

February 28, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
United States Food and Drug Administration
Parklawn Building/Mail Code: HF-1
5600 Fishers Lane
Rockville, MD 20856

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry (Docket No. 2007D-0491) entitled: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Act (73 Fed. Reg. 196, January 2, 2008), and Draft Guidance for Industry (Docket No. 2007D-0496) entitled: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (73 Fed. Reg. 197, January 2, 2008).

Dear Commissioner von Eschenbach:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA, or of the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.¹

As Chief Counsel for Advocacy, I am writing because my office has received inquiries from small dietary supplement manufacturers and their representatives (including the American Herbal Products Association) voicing concern with the Food and Drug Administration's (FDA) Draft Guidance for Industry: Questions and Answers Regarding

¹ Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. §612(a).

the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Act (73 Fed. Reg. 196, January 2, 2008), and Draft Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (73 Fed. Reg. 197, January 2, 2008).² Industry representatives have told Advocacy that they are concerned that the draft guidance will have a significant economic impact on their industry. Therefore, I want to take this opportunity to comment on the draft guidance and alert the FDA about many of the concerns those industry representatives have voiced to Advocacy.

Legislative and Regulatory Background

The Dietary Supplement and Nonprescription Drug Consumer Protection Act (Act) was signed into law on December 22, 2006, and went into effect on December 22, 2007. The Act required the FDA to publish guidance on the minimum data elements that should be included in a serious adverse event report as described by the amendments in the Act. The FDA published the prescribed guidance in the *Federal Register* on October 15, 2007, when it announced the availability of two separate draft guidance documents: one for dietary supplements (72 Fed. Reg. 58313); the other for nonprescription drug products (72 Fed. Reg. 58316).

On January 2, 2008, the FDA published two additional draft guidance documents that provided questions and answers regarding the labeling of dietary supplements (73 Fed. Reg. 197), and for the labeling of nonprescription products (73 Fed. Reg. 196). The FDA asserts that the draft guidance documents represent its recommendations and requirements under the Act.

Considering the likely effect of the draft guidance, the FDA should consider making the guidance a rulemaking subject to notice and comment.

Industry representatives suggested that the true effect of the draft guidance will force businesses to comply with its provisions which will have a significant economic impact on an industry that is comprised of predominately small businesses. The industry justifies this assessment based on the fact that no dietary supplement labels currently carry information to inform consumers that the address or phone number on the dietary supplement label is for reporting serious adverse events. The industry assumes that the draft guidance will require that all dietary supplements will need to be relabeled in order to meet the FDA's recommendations and requirements.

Industry representatives argue therefore, that the draft guidance should be a rulemaking pursuant to the Administrative Procedure Act (APA)³ rather than a mere guidance document. The APA requires agencies to publish rules for public notice and comment. The RFA requires that during rulemaking, the promulgating agency must analyze the

² Hereafter, both guidance documents will be referred to jointly as the "draft guidance."

³ 5 USC section 553.

rule's economic impact on small businesses and analyze regulatory alternatives that minimize the regulation's impact on those businesses; unless it can certify that the rulemaking will not have a significant impact on a substantial number of small businesses.⁴

Affected small businesses point out that in a prior rulemaking in 2003 the FDA estimated that there were 29,514 dietary supplement stock-keeping units (SKUs).⁵ In the same rulemaking FDA estimated that the cost of re-labeling (exclusive of inventory disposal) would be between \$2,400 and \$4,200 per SKU. Therefore, the cost of re-labeling dietary supplements under the draft guidance would be between \$70 million and \$124 million (in 2003 dollars). Industry suggests that the aforementioned estimates may indeed be too low based on data from the Office of Dietary Supplements at the National Institutes of Health (NIH) which places the number of dietary supplements sold in the United States at between 50,000 and 60,000. Utilizing NIH's estimates the cost of re-labeling dietary supplements under the guidance would be between \$120 million and \$252 million.

Most importantly, the FDA's own Good Guidance Practices suggest that guidance documents should not convey the agency's interpretation of, or policy on, a regulatory issue as they are not considered binding.⁶ Industry representatives disagree with the FDA's interpretation of section 3 of the Act. Those representatives argue that the legislative intent of section 3 of the Act does not "mandate" that the product label contain a full U.S. mailing address as the draft guidance suggests.

This is an important distinction because the Office of Management and Budget's (OMB) final bulletin on Agency Good Guidance Practices (GGP), which establishes policies and procedures for the development, issuance, and use of significant guidance documents by Executive Branch Departments and agencies, indicates that given their legally nonbinding nature, significant guidance documents should not include mandatory language, unless the agency is using the words to describe a statutory requirement.^{7 8 9} Moreover, if you accept FDA's and NIH's estimates as to the costs associated with re-labeling dietary supplements to bring them into compliance with the requirements of the Act, FDA would have to seek OMB review of the draft guidance as the costs exceed \$100 million.

While the draft guidance is meant to inform the regulated dietary supplement industry of the FDA's interpretation of the enforcement aspects of the Act, the guidance clearly mandates that product labels must bear a "full" U.S. mailing address that includes the

⁴ Id. at section 603.

⁵ See FDA rulemaking: Food Labeling: Ingredient Labeling of Dietary Supplements that Contain Botanicals (68 Fed. Reg. 51738, August 28, 2003).

⁶ See: www.fda.gov/cder/audiences/iact/forum/200704_derr.pdf.

⁷ 72 Fed. Reg. 3432, January 25, 2007.

⁸ Advocacy suggests that FDA's draft guidance is "significant" as defined in the OMB bulletin which states, "guidance documents are considered "significant" when they have a broad and substantial impact on regulated entities, the public, or other Federal agencies." Id. at 3435.

⁹ OMB's GGP was incorporated into Executive Order (EO) 13422 which amended EO 12866.

street address or P.O. Box, and the city, state, and zip code of the responsible party, if a phone number is not provided. The mandatory nature of this provision suggests that the draft guidance should be considered a rulemaking.

Based on the recommendations from small dietary supplement manufacturers, Advocacy recommends that the FDA consider subjecting the provisions contained in the draft guidance to notice and comment rulemaking.

The FDA may have exceeded the legislative intent of The Dietary Supplement and Nonprescription Drug and Consumer Protection Act, and the draft guidance is inconsistent with existing Federal rules.

Small dietary supplement manufacturers acknowledge that dietary supplement labels are now required to carry a domestic address or domestic phone number through which a responsible person may receive a report of a serious adverse event under section 3 of the Act. Those small businesses take exception with the FDA's draft guidance which incorporates the Act's legislative mandate by stating that, "the statute requires that the product label bear a full U.S. mailing address that includes the street address or P.O. Box, and the city, state and zip code of the responsible person."

Dietary supplement representatives argue that existing labeling regulations require dietary supplement labels to disclose a place of business, a requirement that can be met without a street address, "if it is shown in a current city directory of telephone numbers."¹⁰ Small dietary supplement manufacturers submit that Congress did not contemplate such a substantive change in the labeling requirements currently required under Federal regulation; otherwise Congress would have used more specific language in the Act. More importantly, industry suggests that the guidance's requirement for address labeling should be consistent with the existing labeling requirements for food and drugs so long as any interested person can locate the business to report a serious adverse event.

By requiring that the label bear a full mailing address, the small dietary manufacturers will incur considerable new labeling costs. Subjecting the guidance to rulemaking would require the FDA to entertain alternatives (e.g., not requiring a full mailing address) that would minimize the costs on affected industry.

FDA's recommendation that the dietary label bear a prominent statement informing consumers that the domestic address or phone number is for reporting serious adverse events associated with the use of the product is not required by the Act and will cause manufacturers to incur significant re-labeling costs.

Small dietary supplement manufacturers point out the FDA acknowledges in the draft guidance that the Act does not require the label to include anything other than a domestic address or domestic phone number. Industry representatives are concerned that FDA's "recommendation" that the additional language be placed on the label will ultimately

¹⁰ 21 CFR 101.5(d) for food and 21 CFR 201.5(i) for drugs.

have the effect of establishing a requirement through guidance that will greatly increase costs to the industry. Further, the FDA's recommendation contradicts the legislative intent as expressed in the September 5, 2006, Report of the Senate Committee on Health, Education, Labor and Pensions, which stated that, "the legislation does not require the label to make any statement other than providing the address or phone number."¹¹

Advocacy suggests that the FDA reconsider including this recommendation for labeling in the guidance because it has the potential to greatly increase costs to industry. Further, if the guidance was subject to rulemaking the FDA would have a chance to analyze the impact that such a recommendation would have on industry and an opportunity to design less burdensome alternatives.

Industry representatives argue that the draft guidance will effectively shorten the time small dietary manufacturers would usually have to make label changes under existing FDA regulation.

The FDA's Guidance for Industry Questions and Answers publication indicates that the labeling requirements of section 502(x) of the Act became effective on December 22, 2007; one year after the Act became effective.¹² The draft guidance further states, "We believe that it is reasonable to allow an additional one-year period for firms whose labels do not yet meet the requirements of section 502(x) of the Act to bring their labeling into full compliance."¹³ The FDA states that it will begin enforcing the labeling requirements of section 502(x) of the Act on or after January 1, 2009.¹⁴

Small dietary supplement manufacturers suggest that their options, e.g., the ability to sell existing inventories, have been severely hampered by such a short enforcement delay. The effect of the short enforcement delay will be to significantly impact the industry. They argue that had FDA endeavored to regulate these labeling guidance requirements through rulemaking, the industry would have had more time to make the necessary labeling changes. Industry points out that the draft guidance is inconsistent with FDA's January 1, 2010, uniform compliance date for food labeling issued between January 1, 2007, and December 31, 2008.¹⁵ Per the FDA, the uniform compliance date regulation provides for, "an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time for industry to plan for the use of existing label inventories and the development of new labeling materials."¹⁶

¹¹ Calendar No. 586; 109th Congress, 2d Session; Senate Report 109-324, at page 9.

¹² Guidance for Industry: Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act, December 2007, page 6.

¹³ Guidance for Industry, supra.

¹⁴ Guidance for Industry, supra.

¹⁵ 71 Fed. Reg. 76599, December 21, 2006.

¹⁶ Id.

By establishing the new labeling requirements through the use of guidance, the FDA has effectively limited the time industry has to comply with its requirements in an economical fashion. The FDA should revisit its position on enforcement on this matter and consider the potential benefits of subjecting the draft guidance to rulemaking.

Conclusion

In summary, Advocacy requests that the FDA give consideration to the issues raised in this comment letter. Advocacy encourages FDA to better analyze the possible effects of this regulation on the dietary supplement industry which is predominately comprised of small businesses.

Thank you for your attention to the above matter. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel, Linwood Rayford at (202) 401-6880, or linwood.rayford@sba.gov.

Sincerely,

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Chief Counsel Advocacy

Linwood L. Rayford, III
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cc: The Honorable Susan Dudley, Administrator, Office of Information and Regulatory Affairs, OMB