warning is too large to fit on the principal display pane. Further, the warning label specifically warns the consumer that heart attack, stroke, seizure and death have been reported after consumption of the product. Advocacy is concerned that the warning label as described by the FDA may be construed as misleading because there is ongoing scientific debate as to any causal relationship between the use of ephedrine alkaloids and the medical outcomes described on the label. Further, the FDA's White Paper concludes on page 3 that the agency does, "not have definitive evidence that ephedra has caused serious injury and deaths."

In light of the likely negative economic impact on small businesses, Advocacy requests any warning label promoted by the FDA be science-based. The small business representatives also support an over-the-counter regulatory model for the warning label, which would include indications for use, and dosage limits. Small business representatives also believe this can be adequately achieved with a back panel warning label. Lastly, Advocacy encourages the FDA to consider other less burdensome alternatives with respect to the warning label that may serve to minimize the economic impact on the industry.

Conclusion

In conclusion, the proposed rule presents a number of significant issues for small businesses in the dietary supplement business, the majority of which are small. Advocacy is not suggesting that the industry does need to be regulated, as the industry itself appears to be in agreement that regulation is appropriate. However, Advocacy wants to persuade the FDA to better consider small business in the rulemaking through analysis, the use of public comment and greater agency outreach. Advocacy also asks the FDA to

consider meaningful alternatives to the rule that will serve to minimize the rule's impact on small businesses. Lastly, Advocacy commends the FDA on its continued resolve to study the effects of the use of ephedrine alkaloids by the public and encourages the agency to incorporate their findings as it drafts the final rule.

Sincerely,

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