



March 3, 2008

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

**RE: Docket No. 2007D-0491, CFSAN 200755. Draft Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer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.**

The Council for Responsible Nutrition (CRN)<sup>1</sup> appreciates the opportunity to provide FDA with comments regarding the recently issued draft guidance related to the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the Act) entitled, “*Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act*,” and published on January 2, 2008.<sup>2</sup> CRN and other dietary supplement associations were strong supporters of the legislation leading to this Act which requires the reporting of serious adverse events for dietary supplements and nonprescription, or OTC, medicines marketed without an approved application received by the manufacturer, packer, or distributor to FDA. Our support stems from our long held belief that mandatory reporting of serious adverse events provides consumers with additional assurance of the safety of these products and enhances FDA’s ability to ensure the public health.

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<sup>1</sup> The Council for Responsible Nutrition (CRN) is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. Our 65+ manufacturer and supplier members agree to adhere to voluntary guidelines for manufacturing, labeling and marketing and CRN’s Code of Ethics.

<sup>2</sup> On January 2, 2008, both CDER and CFSAN published separately in the Federal Register draft guidance documents for labeling requirements related to the Act. These appear to be addendums to draft guidance published in October 2007 which dealt with other aspects of the law. Both documents are nearly identical in their language; however, our comments will be limited to the draft guidance dealing with dietary supplements.

Nevertheless, CRN has serious concerns regarding the draft guidance which we will articulate in these comments. As an initial matter, unlike the draft guidance published in October, 2007 (“Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act”), the present draft guidance was not stipulated in the Act by Congress and is entirely unnecessary. In addition, CRN objects to FDA’s attempt to impose these “recommendations” through guidance rather than through notice and comment rulemaking as should be the case for label changes. With regard to substance (as opposed to procedure), CRN opposes FDA’s “recommendation” to include prefatory language on the label of dietary supplements instructing consumers of the purpose of the domestic address or phone number on the label on the grounds that such introductory language is counter to Congressional intent and unnecessary. CRN also disagrees with FDA’s interpretation of the meaning of “domestic address” believing that the statute does not require a street address on the label, and in fact, that FDA’s interpretation flies in the face of 70 years of regulatory requirements for products regulated by FDA. On both counts, we are concerned that the Agency has not properly accounted for the magnitude of costs and time associated with widespread label changes which would need to occur as a result of these interpretations by the Agency. Related to this final point, we urge FDA to make the soonest possible decision with respect to the fate of this draft guidance.

**I. FDA’s decision to issue these new “recommendations” for supplement labeling as a “Guidance for Industry” violates due process and the Administrative Procedures Act given the substantive nature of the requirements.**

For all practical purposes, this draft guidance, if finalized, would set mandatory requirements that are not expressly authorized by the Act for the labeling of dietary supplements, which would revise 70 years of regulatory interpretation as will be demonstrated below. Such new requirements necessitate the full due process afforded for pronouncements that impose such a substantial and financial impact on industry, namely a full notice and comment rulemaking.

For its part, FDA has suggested that the guidance is less than that. The introduction states that “This guidance, when finalized, will represent the current thinking of the [FDA] on this topic. . . You can use an alternative approach if such approach satisfies the requirements of

the applicable statute and regulations.” Admittedly, the introduction goes on to state that FDA’s guidance documents “do not establish legally enforceable responsibilities” and that “guidance documents should be viewed only as recommendations... The use of the word *should* in agency guidance means only that something is suggested or recommended, but not required.”

However, in the questions presented in the guidance, FDA asks “What information must be included on the label....?” (emphasis supplied). The document also states that “FDA concludes that the statute requires the product label to bear a full US mailing address that includes the street address or P.O. box....” (emphasis supplied). So, at least with respect to the street address issue, it is clear that the guidance is not a recommendation at all, but rather a new mandatory requirement for industry. Such a change in the absence of a clear Congressional mandate deserves full opportunity for input of all stakeholders that a notice and comment rulemaking would afford.

Even with respect to the issue of the prefatory statement, the guidance imposes a de facto new substantive requirement for dietary supplements by recommending that “the label bear a prominent statement informing consumers that the domestic address or phone number is for reporting serious adverse events.” It goes on to say that “FDA would have no objections” to a firm’s combining the recommended statement with other language, with the clear implication that FDA *would have objections* if the firm chose to omit the prefatory language altogether. Further, FDA announced its plan to delay its enforcement of the labeling requirements until January 2009. The primary distinction between a substantive rule requiring rulemaking and an interpretive rule or agency statement of policy turns upon whether the Agency intends to bind itself to a particular legal position.<sup>3</sup> From these statements of FDA, it is clear from the guidance document that FDA intends to “bind” itself to these interpretations and to enforce them.

Even if FDA chose to exercise its own enforcement discretion with respect to this “objection,” it is still binding on the industry because of the impact on civil litigation referencing this guidance language. As a practical matter, in any subsequent private litigation relating to any alleged adverse events, a manufacturer’s failure to include a street address in the wake of this guidance would most certainly be introduced into evidence and held against the company. Dietary supplement manufacturers, distributors, or packers would likely not feel free to disregard FDA’s guidance because the failure to comply would create liability in civil product liability

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<sup>3</sup> *Syncor International Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997).

litigation as a result of the guidance. In effect, then, new labeling requirements that represent a departure from longstanding FDA regulations have a substantial and mandatory effect that should only be achieved through notice and comment rulemaking. For the Agency to naively suggest that it is only making “recommendations” to industry is disingenuous at best.

**II. FDA’s Guidance that would “recommend” that dietary supplement labels carry prefatory language expressing the purpose of an address or phone number on the label contravenes the intent of Congress, is misleading to consumers and unnecessary.**

In the January 2<sup>nd</sup> guidance, FDA recommends the inclusion of prefatory language on the label to prompt consumers who have experienced an adverse event to contact the manufacturer at the address or phone number on the label, and even suggests a label statement for use, such as, “*To report a serious adverse event or obtain product information, contact...*”. CRN adamantly opposes this recommendation.

Without question, the inclusion of this language is counter to the intent of Congress which expressly indicated that no such prefatory language was to be required by the Act. While the face of the statute itself is silent about any such requirement (leaving FDA with no authority from the text of the statute to justify this “recommendation”), the legislative history is quite clear to the contrary. The Report of the Senate Health, Education, Labor & Pensions Committee for the legislation provides, “The legislation does not require the label to make any statement other than providing the address or phone number.” Senate Report 109-324, at 9. (September 5, 2006) (emphasis supplied). For FDA to “recommend” that such a statement appear on the label flies in the face of Congress’ statement. Moreover, the intent and spirit of the Act is to require manufacturers to report to FDA the serious adverse events that they receive, and to assure that consumers who want to contact the manufacturer have adequate information to do so. It is not to draw undue attention to the possibility of an adverse event, to predispose consumers to expect they will experience an adverse event while using the product, or to incentivize consumers to report more adverse events to manufacturers. By drawing undue attention to the possibility of an adverse event on the label, FDA is doing just that.

Which leads to CRN’s second concern for the prefatory statement, which is that the address and/or phone number of the manufacturer on a product label serves many purposes other than the reporting of adverse experiences with the product. Consumers may want to contact the

firm to praise the performance of the product, ask questions, or provide feedback on some attribute of the product (taste, size of pills, color, number of tablets in the bottle, tamper-evident features, child resistant packaging, etc.) Consumers may wish to inquire how or where they can purchase more of the product, to report a suspected tampering, or to learn more about promotions connected with the product. If experience is any guide, CRN's members tell us that the vast majority of customer questions and comments they receive through mail and phone calls are unrelated to reports of adverse events. In fact, customer hotlines and mail provide manufacturers with a direct opportunity to interact with their consumers and allow them to learn about the total customer experience. So why draw such attention to the possibility of an adverse event? Product labels serve many other purposes and it is unreasonable to highlight adverse events as the sole, or at least the primary reason to contact the company.

At the same time, FDA appears to believe that without an introductory statement like "*To report a serious adverse event, contact...*" a consumer who does experience an adverse event would be lost as to how to contact the manufacturer. Food, cosmetic, drug and device labels (including dietary supplements) have been required for many years to provide a "place of business" on the label and many manufacturers voluntarily provide a toll-free phone number on their labels as well. Consumers understand that this information on the label is provided so they can communicate with the manufacturer for a variety of reasons, including the reporting of an adverse experience. The sheer fact that manufacturers have in the past, and continue to receive these reports prior to the passage of the Act more than demonstrates that consumers know what to do with the address and/or phone number on the label. While FDA might believe that the addition of one more line of text is inconsequential, it should more than appreciate that every inch of label space is important to the presentation of information. Blank space is equally important in reducing consumers' confusion, directing their attention and increasing their understanding of product directions and nutrition information. The decision to "recommend" additional words on the label should be approached only when there is evidence that the absence of that wording leaves consumers with inadequate information to use the product appropriately. That is not the case here.

Indeed, a significant portion of dietary supplement products already have language on the label comparable to "Comments? Questions?" followed by a phone number. It is our opinion that this voluntary language is sufficient to help direct consumers, and that even in its absence,

consumers are savvy enough to know how to contact a company if they have a question, comment or complaint about a product. We respectfully request that FDA withdraw its recommendation for prefatory language on the label.

**III. FDA’s guidance requirement for domestic address that includes a street address is not authorized by the statute, constitutes a change in Agency interpretation, and unnecessarily burdens the industry.**

FDA’s interpretation of “domestic address” as it appears in the Act differs from that of “place of business” in the Food Drug & Cosmetic Act (FD&C Act) sec. 403(e) (21 U.S.C. sec. 343(e)). The Agency claims that the former means a full street address, city, state and zip code, while the latter means city, state and zip code (provided the company is listed in a current city or telephone directory). FDA therefore concludes that per the Act, companies are required to have either a full phone number or full address on the label. The implication is that companies that have only the “place of business” address without the street address or phone number on their label will be required to undergo label changes to add the street address in order to be in compliance by December 2009.

CRN disagrees with FDA’s interpretation. The Agency’s position is unsupported by 70 years of Agency practice and regulatory interpretation and it is well settled that rulemaking is required where an agency takes a new position that is inconsistent with its prior regulations.<sup>4</sup> In this case, FDA would be departing from its longstanding position, embodied in its regulations for the labeling of all FDA-regulated products, that a street address is not required where it is shown in a current city directory or telephone directory. Presumably, the address, or “place of business” requirement that has existed for these other products addresses the same issue as it does in this case – namely to give consumers a way to contact the company responsible for the product. Why is it not good enough for dietary supplements? Indeed, at the time the Act was passed by Congress, the Agency did not require a street address on any other FDA-regulated product (see

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<sup>4</sup> See, e.g., *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 100, 115 S. Ct. 1232, 1239 (1995) (“We can agree that APA rulemaking would still be required if [the Secretary’s guideline] adopted a new position inconsistent with any of the Secretary’s existing regulations.”) *Sprint Corp v. FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003) (“Whereas a clarification may be embodied in an interpretive rule that is exempt from notice and comment requirements, . . . new rules that work substantive changes in prior regulations are subject to the APA’s procedures.”) (internal citations omitted); *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106, 1112 (D.C. Cir. 1993) (a purported interpretive rule that effectively amends a prior legislative rule is itself a legislative rule requiring notice and comment rulemaking).

chart enclosed). Congress indicated no intention of changing FDA's current labeling regulations other than to require that the address that appears on the label of dietary supplements be a *domestic* one. Accordingly, there are no grounds for FDA to issue a *de novo* interpretation of the "address" requirement in the Act that differs from the labeling requirements of other FDA-regulated products.

FDA argues in the guidance that the inclusion of a street address is necessary to assure delivery of the report and likens the requirement to mandating an area code for a phone number. The analogy does not hold up. Anyone who has ever tried to make a phone call to a number outside one's own area code knows that the call simply will not go through without dialing the area code first. Yet many letters are delivered each day to supplement manufacturers using the "place of business" information already on the label (city, state and zip code). In addition, in this internet age, it is easier than ever to track down a company, even based only on the name of the company or the brand, and to ascertain the full address of the company along with toll-free phone numbers, email addresses and even the names of senior executives. The fact that FDA has permitted city, state and zip code on its regulated products for 70 years and that FDA has presented no evidence that this is insufficient, raises questions as to the reasonableness of the new requirement.

Therefore, we respectfully request that the Agency withdraw the draft requirement that the product label bear a full U.S. mailing address (including P.O. box or street address) and continue to require an address (i.e., a place of business) on the label .

#### **IV. FDA has discounted the impact of this draft guidance and the costs associated with widespread label changes.**

Finally, the draft guidance downplays the cost associated with the label changes that will be required as a result of FDA's pronouncement. FDA has previously estimated costs for changing labels in a one-year time frame to be between \$2,400 and \$4,200 per SKU (see <http://www.fda.gov/OHRMS/DOCKETS/98fr/03-21981.pdf>). If the provisions in the draft guidance remain intact, some portion or even all dietary supplement labels will be required to change.<sup>5</sup> If the industry consists of 22,574 SKUs as FDA indicated in the draft guidance, this

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<sup>5</sup> We are aware of no products that currently have the exact prefatory language "recommended" by FDA. Insistence on that "recommendation" would mandate re-labeling for virtually all dietary supplements. Even if FDA was to

would amount to a cost of approximately \$54 - \$95 million to the industry. Using an adjusted annual inflationary rate of 3% the value would be between \$63 and \$110 million for 2008. We believe the Agency has underestimated the total number of SKUs and the actual number exceeds 50,000. This would amount to a cost closer to \$300 million if FDA's cost per SKU values are used, which we also believe is an underestimate. FDA's estimation of a per SKU label change likely does not reflect the true cost, including artwork, graphic re-design, and routing among departments for approval. Regardless of these details, this represents a significant economic burden which we believe the Agency has not appropriately considered for any labeling change, no matter how insignificant the changes.

Furthermore, in the draft guidance FDA states "FDA intends to begin enforcing the labeling requirements" for products labeled on or after January 1, 2009. Widespread label changes take many months from communication of a change to ultimate production, a total time which exceeds 12 months and is closer to 18 months or more. Therefore, FDA must make a timely decision on the fate of this draft guidance, as the window to allow companies to implement widespread label changes may have already passed. The guidance also overlooks that some manufacturers prepare their labels months in advance and maintain label rooms with stock to last for up to two years into the future. These labels, if not used before December 2009, would have to be destroyed if they do not conform to the street address and prefatory language requirements.

CRN suggests instead that FDA implement the requirements on the face of the Act, withdraw the draft guidance, and then immediately enforce the requirements of the law. The industry has been on notice since the passage of the Act in December 22, 2006 that the law was self-implementing and that the requirement for a domestic address (i.e., "place of business" or domestic phone number) would be effective on December 23, 2007. Industry should be in compliance with that requirement already. By limiting itself to the letter of the law, FDA could begin enforcement now, rather than wait another year or longer to enforce its interpretation of what should be required.

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withdraw this portion of the guidance, many products would still have to re-label because they do not contain a street address or a domestic phone number, only a domestic place of business (city, state, and zip code). We have been unable to estimate the portion of the industry affected by this requirement, but informally we believe it would impact as many as half the SKUs in the market.

## **Conclusion**

In conclusion, we believe the draft guidance issued by FDA on January 2, 2008 pertaining to the AER Act violates due process for Agency decision making and is unnecessary, and potentially misleading for consumers. CRN requests that the Agency make a timely decision and withdraw the guidance, or at a minimum, undergo the normal notice and comment rulemaking process for these interpretations of the Act.

Sincerely,

A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke extending to the right.

Andrew Shao, Ph.D.  
Vice President, Scientific & Regulatory Affairs

<b>Table 1 – “Name and Place of Business” Requirements for Labeling of FDA-Regulated Products in FDCA</b>		
<b>Product Type and FDCA Section [US Code Citation]</b>	<b>Context</b>	<b>Corresponding FDA Regulations</b>
Food 403(e)(1) [21 U.S.C. 343(e)(1)]	Food labels must bear name and place of business of manufacturer, packer, or distributor	21 C.F.R. 101.5(a); (d)*; (e) 21 C.F.R. 501.5(a); (d)*; (e)
Drugs and Devices 502(b)(1) [21 U.S.C. 352(b)(1)]	Drug and device labels must bear name and place of business of the manufacturer, packer, or distributor	21 C.F.R. 201.1(i)* 21 C.F.R. 801.1(a); (d)*; (e)
Animal Feed 504(a)(3)(C) [21 U.S.C. 354(a)(3)(C)]	Required notification to the Secretary of Agriculture must contain name and place of business of distributor of animal feed containing veterinary feed directive drugs	21 C.F.R. 558.6(d)(1)(i)
Cosmetics 602(b)(1) [21 U.S.C. 362(b)(1)]	Cosmetics labels must bear name and place of business of manufacturer, packer, or distributor	21 C.F.R. 701.12(a); (d)*; (e)

\* Provides that the statement of the place of business shall include the street address, city, state, and zip code, but that the street address may be omitted if it is shown in a current city directory or telephone directory.