



September 14, 2007

Dr. Andrew von Eschenbach
Commissioner
Room 14-71
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: FDA Guidance for Industry on Complying with the Dietary Supplement and Nonprescription Drug Consumer Protection Act

Dear Dr. von Eschenbach:

The Center for Science in the Public Interest (CSPI) wishes to commend the Food and Drug Administration (FDA) for its efforts to ensure that companies faithfully comply with the requirements of the new Dietary Supplement and Nonprescription Drug Consumer Protection Act. That Act requires companies to provide a telephone number or an address that consumers can use to report serious adverse reactions to such products, and requires that such reports be turned over to the FDA.

As instructed by Congress, the FDA is preparing a guide for industry on how to comply with the new law. It has been reported that the Agency's forthcoming guidance document may include two very important provisions which we support.

1) One element of the FDA's guidance document may specify the wording of a statement on product labels informing consumers that they can report serious adverse reactions by calling the telephone number or writing to the address that is required to be printed on the label.

CSPI believes that this provision should be included in the final version of the FDA's forthcoming guidance document. The provision is consistent with the legislative history of the Act and reflects the spirit of the legislation. Congress gave the FDA authority to require manufacturers to report serious adverse reactions because the lack of such authority has hampered the Agency's ability to protect the public. For example, in the absence of such a requirement, it took the FDA nearly 10 years to ban the sale of ephedra, which was linked to 155 deaths and many more serious injuries, even though companies knew of thousands of complaints of adverse reactions to that dietary supplement.

Under the Dietary Supplement Health and Education Act (DSHEA), FDA must prove that a supplement poses a "significant or unreasonable risk" before it can take the product off the

market. To meet its burden of proof, FDA needs evidence – such as data contained in adverse reaction reports – before it can take action to protect the public. But under the previous voluntary adverse event reporting system, the Office of the Inspector General (OIG) at the Department of Health and Human Services determined that the Agency received reports of less than one percent of all adverse reactions associated with dietary supplements.

During the Senate’s consideration of the Act, Senator Hatch, the lead sponsor of the legislation, explained:

“[e]ncouraging consumers to report to manufacturers through a phone number or address on the product’s label will ensure a more thorough reporting system.”

Thus, it is clear that the intent of the legislation was to encourage consumers to report serious adverse reactions. The Senate report on the bill stated that companies could include other label statements that “would conform to all requirements of the FFDCA.” (Federal Food Drug and Cosmetic Act) S. Rpt. No. 109-324 at 8 (109th Cong. 2d Sess. Sept. 5, 2006). FDA guidance to industry specifying the language that should be used on labels to alert consumers that they can report serious side effects would encourage individuals to take such action.

2) A second provision in the draft guidance document would require that if a company provides an address in lieu of a telephone number, the company must provide a complete mailing address, rather than merely the city and state in which the firm is located. This provision is also supported by the legislative history of the Act and is consistent with the intent of the legislation.

Congress wanted to be sure that reports of adverse reactions could be readily mailed to companies. That is why the new law requires that a “domestic address” be used. This contrasts with the more general language in Section 403 (e)(1) of the FFDCA which calls for a “place of business” to be listed on food labels. The Congressional Budget Office explained the distinction:

In cases where a phone number is not listed, S. 3546 would require makers of nonprescription drugs and dietary supplements to include an address on their labels. CBO interprets an address to be a description of the location of a person or organization, including all information necessary for the Postal service to deliver mail, which is more information than is required for a place of business. Therefore, we assume that many makers of nonprescription drugs and dietary supplements would be required to include a street address on their labels.

Congressional Budget Office Cost Estimate, S. 3546 Dietary Supplement and Nonprescription Drug and Consumer Protection Act (Sept. 12, 2006).

Although the American Herbal Products Association (AHPA) and Council for Responsible Nutrition (CRN) believe that including an extra line in the address would be burdensome and costly to industry, the Congressional Budget Office disagrees. In its Sept. 12, 2006 Cost Estimate, CBO stated that:

the total cost of compliance with the labeling requirement would, however, be low. The address requirement would not apply to those businesses listing a phone number on their label. Moreover, the requirement would apply only to those products labeled later than one year following enactment of the bill, allowing makers of nonprescription drugs and dietary supplements ample time to add a single line to their labels.

CBO Estimate at 7.

In sum, CSPI believes that FDA's ideas for its guidance document that will explain how companies can comply with the new law are fully appropriate, consistent with congressional intent, and in the best interest of consumers.

Sincerely,



Bruce Silverglade
Director, Legal Affairs



Ilene Ringel Heller
Senior Staff Attorney

CC:

Senator Richard Durbin
Senator Edward Kennedy
Congressman John Dingell
Congressman Henry Waxman