

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**DIETARY SUPPLEMENT LABELS:  
AN ASSESSMENT**



**JANET REHNQUIST  
INSPECTOR GENERAL**

**MARCH 2003  
OEI-01-01-00121**

# ***OFFICE OF INSPECTOR GENERAL***

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# EXECUTIVE SUMMARY

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## OBJECTIVE

To assess the extent to which existing dietary supplement labels reflect the key elements identified in our dietary supplement label template.

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## BACKGROUND

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA). DSHEA defined the term “dietary supplement” to include substances, such as vitamins, minerals, botanicals, and amino acids. The Food and Drug Administration (FDA) has primary oversight responsibilities for dietary supplements and their labels.

**Widespread Use of Dietary Supplements.** An estimated 70 percent of the U.S. population, or 152 million people, tried at least one dietary supplement in 2001. Dietary supplements are nearly a \$17 billion industry.

**Benefits and Risks of Dietary Supplements.** Dietary supplements have potential health benefits, but may also pose safety risks. For example, calcium and vitamin D supplementation can help to reduce bone loss in the elderly. Yet, FDA has received reports of adverse events associating ephedra with heart attacks, strokes, seizures, and high blood pressure.

**Importance of Dietary Supplement Labels.** In DSHEA, Congress recognized the importance of labels, calling for them to include information, such that “consumers may make informed and appropriate health care choices for themselves and their families.” Labels can be particularly significant given that dietary supplements are often used as self-care products and labels are an easily accessible source of information. Furthermore, label oversight is a key regulatory tool for FDA to promote the safe use of dietary supplements among consumers.

**Concerns about Dietary Supplement Labels.** Our 2001 report entitled *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve* (OEI-01-00-00180) highlighted the need for consumers to have more complete information about dietary supplements than is currently required. In 2000, the General Accounting Office cited problems with label content for dietary supplements.

**Consumer Health Information for Better Nutrition Initiative.** In December 2002, FDA announced the Consumer Health Information for Better Nutrition Initiative, which seeks to enhance the credibility of food and dietary supplement labels through the inclusion of more accurate, science-based information. This multi-part initiative includes the publication of guidance on qualified health claims for conventional foods and dietary

supplements, strong enforcement of dietary supplement rules, and the establishment of an FDA task force on consumer health information for better nutrition.

**This Report.** We performed an original analysis of the labels of 100 dietary supplements that consumers commonly use in order to examine the current state of labels in relation to our template of key label elements. That template, which was designed to identify key elements that can increase the potential for dietary supplement labels to help consumers make informed and appropriate choices about supplement use, is described in detail in our companion report, *Dietary Supplement Labels: Key Elements* (OEI-01-01-00120).

We supported the observations from our label analysis by interviewing 76 key stakeholders, such as regulators, industry representatives, and consumer groups, and 7 focus groups with consumers and health professionals. We also integrated data from industry groups and independent research organizations, and conducted a comprehensive literature review on supplement use and labels, including congressional testimony and national survey data on supplement use.

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## FINDINGS

Our analysis suggests that dietary supplement labels fail to adhere to the key elements in our template. We found that the labels are limited in their ability to guide the informed and appropriate use of supplements among consumers and often do not present information in a manner that facilitates consumer understanding.

In part, the current state of labels is due to the absence of a standardized format for the presentation and type of information given on the label. Moreover, FDA lacks clearly defined standards for disclosing safety information and for ensuring product authenticity. In their current state, dietary supplement labels could potentially lead consumers to use supplements inappropriately. In fact, consumers and health professionals in our focus groups expressed that labels were often not a useful source of information and noted that they may disregard them or to turn to alternative sources of information about supplement use.

### **Dietary Supplement Labels Fail to Adhere to the Key Elements in Our Template.**

Our sample of 100 labels did not meet nine of the ten elements in our template. For a full description of the template, which was designed to identify key elements that can increase the potential for dietary supplement labels to help consumers make informed and appropriate choices about supplement use, see our companion report, *Dietary Supplement Labels: Key Elements* (OEI-01-01-00120).

## **Labels often fail to provide sufficient information to guide the informed and appropriate use of supplements.**

- ▶ ***Ingredient information is often difficult to interpret.*** Supplement labels often fail to provide enough detail about supplement composition for users to understand exactly about what they are taking. Of the 100 labels we reviewed, 93 did not make clear which ingredients were active and 94 did not make clear the extent to which ingredients were bioavailable (absorbed in the body); all of the 15 privately-held formulations (proprietary blends) lacked information on the amount of individual ingredients.
- ▶ ***Statements of intended use often provide limited information.*** Supplement claims we examined are often confusing to consumers because they do not adequately convey the intended use of the supplement. Consumers and health professionals in our focus groups could not distinguish between types of claims.
- ▶ ***Safety information is often incomplete.*** From our sample of 100 labels, 89 lacked information about adverse reactions or side effects, 87 about interactions, 85 about maximum dose, 61 about contraindications, and 25 about expiration. Even when labels did include these types of information, we found that warning statements varied in detail.
- ▶ ***Directions for use are often insufficient.*** Supplement labels are required to list a serving size, but not necessarily recommended daily dose. When that information is listed, it can be difficult to interpret. For example, dose information may be described in relation to a symptom, but the boundaries of that symptom may not be clear.

## **Labels often fail to present information in a manner that facilitates consumer understanding.**

- ▶ ***No standardized format exists.*** There is little consistency in how important categories of information are referenced on labels. For example, of the 66 supplements in our sample packaged in bottles, 13 had safety information to the right of the front panel, 14 had the information to the left, and 39 did not have that information at all.
- ▶ ***Supplement labels have few distinguishing features.*** Some of the supplement labels in our sample were suggestive of pharmaceutical products. We found examples of supplements that contained pictures of people wearing physician lab coats and stethoscopes and that had product names like “Prescribed Choice.”
- ▶ ***Complex language and small font size inhibit readability.*** This prevents a broad range of consumers from easily reading and understanding label information. A number of elderly consumers in our focus groups and some health professionals had a difficult time reading supplement labels and understanding the terminology used.

- ▶ **Information on benefits and risks is often imbalanced.** Unequal space is often given to product benefits compared to risks. For example, 69 of the labels in our sample contained statements about a supplement’s potential benefits, but 38 of those did not disclose any safety information.

## **Several Factors Inhibit Supplement Labels From Adhering to Our Template.**

**Lack of clearly defined FDA standards.** No uniform standards exist to guide manufacturers in determining what constitutes a ‘material fact’ requiring safety information to be placed on supplement labels. Furthermore, FDA has not defined standards for the amount and kinds of evidence necessary to substantiate claims. Without clearly defined standards, manufacturers find it is difficult to achieve a level playing field.

**Few measures for ensuring product authenticity.** Neither an official monograph system nor validated testing methods for supplements exist, making it difficult for manufacturers to ensure ingredient quality and potency. The lack of such measures contributes to inconsistent supplement preparations and label declarations.

**Limited wording of claims.** Manufacturers have difficulty in clearly expressing the benefits of dietary supplements on labels because of restrictions in how claims may be worded.

## **Evidence Suggests that Consumers and Health Professionals Find Supplement Labels of Limited Use.**

Our focus groups pointed to mistrust of the label as one of the main reasons why consumers turn to other sources of information, such as health professionals. However, health professionals’ limited knowledge about supplements and difficulty in interpreting labels inhibit many of them from serving as a resource for supplement users. According to a recent survey, only a third of consumers were very confident in the accuracy of information found on supplement labels.

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## **CONCLUSION**

Our analysis of 100 dietary supplement labels found that few reflected the label elements that our template identified as key to guiding the informed and appropriate use of supplements among consumers. These findings were confirmed by our interviews and focus groups, as well as by independent data analyses and professional literature. Our analysis also found that several barriers may prevent manufacturers from developing labels that can adhere to our template, and that the current state of supplement labels may limit the extent to which consumers and health professionals use labels.

We recognize that FDA has numerous efforts underway to address the current state of dietary supplement labels, and that limited resources, limited scientific evidence about the safety and efficacy of supplements, and competing priorities inhibit FDA's capacity to make timely progress. Our analysis is designed to assist FDA as it addresses the legal framework related to dietary supplement labels, and as it reviews its standards for disclosing safety risks on labels, substantiating evidence related to label claims, and developing analytical methods and reference materials for testing supplements.

# TABLE OF CONTENTS

	<b>PAGE</b>
<b>EXECUTIVE SUMMARY</b> .....	i
<b>INTRODUCTION</b> .....	1
<b>PRIMER ON DIETARY SUPPLEMENT LABELS</b> .....	4
<b>FINDINGS</b>	
Dietary supplement labels fail to adhere to the key elements in our template .....	5
Several factors inhibit supplement labels from adhering to our template. ....	19
Consumers and health professionals find labels of limited use .....	23
<b>CONCLUSION</b> .....	26
<b>APPENDICES</b>	
A: Template of key elements for dietary supplement labels .....	27
B: Information included on supplement labels .....	28
C: FDA initiatives related to dietary supplements .....	29
D: Methodology .....	31
E: Endnotes .....	33
<b>ACKNOWLEDGMENTS</b> .....	38

# INTRODUCTION

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## OBJECTIVE

To assess the extent to which existing dietary supplement labels reflect the key elements identified in our dietary supplement label template.

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## BACKGROUND

In 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA). DSHEA defined the term “dietary supplement” to include substances, such as vitamins, minerals, botanicals, and amino acids. It also created a new legal framework for dietary supplements and expanded the information that could be placed on labels.

### Widespread Use of Dietary Supplements

An estimated 70 percent of the U.S. population, or 152 million people, tried at least one dietary supplement in 2001.<sup>1</sup> Many consumers use supplements to enhance their nutritional intake or to maintain their health and well-being, while others hope to improve their energy levels and to prevent or treat common illnesses. The dietary supplement industry has responded to consumer demand by marketing an increasing number and variety of supplements. The Food and Drug Administration (FDA) estimates that about 29,000 dietary supplements are on the market.<sup>2</sup> Dietary supplements are now nearly a \$17 billion industry.<sup>3</sup>

### Benefits and Risks of Dietary Supplements

The growth of the dietary supplement market presents greater potential for consumers to experience the benefits of supplement use, and at the same time increases the chance that consumers will encounter safety risks. For example, the long-term consumption of vitamin C supplements may reduce the development of age-related lens opacities, and dietary calcium and vitamin D supplementation may help to reduce bone loss in the elderly. Yet, FDA has also received reports of adverse events associating ephedra with heart attacks, strokes, seizures, and high blood pressure, and kava kava with liver damage.

### Importance of Dietary Supplement Labels

In DSHEA, Congress recognized the importance of labels, calling for them to include information, such that “consumers may make informed and appropriate health care choices for themselves and their families.” Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN) has the authority to regulate supplements by issuing labeling rules and good manufacturing practice (GMP) regulations to the dietary supplement

industry and by monitoring adverse events related to supplement use. However, supplement-specific GMP regulations have not been issued, and the adverse event system is still being enhanced. Therefore, label oversight can serve as a key regulatory tool for promoting the informed and appropriate use of dietary supplements among consumers.

It is especially important for labels to provide objective and accurate information on supplement usage to balance the claims about supplements that consumers learn about through advertisements. In our brief review of advertisements, which are regulated by the Federal Trade Commission (FTC), we found dietary supplements claiming to bring relief from crippling pain within days, and herbal weight loss formulas claiming to help individuals lose 70 pounds in 8 weeks with no calorie counting and no hunger.

## **Concerns about Dietary Supplement Labels**

Our 2001 report entitled *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve* (OEI-01-00-00180) highlighted the need for consumers to have more complete information about dietary supplements than is currently required. In 2000, the General Accounting Office cited problems with label content for dietary supplements.<sup>4</sup> Concerns have also been raised by consumer and industry groups, federal and state regulators, and the media.

## **Consumer Health Information for Better Nutrition Initiative**

In December 2002, FDA announced the Consumer Health Information for Better Nutrition Initiative, which seeks to enhance the credibility of food and dietary supplement labels through the inclusion of more accurate, science-based information. This multi-part initiative includes the publication of guidance on qualified health claims for conventional foods and dietary supplements, strong enforcement of dietary supplement rules, and the establishment of an FDA task force on consumer health information for better nutrition. In a report on dietary supplement enforcement, which accompanied the announcement of the initiative, FDA stated its intention to develop mechanisms to communicate critical information and useful strategies about dietary supplements to consumers.<sup>5</sup>

## **Methodology**

Our analysis of dietary supplement labels was based on our template of the key elements of a label as described in our companion report *Dietary Supplement Labels: Key Elements* (OEI-01-01-00120). The template was developed in response to FDA's request that we present a vision of the kind of label that could serve to better assist consumers in making informed and appropriate choices about supplement use.

We performed an original analysis of the labels of 100 products that consumers recognize as dietary supplements and commonly use. For a summary of our label analysis, see Appendix B. We obtained the products from supermarkets, pharmacies, and natural food stores in the greater Boston area and from samples distributed at industry conferences.

Our diverse sample, which represents 36 manufacturers and 36 distributors, was a judgmental one. Without the existence of an official registry of the number and types of supplements on the market, we could not conduct probability sampling.

We also conducted 76 interviews with federal and state regulators, each of the major supplement industry trade groups, consumer advocacy groups, private quality oversight organizations, professional nutrition associations, academic researchers, marketers, and practicing herbalists. To learn more about specific concerns facing particular groups of supplement users, we conducted 7 focus groups with consumers and with health care professionals, and reviewed the findings of other focus groups.

We reviewed relevant federal legislation and regulation, as well as other materials prepared by government agencies, trade organizations, and consumer groups related to dietary supplements and supplement use. As part of our literature search, we reviewed existing data from national surveys on consumer use of dietary supplements and their labels, as well as data on the economic characteristics of the supplement industry.

For a more detailed description of our methods, see Appendix D.

## **This Report and its Companion Report**

This report assesses the extent to which existing dietary supplement labels reflect the key elements identified in our dietary supplement label template. Our findings are based on an original analysis of the labels of 100 dietary supplements that consumers commonly use and supported by interviews, focus groups, independent data analyses, and professional literature.

Our companion report, *Dietary Supplement Labels: Key Elements* (OEI-01-01-00120) provides more detail on the template. At the request of FDA, we designed a template to identify key elements that can increase the potential for dietary supplement labels to help consumers make informed and appropriate choices about supplement use. The template represents common ideas from a broad group of stakeholders and is intended to be a framework that government officials, consumer groups, industry representatives, academics, and others can use as they seek to find common ground on the specific content and presentation of labels.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

# PRIMER ON DIETARY SUPPLEMENT LABELS

## What is a Dietary Supplement?

The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines the term “dietary supplement” to mean “a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the aforementioned ingredients.” Furthermore, a dietary supplement must be labeled as a dietary supplement and be intended for ingestion and must not be represented for use as conventional food or as a sole item of a meal or of the diet. In addition, a dietary supplement cannot be approved or authorized for investigation as a new drug, antibiotic, or biologic, unless it was marketed as a food or a dietary supplement before such approval or authorization. Under DSHEA, dietary supplements are deemed to be food, except for purposes of the drug definition.

## What is a Dietary Supplement Label?

A ‘label’ is a display of written, printed, or graphic matter upon the immediate container of any article. In contrast, ‘labeling’ is a more general term that includes the label and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying the article.

## What is Currently Required on a Dietary Supplement Label?

DSHEA and other federal regulations require the following information to appear on dietary supplement labels:

- a statement of identity that contains the words “dietary supplement.” The word “dietary” may be replaced by the name of the dietary ingredient (e.g., “ginseng supplement”);
- net quantity of contents (e.g., “60 capsules”);
- nutrition information in the form of a “Supplement Facts” panel, including the product serving size, the amount, and percent daily value, if established, of each dietary ingredient;
- if a supplement contains a proprietary blend, the net weight of the blend as well as a listing of each ingredient in descending order of weight must be identified;
- the part of the plant used, if an herb or botanical;
- the name and place of business of the manufacturer, packer, or distributor;
- a complete list of ingredients by their common or usual names, either in descending order of prominence or with the source of the dietary ingredient in the “Supplement Facts” panel following the name of the dietary ingredient (e.g., calcium (from calcium carbonate));
- safety information that is considered “material” to the consequences that may result from the use of the supplement; and
- the disclaimer “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease” if the supplement bears a claim to affect the structure or function of the body (structure/function claim), a claim of general well-being, or a claim of a benefit related to a classical nutrient deficiency disease.

At their discretion, manufacturers may add additional information on labels (such as claims and statements of quality assurance), and may decide on the placement of that information on their labels.

## Who Oversees Dietary Supplement Labels?

The Food and Drug Administration (FDA) is the federal agency primarily responsible for regulating dietary supplements and their labels. FDA regulates supplements in a post-market system, meaning manufacturers are allowed to market supplements without prior authorization. FDA has the burden of proof to show that a supplement presents a significant or unreasonable risk of illness or injury if taken as instructed on the label, or is otherwise adulterated. FDA also has the burden of proof to show that label information is misleading or not true. To establish proof, FDA conducts field exams, tests supplement ingredients, and reviews label claims. As necessary, FDA may take actions through courtesy letters, warning letters, recalls, seizures, and injunctions.

# FINDINGS

We found that few dietary supplement labels in our sample met the elements identified in our template, which was designed to help consumers make informed and appropriate choices about supplement use. Important information related to ingredients, intended use, safety, and directions for use was often incomplete, inconsistent, or missing for supplement labels in our sample. Labels also often failed to present information in a manner that facilitates understanding among consumers. No standardized format exists for labels, and labels have few distinguishing features to help consumers differentiate supplements from other self-care products.

We drew on several sources of data for this analysis. To assess the extent to which existing labels adhere to the elements identified in our template, we performed an original analysis of 100 products that consumers recognize as dietary supplements and commonly use. The template is detailed in our companion report *Dietary Supplement Labels: Key Elements* (OEI-01-01-00120). We supported those findings with 76 stakeholder interviews with regulators, industry representatives, and consumer groups, as well as 7 focus groups with consumers and health professionals. We also reviewed relevant literature, laws, and regulations, including congressional testimony, FDA consumer studies, and national survey data on supplement use.

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## Dietary Supplement Labels Fail to Adhere to the Key Elements in Our Template.

Consumers need accurate and sufficient information on labels to make informed and appropriate choices about supplement use. This is particularly important, given the widespread use of dietary supplements as self-care products, and the relative lack of other reliable sources of information.

In our companion report entitled *Dietary Supplement Labels: Key Elements* (OEI-01-01-00120), we presented the template of the key elements of a label that can help consumers make informed and appropriate choices about supplement use. (see box for a list of those elements.) We used the current federal requirements for supplement labels as a starting framework. We then incorporated the feedback from our interviews, focus groups, and literature reviews. The template sets forth a framework for key

Template of Key Label Elements	
<u>Content</u>	<u>Presentation</u>
✓ Ingredients	✓ Standardized format
✓ Intended use	✓ Distinct product features
✓ Safety information	✓ Readability
✓ Directions for use	✓ Balance
✓ Product information	✓ Constructive use of space

label elements in terms of essential information and precepts for presenting that information. In this report, we assess the extent to which existing dietary supplement labels reflect the key elements identified in our dietary supplement label template. When our assessment applies primarily to one type of supplement, we note it in the text. We organize our review by template element (see Appendix A for a complete description of the template).

## **Labels Often Fail to Provide Sufficient Information to Guide the Informed and Appropriate Use of Supplements.**

We found that supplement labels routinely lack information or contain confusing information in four areas of our template: ingredient composition, intended use, directions for use, and safety information. Our label review, focus groups, and interviews with key stakeholders raised few concerns related to a fifth element: product information.

### **Ingredient information is often difficult to interpret.**

Supplement labels ought to provide accurate and sufficient detail about supplement composition for users to understand exactly what they are taking. Without such information, consumers may be putting their health at risk by overdosing on certain ingredients, or they may be spending money on supplements that are not formulated to meet their needs.

#### ***Labels with testing guarantees often give misleading assurances of ingredient quality.***

In our review of 100 labels, we found several labels containing their own symbols and statements guaranteeing ingredient testing and quality. These guarantees often appear to be misleading, indicating no clear basis of what supports them (see box for examples). One health provider told us that when she called a company to determine their standardization criteria, a company representative told her “the company standardizes its products to excellence.” A number of the regulators and health professionals we spoke with raised concerns that such statements and symbols can mislead consumers.



***Labels often do not clearly distinguish active ingredients from inactive ones.*** Ninety-three out of the 100 labels we reviewed did not make clear which ingredients were active. Some of the labels contained discussion about active properties, but it was difficult to determine whether this was marketing hype or factual information. DSHEA does not require dietary supplement labels to make clear which ingredients are active. Without being able to distinguish the active ingredients from the nonactive ones, it can be difficult

for consumers to assess products' content and to compare supplements in an informed manner.

Furthermore, 94 of the labels we reviewed did not make clear the extent to which ingredients could be absorbed into the bloodstream (bioavailability). A few labels alluded to bioavailability, disintegration, or time release, but did not make clear to what extent the ingredients were available for absorption. DSHEA does not require dietary supplement labels to make clear the extent of bioavailability of ingredients. Without this information, consumers and health care professionals cannot readily assess product efficacy or the potential for adverse reactions. The bioavailability of a supplement may depend on the form in which a supplement is taken. For example, the bioavailability of an ephedrine extract is far greater than the bioavailability of the unprocessed herb.

***Ingredient names may be inconsistent across supplement labels.*** This is particularly problematic for botanical supplements, which account for a quarter of dietary supplement sales.<sup>6</sup> FDA labeling regulations for herbal supplements require that ingredients be listed under their Latin binomial names, except when they are listed in the *Herbs of Commerce*.<sup>7</sup> However, even the *Herbs of Commerce* contains multiple common names in some instances. One commonly cited example relates to products containing ephedra. The species *Ephedra equisetina* may be called Chinese jointfir, ma huang, ephedra, or Chinese ephedra. A second species, *Ephedra nevadensis*, may be referred to as Mormon tea, Brigham-tea, or desert tea. Similarly, *Echinacea angustifolia* may be listed as echinacea, narrow-leaved echinacea, Kansas snakeroot, or narrow-leaved purple coneflower. Consumers may be unaware of the existence of multiple common names, and may end up purchasing several products containing the same ingredients. In fact, one of the health professionals in our focus groups shared a story of a patient who was taking three different weight loss supplements without realizing that all three contained Ephedra, thus putting herself at a potential risk for overdose.

***Supplement Facts panel may be of limited usefulness to consumers.*** The Supplement Facts panel provides important ingredient information, including the recommended serving size and the corresponding percent daily value. Many of the regulators, consumers, and health professionals we interviewed told us that the uniform format of the Supplement Facts panel has been very effective as a means of standardizing information

consumers to more easily find and compare ingredient information.

However, many of these same interviewees raised concerns about the usefulness of the Supplement Facts panel. They pointed out that the format of the panel makes little sense for botanical and specialty substances, which do not have established Referenced Daily Intakes (RDI) or Daily Reference Values (RDV) (see box to right). Moreover, some nutritionists and health care professionals we spoke with questioned the current RDI for vitamins and suggested that quantities greater than the 100 percent of the RDI may be beneficial when these products are taken for therapeutic purposes.

The Percent Daily Value column makes little sense for botanical supplements:

Supplement Facts	
Serving Size 2 Tablets	
Amount Per Serving	% Daily Value
St. John's Wort ( <i>Hypericum perforatum</i> )(root) (Standardized for 3% hypericin)	400 mg *
Citrus Aurantium ( <i>Synephrine</i> )(Fruit)	600 mg *
5 HTP ( <i>Griffonia simplicifolia</i> )(10% 5HTP=15mg)	150 mg *
Yerbamate ( <i>Ilex paraguayensis</i> )(leaves) (supplying 20% methyizantine)	250 mg *
Natpirin ( <i>White Willow Brook</i> )(bark)	400 mg *
*Daily Value not established	

Other Ingredients: calcium phosphate, cellulose, magnesium stearate, silica, stearic acid.

contains a unique combination of safe herbal extracts, to aid in dietary disciplines.

**Labels often do not provide information about the quantity of individual ingredients in “proprietary blends.”** DSHEA requires that proprietary blends (in which the supplement formulation is privately-held) declare on the label the net weight of the blend and list the ingredients in descending order of weight. The labels are not required, however, to list the specific quantities of each individual ingredient. None of the 15 supplements containing proprietary blends that we reviewed during our inquiry disclosed any information about the amount of individual ingredients.

Limited disclosure of ingredient information in ‘proprietary blends’:

Supplement Facts	
Serving Size 1 Caplet	
Servings Per Container 90 Caplets	
Amount Per Caplet	% Daily Value
Vitamin E (as dl-alpha-tocopheryl acetate).....6 I.U.	20%
Magnesium (as Magnesium Citrate).....25 mg	10%
Zinc (as Zinc Chelate).....5 mg	33%
Chromium (as Chromium Picolinate).....75 mcg	52%
Proprietary Blend.....728 mg.....*	
Guarana (seed), Ephedra (Ma Huang) extract (ephedrine group alkaloids) (aerial part), Box Pollen, Siberian Ginseng (root), Ginger (root), Licit in, Bovine Complex, Damiana (leaf), Sarsaparilla (root), Codonopsis (aerial part), Nettle (leaf), Gotu Kola (aerial part), Spirulina, Piyajal Jelly	
*Daily Value not established	

Other Ingredients: Citric acid, glycerine, caffeine, croscarmellose gum, protein hydrolysate, silica, modified cellulose, magnesium stearate, dextrin, dextrose, sodium hydroxide, croscarmellose gum, sodium citrate, ascorbic acid.

Yet, information about the quantity of specific ingredients can be important for supplements that contain pharmacologically active substances, such as St. John’s Wort or Ephedra. As blended products become an increasing segment of the herbal market, concerns about the lack of disclosure for the amount of individual ingredients becomes more pressing (see box to left). The propriety blend provision was initially written into FDA label regulations to protect proprietary recipes in an environment in which there is no patent protection. However, several interviewees raised concern that the proprietary blend provision is specifically being used by some manufacturers to avoid full disclosure of ingredients.

**Statements of intended use often provide limited information.**

FDA label regulations do not require that supplement labels contain information about the intended use of the supplement, although they do allow manufacturers to make certain types of claims about the supplement’s benefits. Many manufacturers use structure/function claims, health claims, or qualified health claims to communicate to consumers the intended use(s) of their supplements.

Structure/function claims are statements that a supplement will affect the body’s structure (such as the skeletal system) or one of its functions (such as circulation). These claims were first permitted on dietary supplements for non-nutritive purposes by DSHEA. These claims must be accompanied by a disclaimer (see box to right).

**The disclaimer required to accompany structure/function claims:**

“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”

A health claim is a statement that expressly or by implication characterizes the relationship of a nutrient in a supplement to a disease or health-related condition. These claims were permitted on dietary supplements under the Nutrition Labeling and Education Act of 1990. No disclaimer is required to accompany a health claim.

A qualified health claim is similar to a health claim in the statements it can make, but is more tentative in its tone and may be required to be accompanied by a disclaimer. Qualified claims have only recently been permitted on dietary supplements as result of court cases.

***Structure/function claims often do not clearly communicate intended use.***

Structure/function claims constitute the vast majority of all claims on supplements, with as many as 12,000 supplements making a structure/function statement (see box to left for examples). A

**Typical structure/function claims found on dietary supplements:**

- “Promotes well-being”
- “Cerebral circulation”
- “Supports joint function”
- “Promotes fast and accurate thinking”
- “For bone health”
- “May support women’s needs”

number of our interviewees, including health professionals, consumer groups, and industry representatives, raised concerns that structure/function claims are often worded in a confusing way, and in many cases are too general to be meaningful. They highlighted the fact that vague wording could lead to inappropriate use of the supplements.

During our review of supplement labels we found the claim of “promotes well-being” on Ginseng, Echinacea, SAMe, and St. John’s Wort supplements. This statement, which is characteristic of the way in which structure/function claims are worded, does not disclose the ways in which the supplements promote well-being, the aspects of well-being targeted by the supplements, or the conditions under which the supplements should be taken. Furthermore, consumers may mistakenly think that St. John’s Wort, Echinacea, SAMe, and Ginseng supplements with the same claim are interchangeable, when in fact they are not.

***Health claims and qualified health claims may also be of limited value to consumers.***

Currently, there are 19 authorized health claims for dietary supplements. Although the consumers and health professionals in our focus groups liked the specificity of health claims and qualified claims, they did not find them to be user-friendly. The length of the claims and complexity of the language made it difficult for them to understand the underlying message. The tentative tone of the claims further obscured the underlying message. Consumers in our focus groups expressed more confidence in the shorter, more direct statements in structure/function claims, and stated that they were likely to ignore health claims and qualified health claims.

Our focus group participants raised two major concerns about the authorized health claim for calcium and osteoporosis (see box). First, they were confused as to why the claim singled out benefits to certain groups (i.e., teens and young adult Caucasian women) and not others. It was not clear to them whether products carrying this claim would be beneficial to consumers of other ages and races. Second, many of consumers and health professionals in our focus groups were concerned by the word ‘may,’ because they believed that it detracted from the certitude of the statement.

**Authorized Health Claim Found on Calcium Products:**

“Regular exercise and a healthy diet with enough calcium helps teen and young adult Caucasian women maintain good bone health and may reduce their risk of osteoporosis later in life.”

**Recently Authorized Qualified Health Claim for Omega-3 Fatty Acids:**

“It is known that diets low in saturated fat and cholesterol may reduce the risk of heart disease. The scientific evidence about whether omega-3 fatty acids may reduce the risk of coronary heart disease (CHD) is suggestive, but not conclusive. Studies in the general population have looked at diets containing fish and it is not known whether diets or omega-3 fatty acids in fish may have a possible effect on a reduced risk of CHD. It is not known what effect omega-3 fatty acids may or may not have on risk of CHD in the general population.”

Currently, there are three authorized qualified health claims. Our focus group participants’ primary concerns about the qualified claim for omega-3 fatty acids and coronary heart disease (see box) centered on the seemingly contradictory language of the claim. For example, the health professionals were concerned that a long statement of potential evidence followed by a statement beginning “It is not known” would seem contradictory to consumers. They also believed that terms, such as “suggestive but not conclusive,” might confuse consumers.

***Consumers and health professionals often have difficulty differentiating between health claims and structure/function claims.*** We found that none of the consumers and health professionals in our focus groups were able to distinguish between health claims and structure/function claims. FDA found similar results in the nine consumer focus groups it conducted.<sup>8</sup> The presence of the FDA disclaimer may help consumers distinguish between structure/function claims and health claims because a health claim does not require a disclaimer. However, neither the consumers nor the health professionals in our focus groups could make the link between the disclaimer and the presence of a structure/function claim.

Moreover, in its review of dietary supplement claims, the General Accounting Office suggested that consumers may incorrectly equate products claiming to maintain health (structure/function claims) with products claiming to reduce the risk of disease (health claims), and thus may attempt to treat a disease with a product not capable of producing that benefit. If consumers do not appreciate the difference in the amount of regulatory oversight for each type of claim, they cannot factor information about the credibility of a product's claim into their purchasing decision.

***Auxiliary statements on labels may lead to false expectations about the purposes or efficacy of supplements.*** In our review of 100 supplement labels, we found 12 that claimed to be scientifically tested. While "clinically tested" or "scientifically proven" may be a valid claim, it also has the potential to mislead consumers into thinking that a supplement has been tested in a pre-market fashion akin to prescription drugs, and thus may create a false perception of proven safety and efficacy. FDA's focus group research found that some consumers believe that supplement manufacturers conduct controlled clinical trials to test the efficacy of specific supplements, when in fact few do. Many of the health professionals and consumer advocacy groups we spoke with believed that, if manufacturers were going to put such statements on their labels, they should include information on the type of trial conducted and the dose used during the clinical trial. However, of the 12 labels, which claimed to be clinically tested or scientifically proven, 9 did not provide a reference for the research claimed.

***Many supplements lack any type of claim, and thus provided no information to consumers on the purposes of the supplement.*** FDA estimates that there are 29,000 supplements on the market. Yet, FDA has authorized only 19 health claims, and received notification letters for almost 12,000 structure/function claims since the passage of DSHEA. Based on these numbers, it appears that many labels contain no claims. In fact, in our sample of 100 supplements, 31 did not provide any information to the consumer on the purpose of the supplement. Since there are no approved mechanisms for communicating intended use on a label other than claims, this suggests that a large number of supplements may not communicate the supplement's purpose(s). Such information may be particularly important for those supplements that have no clear nutritive value.

## Safety information is often incomplete.

While the vast majority of supplements appears to be safe within a broad range of intake, some supplements can have adverse effects. Because consumers are typically taking supplements on their own initiative and often in combination with other products, it is essential that they have enough safety information to take supplements in an informed and appropriate manner.<sup>9</sup>

***Many labels provide insufficient information on maximum doses.*** Eighty-five of the 100 labels we reviewed did not contain a clear statement about maximum dose. Such information is critical for supplements which, if taken in large doses, could have harmful effects. For example, research studies have shown that doses greater than 10,000 IU of vitamin A are associated with birth defects,<sup>10</sup> yet few bottles containing a supplement with vitamin A provide information on maximum dose.

Exceeding the recommended dose could potentially present a significant public health problem. *Prevention* magazine extrapolated from the results of a recent survey and estimated that about 7.3 million consumers of vitamins and minerals, 4.5 million consumers of herbal remedies, and 3.8 million consumers of specialty products take more than the amount recommended on the label.<sup>11</sup> Overdosing is of particular concern for consumers who are taking supplements to treat or prevent medical conditions.

***Many labels provide insufficient information about the medical conditions or populations for which the supplement may be contraindicated.*** Sixty-one of the 100 labels we reviewed did not mention specific contraindications. The cautions for particular populations on the remaining products greatly varied in the scope and specificity of the information they conveyed. We found this variability even among supplements containing identical ingredients in identical doses, which clearly have equivalent safety risks (see box).

### **Precautionary Information on 60 mg Ginkgo Biloba Supplements:**

**Supplement 1:** “If you are taking a prescription medicine, such as an anticoagulant agent, are pregnant or are lactating, please contact your doctor before taking this product.”

**Supplement 2:** “If you are taking medication, facing surgery or have bleeding problems, consult your physician before taking this product.”

**Supplement 3:** No information given.

Many of our interviewees, especially the health professionals and consumer advocates, were particularly concerned about the lack of warnings on supplements for women who are pregnant or nursing. They believed that, unless studies have proven supplements to be safe for women who are pregnant or nursing, labels should automatically contain a precautionary statement. Seventy-one of the 100 labels we reviewed did not have such a statement. Others expressed concern about the lack of specific

warnings for the elderly, who metabolize chemical substances more slowly, and for children, who may need to take smaller doses or should avoid use of supplements completely. None of the supplement labels we reviewed contained cautions for the elderly and only 13 mentioned special considerations for children. FDA has recently declared its intent to propose a rule requiring the inclusion of warning statements for women who are or may become pregnant.

***Many labels provide insufficient information on potential interactions with other supplements, over-the-counter drugs, or prescription drugs.*** Eighty-seven of the 100

labels we reviewed did not list interactions with other products. When they did, we found great variability in the information provided about interactions. For example, the SAME products we reviewed, all containing 200 milligrams, contained various levels of detail about interactions (see box). Given the wide variability in information provided and terminology used, it is not surprising that consumers have difficulty finding information on interactions.<sup>12</sup>

According to *Prevention* magazine, nearly a third of consumers report taking supplements in combination with prescription drugs or with over-the-counter (OTC) medicines, which suggest an important place for information on interactions on the label.<sup>13</sup>

**Precautionary Information on SAME 200 mg Supplements:**

**Supplement 1:** “If you are pregnant, breastfeeding or are taking antidepressant medication, consult your physician before using this product. Take this product under medical supervision if you have a bipolar disorder.”

**Supplement 2:** “Persons who have a health condition should consult with a health care professional before using this product.”

**Supplement 3:** No information given.

***Many labels provide insufficient information on potential adverse reactions or side effects that consumers may experience.*** Eighty-nine of the 100 labels we reviewed did not list possible adverse reactions or side effects. Yet, the Dietary Supplement Education Alliance states that “side effects are possible with any dietary supplement.”<sup>14</sup> This lack of information on the label means that consumers may not know if a symptom they are experiencing should be anticipated, or whether it is one that should alert them to discontinue use and seek care from a qualified health professional. This may compromise consumers’ ability to make an informed choice about what supplements are appropriate for them.

In the 11 cases where the labels did contain information on potential adverse reactions or side effects, they often failed to provide information on whom to contact in case of an adverse event. Seven of those 11 labels did not carry language calling for consumers to contact a health professional in case of accidental ingestion/overdose. None of the 11 supplements carried FDA’s Medwatch phone number for consumers to alert FDA of any serious reactions or problems they may experience in taking a supplement. Yet, according to *Prevention* magazine, 12 percent of herbal consumers (about 11.9 million people) and 13 percent of specialty product users (about 6.5 million people) say they have experienced a side effect or adverse reaction.<sup>15</sup>

***Many labels lack information on supplement expiration.*** Twenty-five of the 100 labels we reviewed did not have an expiration date. Of the 75 labels that did include expiration dates, 15 were smudged, faint, or otherwise hard-to-read, making it difficult for consumers to find and to read this information.

There was some disagreement among the stakeholders that we interviewed about the significance of the lack of expiration dates on supplements. Some pointed out that an expiration date can provide important information about the extent to which a supplement maintains its labeled potency, purity, and physical characteristics. Without an expiration date, it would be impossible for consumers to determine whether a supplement is still potent. Others believed that while an expiration date is theoretically important, it is of limited value on supplements because no uniform method exists for determining the expiration date. In fact, one FDA official told us that some manufacturers put expiration dates on supplements for marketing purposes, to give supplements “an aura of respectability.” In such a case, the existence of an expiration date is not only misleading to consumers, but may also be meaningless.

**Directions for use are often insufficient.**

While DSHEA allows for supplement labels to contain information about the “directions or conditions of use,” this information is not required. The only information that must be present on labels is a recommended serving size, which is defined as the “amount recommended for consumption per an eating occasion.” There is no requirement that labels disclose the number of servings necessary to achieve the claimed benefit, or under what conditions those servings should be taken to achieve maximum effectiveness. As a result, labels often lack sufficient information about how and when consumers should take supplements to achieve the benefits claimed on the supplement label.

***Dosage information is often unclear.*** There is great variability in the directions for use, and how that information is communicated on supplement labels. Several factors account for the confusion. First, the serving size and recommended daily dose need not be the same. Labels are not required to make clear the number of servings necessary to consume an effective daily dose. Second, locating information about the directions of use can be difficult. While the serving size is prominently displayed as part of the Supplement Facts panel, information on additional directions for use is usually buried in the label. While 99 of the 100 supplement labels that we reviewed did contain a section on directions for use, in many cases it was difficult to find.

Variability in the disclosure of dosage information has a number of implications for the informed and appropriate use of supplements by consumers. It makes comparison shopping for supplements difficult, as it requires consumers to multiply (or divide, depending on the instruction) the serving size by the recommended number of occasions for supplement intake in order to understand the total daily dose that they are consuming. It can also contribute to noncompliance. Consumers may not understand that they have to take multiple pills to get the desired effect. Furthermore, if consumers switch supplement brands, they may not be aware of a change in dose or intake pattern.

Finally, sometimes dose information is described in relation to an effect on the structure or function of the body, but the boundaries of that symptom may not be clear. In our review of directions for use for 100 labels, we found 8 products in which the dosage depended on the severity of the condition. Yet we could not find definitions for the terms used on the label, such as “severe memory loss,” “individual needs” and “intensive use,” to differentiate between doses (see box).

***Many labels do not specify a minimum amount of time for which the product should be taken before consumers can expect to see an effect.***

Ninety-five of the 100 labels we reviewed did not list the minimum duration of use. Furthermore, the 8 mini-packages in our collection

(which contained only one serving each) did not make clear to consumers that multiple servings of the supplement would be necessary to achieve the label claims. Unlike most over-the-counter drugs, which start working in a matter of minutes, dietary supplements such as St. John’s Wort or Saw Palmetto may take up to 6 weeks.

However, many consumers do not understand that supplements often take longer than prescription and OTC drugs to take effect, and may stop supplement use within a month of taking a supplement if they do not see results.<sup>16</sup> In fact, a recent study by the Dietary Supplement Education Alliance found that one in five consumers erroneously believes supplements produce a benefit within a week.<sup>17</sup>

## **Labels Often Fail to Present Information in a Manner that Facilitates Consumer Understanding.**

To help consumers make informed and appropriate choices about supplement use, a dietary supplement label should not only have adequate information but also present that information in a way that facilitates consumer understanding of the supplement. FDA recognized the importance of label presentation when it revised food labels in 1993 and OTC labels in 1999.

However, neither DSHEA nor other federal regulations address label presentation for dietary supplements, except in requiring a Supplement Facts panel and the word “supplement” on the front panel of the label. With few federal guidelines on label presentation, manufacturers print and organize label information in a variety of ways. This can lead to great innovation on the part of manufacturers, but it can also add to consumer confusion and difficulty in finding important label information.

### **Dose Information Can Be Confusing:**

#### *Supplement A (Memory Enhancing Supplement)\**

- To maintain memory function, take 1 or 2 capsules daily.
- To enhance memory function, intake can vary depending on individual needs and may be increased up to 6 capsules daily.
- For severe memory loss, consult your physician.

#### *Supplement B (for Improving Mental Sharpness)*

- Take one tablet twice daily.
- For intensive use, take up to two tablets twice daily.

\* The following information was listed on the package insert; the label referenced this insert.

**No standardized format exists.**

In designing supplement labels, manufacturers may follow many different formats, use varying terminology, and sometimes even provide inconsistent information, even across similar substances. The lack of a logical and systematic framework for presenting label information may make it difficult for consumers and health professionals to locate and read important information and to select the most appropriate supplement.<sup>18</sup>

**Information placement often varies.** In our review of 100 supplement labels, we found that safety information did not have a consistent position in relation to the front panel. Of the 26 supplements sold in boxes, 9 had safety information on the back panel, 3 on side panels, and 14 did not have the information at all. Of the 66 supplements sold in bottles, 13 had safety information to the right of the front panel, while 14 had the information to the left. We found similar inconsistencies in the placement of directions for use information: 32 had the information listed above the Supplement Facts panel, 17 below, 17 to the right, 5 to the left, and 28 on the opposite side. With such inconsistent placement of information, consumers may find it difficult to locate the information they need. For example, when asked to identify and read aloud claims, safety information, and standardization symbols and statements, participants in our focus groups spent several minutes looking at the label, often needing assistance finding the information or having to read through the entire label first.

**Headings for identifying information are often inconsistent.** Headings can provide important visual clues to help consumers quickly distinguish between different types of information. In its proposed OTC label revisions, FDA identified uniform headings and subheadings as one of three contributing factors to the readability and understanding of labels. However, in our review of 100 supplement labels, we found several different headings that referred to similar information (see box). Of the 44 labels that disclosed safety information, 9 did not have a heading to draw attention to that information, and 4 included that information in the section on directions for use.

<b>Directions for use and safety information can have many different headings on supplements labels:</b>	
<i>Directions for use:</i>	<i>Safety:</i>
1. Recommendation(s)	1. Warning(s)
2. Recommended Dose(age)	2. Note
3. Recommended Adult Intake	3. Caution
4. Suggested Use	4. Precaution
5. Directions for Adult Use	

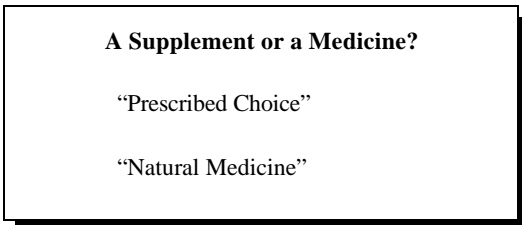
**Supplement labels had few distinguishing features.**

In its 1997 label regulations, FDA aimed to distinguish supplements from other products through requiring the title “Supplement Facts” for the nutrition panel and the word “supplement” on the front panel. However, these measures may be insufficient in distinguishing supplements from other self-care products, given the proximity of supplements to other types of self-care products. First, supplements are often placed near

OTC drugs, homeopathic products, and functional foods in stores. Second, some supplements share similar ingredients with these products; for example, both senna and cascara can be sold as an herbal supplement and as an OTC drug.

***Supplement claims are often indistinguishable from OTC claims.*** In its final rule for structure/function claims, FDA allowed supplement labels to contain claims previously authorized for OTC drugs as long as the labels carried the mandatory FDA disclaimer and otherwise met the requirements set forth in DSHEA. For example, supplements for motion-sickness can carry a structure/function claim “for the prevention and treatment of nausea, vomiting, or dizziness associated with motion,” and supplements to promote sleep can carry a structure/function claim “for the relief of occasional sleeplessness.” However, as discussed earlier in the report, the FDA disclaimer does little to alert consumers to the presence of a structure/function claim. Unable to distinguish between supplement structure/function claims and OTC claims, consumers may believe that OTC drugs and supplements are interchangeable.

***Language and illustrations on supplement labels may be suggestive of pharmaceutical products.*** In our review of 100 supplement labels, we found statements that the supplement is “sold through physicians’ offices and pharmacies,” or is “doctor recommended.” Some



supplement labels contained pictures of people wearing physician lab coats and stethoscopes. Some supplements also had company names and trademarks that sound like they could be pharmaceutical products (see box). We also found a few supplements made by well-known pharmaceutical companies, which might lead consumers to believe that supplements are the

same as pharmaceutical products. While such practices may be technically allowed under FDA regulation, our interviewees raised concerns that they may lead to false expectations. Supplements bearing structure/function claims are expressly not intended to diagnose, treat, cure, or prevent any disease.

**Complex language and small font size inhibit readability.**

Certain users of supplements may benefit from visual cues that highlight important information and from simple language that increases readability. This may be particularly true for elderly consumers and nonnative English speakers. However, we found that many supplement labels lacked visual cues and used complex language, preventing a broad range of consumers from easily reading and understanding label information.

***Font size is often inadequate for many consumers.*** Federal regulations allow manufacturers to use a minimum 4.5-point type size on supplement labels. By contrast, FDA determined that a 4.5-point type size for OTC drugs was too hard to read by consumers, especially those over 51 years old, and thereby mandated a minimum 6-point

type size. Many of the elderly consumers in our focus groups complained that they had difficulty reading supplement labels due to their small font size; some participants recounted bringing a magnifying glass to the store to ensure that they could adequately read the label. When asked to read supplement labels, several health professionals in our focus groups also had difficulty.

***Some supplement labels use complex language.*** We found that some consumers in our focus groups were unable to pronounce and understand safety information printed on supplement labels. These consumers expressed confusion over medical terminology such as “anticoagulant,” and preferred safety information to be in simple language. One participant said that claims, like the FDA-approved qualified claim for omega-3 fatty acids, are too “wordy,” discouraging consumers like him from reading the label. A few pharmacists in our focus groups also told us about patients asking them to “translate” the label information into more readable language.

**Information on benefits and risks is often imbalanced.**

Federal laws and regulations do not formally require a supplement label to balance negative and positive messages. However, FDA does require supplement manufacturers to print certain factual information and to disclose “material facts.” But, because FDA has yet to define the material facts provision, industry representatives told us that supplement manufacturers have varying criteria for disclosing safety information, contributing to the imbalance of label information.

***Limited space given to risks.*** Thirty-eight of the 69 supplement labels in our sample had statements about a supplement’s potential benefits but did not disclose any safety information. Of the supplements that provided safety information, most used fewer lines for the safety information than for the product’s benefits, and a few used smaller fonts. Industry representatives we interviewed said that supplement labels play a major role in marketing, and raised concerns that without federal standards for required safety information manufacturers may inconsistently highlight the value and benefits of supplements over risks or special considerations.

**Websites referenced on labels may not provide consumers with accurate information.**

Given the limited space on supplement labels, many manufacturers reference Internet websites on their labels as a source for additional information. In our review of 100 supplement labels, we found that 45 labels contained website references. The Internet is an emerging source of health information, with potential to provide more information about supplements beyond the label. Many of the consumers and health professionals in our focus groups told us that they perceived website references as useful ways to get additional information.

*Some websites contain inaccurate and misleading information.* The Federal Trade Commission, in partnership with FDA and other government agencies, has found that “examples of questionable products being peddled on the Web abound.”<sup>19</sup> These agencies discovered over 200 websites fraudulently claiming that dietary supplements and other products could treat illnesses like anthrax.<sup>20</sup> Between October 1999 and August 2001, FTC received over 20,000 hits from consumers accessing its health-related “teaser” Websites that mimic sites that the agency has found to provide fraudulent information. A 2001 General Accounting Office report also highlighted how Websites that sell supplements geared to the elderly may use misleading and inaccurate claims.<sup>21</sup>

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## **Several Factors Inhibit Supplement Labels From Adhering to Our Template.**

### **Lack of clearly defined FDA standards.**

Supplement manufacturers conduct business in a highly competitive marketplace. Discount retailers, pharmacies, and grocery stores have begun to manufacture their own brands of dietary supplements, and to form partnerships with Internet companies to market supplements. Pharmaceutical companies have also entered the supplement industry, using their established brand names in prescription drugs as a marketing advantage in selling supplements.

In this environment, uniform standards that delineate a baseline of acceptable label practices are vital in ensuring that both well-established and new manufacturers label their supplements accurately and consistently. Without such standards, manufacturers do not have the tools to create or sustain a level playing field. Below we identify three key areas where standards are lacking.

*No guidance on what constitutes a material fact.* The federal Food, Drug, and Cosmetic Act requires manufacturers to disclose on the label “facts material...to consequences” that may result from taking a supplement. FDA stressed the importance of the material facts provision in its structure/function final rule, and listed clarification of the material facts provision as a B-list priority in the Center for Food Safety and Applied Nutrition’s (CFSAN) 2001 Program Priorities. However, FDA has not taken steps to determine the level of evidence necessary for a safety risk to become a material fact, what supplements currently fall under the material fact provision, and what language may be used on the label to describe the material fact. Manufacturers acknowledge that FDA makes efforts to alert the public and industry of harmful products through its website and letters to industry and health professionals, but criticize these efforts as not being enough to ensure consistent labels.

Without a publicly articulated policy by FDA, manufacturers do not operate on a level playing field. Manufacturers told us that, without written guidelines, they have few ways to determine which products fall under the material facts provision. While a number of manufacturers put warning information on their labels in response to public concerns,

they voiced concern that too many warning statements on labels would overwhelm consumers, causing them to ignore the safety information altogether.

To further complicate matters, a number of states have begun to require warning statements for certain supplements. For example, Texas requires warning statements for supplements containing the stimulant ephedra, and California requires warning statements on supplements containing dieter's teas. In recent months, a number of other states and localities have considered requiring warning statements for products containing ephedra. Many interviewees, particularly industry representatives, raised a concern that variations in state warnings can cause confusion among consumers and frustration for manufacturers. For example, Texas requires specific warning language on ephedra supplements and requires that manufacturers list FDA's toll-free Medwatch telephone number on the label. By contrast, the State of Ohio does not have a required warning statement for ephedra supplements. It does, however, require a number of other pieces of information to appear on the label, such as a maximum recommended dose. The Texas warning is silent on the issue of maximum dose for ephedra supplements.

In 2001, the Federal Trade Commission (FTC) took six enforcement actions against individual companies making unfounded claims on the Internet. As part of the settlement, the FTC required two companies promoting the herb St. John's Wort and one manufacturer of ephedra to disclose warnings of potential interactions on their labels, advertisements, and promotional materials. It is significant to note that FTC's required warning statement for ephedra differs from the ones required by most states. For example, the FTC statement mentions risk of injury that "may include heart attack, stroke, seizure, or death," whereas the warning in Texas only requires that the supplement "may cause serious adverse health effects." Yet, a number of manufacturers told us they are concerned that FTC's actions may cause confusion, as some manufacturers may interpret FTC's actions as applying to entire categories of products, when in fact they only apply to the offending companies.

Both industry and consumer groups have called for FDA to define material facts and to issue guidance or regulation accordingly. To fill this regulatory void, several of the larger trade associations have developed a list of ingredients that should carry safety information; all member companies manufacturing supplements containing these ingredients must carry the safety information on labels. While some non-member companies do adhere to these industry guidelines, others do not. The guidelines are voluntary and thus non-members have little incentive to follow them.

***No guidance on the evidence needed for substantiation files.*** Manufacturers are required to have substantiation for each structure/function claim made on a label. However, FDA has yet to define what level or type of evidence manufacturers should have even though it identified substantiation as a priority in CFSAN's Ten-Year Strategic Plan. In some cases, the substantiating evidence behind structure/function claims appears

to be quite weak. For example, at a FDA Dietary Supplement Stakeholder Meeting in July 1999, a participant noted that, when she asked manufacturers of chitin for documents substantiating their claims, “98% of [it] has nothing to do with the claim made. The other 2% has to do with animal research.”<sup>22</sup>

Given the variability in substantiation data, manufacturers told us it is difficult to achieve a level playing field. However, manufacturers also told us that they are reluctant to make substantiation data public because companies do not have patent protection for supplements. At the same time, manufacturers said that they would be more confident in the quality of the data if FDA reviewed substantiation files.

***No guidance on the use of terms and phrases of product quality.*** Neither FDA nor industry groups have defined what constitutes label claims, such as “pure,” “natural,” and “standardized,” and phrases, such as “clinically proven” and “doctor recommended.” Manufacturers are frequently printing these terms and phrases on supplement labels as a way to market their supplements. Often, symbols and stamps, such as a gold-colored emblem, accompany the terms and phrases to bring attention to the supplement’s quality claim. Our focus groups confirmed that such terms and phrases appeal to them and elicit an additional level of trust in the product. But, without uniform standards established by FDA or by industry groups, manufacturers cannot compare the quality of their products or hold each other accountable.

### **Few measures for ensuring product authenticity.**

***No official monograph system for supplements.*** Monographs can synthesize authoritative traditional and scientific literature on supplement properties, production, and use. Monographs may also provide information about health benefits and risk for individual ingredients as well as information on safe doses. Without official monographs for supplements, manufacturers lack uniform standards against which to produce and label supplements, resulting in a wide spectrum of supplement preparations and recommended uses.

In the absence of federally sanctioned monographs, organizations, such as the American Herbal Pharmacopeia, United States Pharmacopeia, and American Botanical Council, have published monographs on their own and are in the process of developing more. While these serve as important steps toward a more uniform standard of supplement production and use, a number of concerns are associated with these private efforts. The monographs are voluntary, do not cover the same information, and do not represent the vast number of herbal products on the market. The monographs are costly and resource-intensive to design and, without steady funding streams, it is difficult for any one organization to make significant progress. Further, manufacturers may find it difficult to follow monographs because their criteria may require special machinery and procedures, like meeting GMPs, that only a few manufacturers are able to afford.

***No validated testing methods.*** According to DSHEA, FDA can test dietary supplements only using established and officially accepted testing methods.<sup>23</sup> However, GMP regulations may not impose standards for which there is no current and available analytical methodology. As a result, neither FDA nor industry have adopted uniform methods of analysis for identifying and quantifying active constituents in botanicals and specialty supplements. Several organizations are trying to develop validated testing methods, but a lack of funding and cohesion hinder this costly and resource-intensive process. In part, efforts are slowed by the fact that many supplements work synergistically, and it is not clear what aspect of the supplements should be tested. A number of manufacturers have developed their own in-house validation procedures, yet there is little uniformity in how they test supplements.<sup>24</sup> This may be one explanation for why independent laboratory analyses of supplement labels often reveal a different amount of active ingredient than the one disclosed by the manufacturer on the label.<sup>25</sup>

### **Limited wording of claims.**

***Claims may not allow for clear communication of a supplement's intended use.*** FDA regulations for structure/function claims, health claims, and qualified health claims make it difficult for manufacturers to clearly express the health benefits of supplements.

Structure/function claims are limited because while they are allowed to describe health to the structure or function of the body, they cannot make references to any type of medical condition or illness. Structure/function claims cannot suggest that a supplement in any way treats, prevents, mitigates, or cures a disease. This creates a disconnect with the way consumers are using supplements, which is often for therapeutic benefit. A number of manufacturers we spoke with expressed frustration at having to use vague language so that their claim could meet the legal definition of structure/function claim.

While health claims and qualified claims allow manufacturers to make explicit statements about reducing the risk of disease, they may also be of limited value in communicating intended use to consumers. In an attempt to make the state of current knowledge about supplements clear, FDA may in fact further confuse consumers by authorizing statements that are too long and too complex to be useful. Some of the manufacturers we spoke with stated that the language on health claims and qualified health claims was not “user-friendly.” FDA officials told us they do not test either health claims or qualified health claims on consumers prior to authorizing them.

***Little incentive exists for manufacturers to seek health claims.*** Given the current claims structure, manufacturers are most likely to use structure/function claims to communicate a product's intended use. These are the easiest types of claims to make as they require no pre-authorization from the agency.

If a manufacturer sought to develop a new health claim for a supplement, it would need to conduct extensive research or gather secondary evidence in order to meet FDA's standard of "significant scientific agreement." One industry guidance estimated that manufacturers typically need to submit between 20 and 30 studies to FDA for review.<sup>26</sup> Yet the manufacturer will not receive any reward for investing in that research. Once FDA approves a health claim, any manufacturer may use it at no cost.

Manufacturers have a similar disincentive from seeking qualified health claims. At this point, manufacturers cannot seek a qualified health claim unless they have submitted a health claim, and it has been rejected for not meeting the principle of "significant scientific agreement." Getting a qualified health claim approved can take a long time, and may involve long legal battles with FDA over the acceptability of wording. FDA has not yet defined what constitutes an acceptable level of evidence to make a qualified health claim, and it is likely that further legal battles will ensue over this issue. As a result, many manufacturers are hesitant to seek qualified health claims. However, as these claims evolve, they may gain popularity in the future.

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## **Evidence Suggests that Consumers and Health Professionals Find Supplement Labels of Limited Use.**

### **Labels may be of limited use for consumers.**

Consumers look to labels for information about supplement safety and effectiveness, but often find labels of little use. They are particularly likely to read a supplement label the first time they purchase a supplement.<sup>27</sup> They look to the labels primarily for information on directions for use, intended use, ingredients, and warnings, such as side effects, interactions, and contraindications.<sup>28</sup> But, as we indicated earlier, this important information is lacking or has shortcomings, which may prevent consumers from using labels in an informed and appropriate manner (see box).

Even though consumers read labels, they appear to have limited

#### **Illustrative statements from our focus groups of older adults about the limited usefulness of labels:**

"Because they don't tell you anything about side reactions...I don't believe the label sometimes...I'm awfully timid about [trusting] it.

"Labels don't say what they do for you. They just say that [the supplement] has this and that and the other. But I don't know what this that and the other are! Because of that, I have to ask my doctor or pharmacist."

"It's a major feat to look at most labels...the print is so small...I don't know how older people are suppose to read them. I can't buy [supplements] unless I have my magnifying glass.

"We read the label...but we don't know enough to tell what is good or bad. We don't have the background to tell the difference."

confidence in the information that labels provide. According to a recent national survey by *Prevention Magazine*, the majority of consumers are not confident in the accuracy of information found on supplement labels. Only 32 percent of consumers who shop for herbal remedies reported that they were very confident in the accuracy of the labels, and only 34 percent of those who shop for vitamins and minerals reported that they were very confident. Furthermore, nearly half of those surveyed by *Prevention Magazine* did not believe or did not know if dietary supplements provide the health benefits that they claim.<sup>29</sup> Our focus groups pointed to mistrust of the label as one of the main reasons why consumers turn to other sources of information, such as newsletters, the Internet, and health professionals. Many of our focus group participants who had pre-existing medical conditions, like diabetes, recounted experiencing side effects and interactions that were not indicated on the label, which led them to no longer use the label as a primary source of information.

### **Labels may be of limited use for health professionals.**

Finding the label of limited usefulness, many consumers turn to other sources of information to decipher the label. Some rely on health professionals, such as physicians, pharmacists, nurses, and dietitians, to provide information about supplements and to advise them in taking supplements safely.<sup>30</sup> During focus groups, health professionals told us that they view labels as important, because they are one of the few easily accessible information sources that relate specifically to the supplements their patients take. They also told us that labels have the potential to be a key source of information for detecting interactions that their patients may experience.

Like consumers, many health professionals find labels of limited usefulness (see box). During our focus groups, health professionals told us that the information they most often look for on labels, such as active ingredient(s), substance preparation, dose, interactions and contraindications, is lacking or has significant shortcomings. Moreover, many found labels hard to understand, because they did not have enough general knowledge about dietary supplements. Recent studies have pointed out the limited knowledge many health professionals have of supplements. For example, a recent study reported that pharmacists scored an average of less than 50 percent on tests

**Illustrative statements from our focus groups of health professionals about the limited usefulness of labels:**

“I don’t use the label...labels are misleading...How am I suppose to advise my patients if I can’t believe what’s on the label? These [supplement] products are not standardized or validated...I think this is a tremendous problem...especially in terms of doing any reasonable counseling to patients.”

“I don’t use labels because I find them pretty useless, but luckily, pharmacists have access to good reference materials.”

“It’s difficult for us [physicians], much less consumers, to read the fine print.”

measuring their knowledge of herbal medication.<sup>31</sup> Similarly, a prior study found that nurse practitioners scored an average of 3.36 out of a possible 19 on a test measuring their knowledge of the use and contraindications of herbal medications.<sup>32</sup> Focus group participants told us that they received little professional training in nutrition and herbal medicine while they were in school. The lack of training about dietary supplements makes health professionals all the more dependent on the label information provided by manufacturers.

## CONCLUSION

Our analysis of 100 dietary supplement labels found that few reflected the label elements contained in our template. These findings were confirmed by our interviews and focus groups as well as by independent data analyses and professional literature. Our analysis also found that several barriers may prevent manufacturers from developing labels that can adhere to our template, and that the current state of supplement labels may limit the extent to which consumers and health professionals use labels.

We recognize that FDA has numerous efforts underway to address the current state of dietary supplement labels, and that limited resources, limited scientific evidence about the safety and efficacy of supplements, and competing priorities inhibit FDA's capacity to make timely progress (see Appendix C for a description of activities underway). Our analysis is designed to assist FDA as it addresses the legal framework related to dietary supplement labels, and as it reviews its standards for disclosing safety risks on labels, substantiating evidence related to label claims, and developing analytical methods and reference materials for testing supplements.

## Template of Key Elements for Dietary Supplement Labels

According to DSHEA, a dietary supplement label should help consumers make informed and appropriate choices about supplement use. For this inquiry, we developed a template of the key elements for a dietary supplement label. This template is based on several sources, including a review of 100 dietary supplement labels; 76 interviews with key stakeholders; data from industry groups and independent research organizations; and a comprehensive literature review. Our intention is to set forth a vision for supplement labels in terms of essential information and precepts for presenting information.

### TEMPLATE OF THE KEY ELEMENTS FOR A DIETARY SUPPLEMENT LABEL

#### *Label Content:*

- ✓ **Ingredients.** It would fully and clearly disclose the ingredients contained in a supplement. The ingredient declaration would accurately reflect the amount of each dietary ingredient included in the supplement.
- ✓ **Intended Use.** It would provide consumers with sufficient information about the range of uses for a supplement. All intended use claims would be based on accepted scientific evidence.
- ✓ **Safety Information.** It would provide consumers with known safety information. This would include interactions, contraindications, and possible side effects and adverse reactions.
- ✓ **Directions for Use.** It would provide consumers with adequate directions for use. The directions would include guidance on proper doses, if the information is available.
- ✓ **Product Information.** It would identify the manufacturer, production source and batch, and information about the net quantity of contents found in the supplement.

#### *Label Presentation:*

- ✓ **Standardized Format.** It would present similar types of information in a similar order across supplements. It would use widely accepted terminology and headings.
- ✓ **Distinct Product Features.** It would have a unique design, format, or specific language that assists consumers in distinguishing supplements from other self-care products.
- ✓ **Readability.** The label would contain language that is easily understood by a broad group of consumers.
- ✓ **Balance.** It would present information in a balanced manner. It would give fair treatment to benefits and risks, to claims and disclaimers, and to factual and marketing information.
- ✓ **Constructive Use of Space.** It would seek to expand the limited label space through creative packaging and pointing consumers to alternative sources of information.

## Information Included on Supplement Labels

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Based on 76 interviews with consumers, health providers, industry representatives, and regulators, we generated a template of the key elements of a dietary supplement label that can help consumers make informed and appropriate choices about supplement use. In this report, we reviewed 100 supplements to see how many of them adhered to our template. The table below summarizes our findings.

For the label analysis, we selected supplements that consumers commonly use, including some of the vitamin, mineral, and herbal supplements that account for the greatest proportion of sales. Our sample attempted to reflect the variety in brands and in packaging currently on the market; our sample represents 36 manufacturers and 36 distributors. We obtained these supplements from retail stores in the greater Boston area and from samples distributed at industry conferences. For more information on our methodology, see Appendix D.

<u>Types of Information on Supplement Labels</u>	<u>Number without that Information (n=100)</u>
<b>Minimum duration of use</b>	<b>95</b>
<b>Bioavailability of ingredients</b>	<b>94</b>
<b>Active ingredients</b>	<b>93</b>
<b>Possible adverse reactions or side effects</b>	<b>89</b>
<b>Possible interactions</b>	<b>87</b>
<b>Maximum dose</b>	<b>85</b>
<b>Specific contraindications</b>	<b>61</b>
<b>Purpose of the supplement</b>	<b>31</b>
<b>Expiration date</b>	<b>25</b>
<b>Amount of individual ingredients in proprietary blends</b>	<b>15*</b>

*\* Only 15 products in our sample of 100 were proprietary blends.*

## FDA Initiatives Related to Dietary Supplements

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Below we highlight several initiatives that FDA has recently initiated or completed:

### *Supplement Safety*

- ▶ **Contract to Develop Safety Framework.** FDA has contracted with the Institute of Medicine and the National Academy of Sciences to develop a framework for categorizing and prioritizing supplement ingredients based on safety. FDA expects the final report to be completed by September 2003.
- ▶ **Warning Statement for Pregnancy.** In May 2001, FDA declared its intent to issue a proposed rule requiring warning statements for women, who are or may be pregnant, on all products making structure/function claims, unless they can prove that the products are safe for pregnant women.

### *Accuracy of Label Declarations*

- ▶ **Consumer Health Information for Better Nutrition Initiative.** In December 2002, FDA announced that it seeks to enhance the credibility of food and dietary supplement labels through the inclusion of more accurate, science-based information. This multi-part initiative includes the publication of guidance on qualified health claims for conventional foods and dietary supplements, strong enforcement of dietary supplement rules, and the establishment of an FDA task force on consumer health information for better nutrition.
- ▶ **Contract to Develop Reference Materials.** FDA has an interagency agreement with the National Institutes of Health (NIH) and the Department of Commerce's National Institute of Standards and Technology to develop reference materials from which to develop validated analytical methods for botanicals. Ephedra and kava kava are the first botanicals to be tested.
- ▶ **Contract to Develop Validated Analytical Methods.** FDA has contracted with the Association of Analytical Chemists International and the NIH to produce analytical methods for ephedrine alkaloids and aristolochic acid.

### *Understanding of Consumer Needs*

- ▶ **Health and Diet Survey.** FDA issued a *Federal Register* notice in August 2001 for comment on its plans for conducting a survey to determine consumer opinion on uses and usefulness of labels.

### *Public Information and Outreach*

- ▶ **Enhanced Website.** FDA has recently redesigned and reorganized its dietary supplement website to make searches more intuitive and information more current and transparent, and has developed new information to fill in identified gaps. The website includes a number of key sections, including: Warning and Safety Information, Adverse Event Reporting, Industry Information and Regulations, Announcements and Meetings, and Questions and Answers.
- ▶ **On-line Publications.** FDA has issued a document entitled “Tips for the Savvy Supplement User: Making Informed Decisions and Evaluating Information,” which is available in both English and Spanish. It has also developed an electronic newsletter that gives interested parties access to key information and updates on dietary supplements, food labeling, and nutrition issues. Moreover, FDA has joined with the Federal Trade Commission (FTC) to publish “Miracle Health Claims: Add a Dose of Skepticism” to help consumers assess claims.
- ▶ **Stakeholder Email List.** In 2001, FDA developed a list of key stakeholders to which it can quickly send out electronic notices about issues, such as safety alerts. This system replaces its fax-on-demand system.
- ▶ **Websites intended to Alert Consumers of Internet Health Fraud.** As part of *Operation Cure.All*, FDA has joined with FTC to simulate websites that make misleading and false claims. Upon attempting to buy dietary supplements through these “teaser” websites, consumers are alerted about the purpose of the websites and are informed about ways to avoid becoming future victims of Internet health fraud.

### *Industry Guidance*

- ▶ **Small Entity Compliance Guide for Structure/Function Claims.** FDA issued guidance in January 2002 to clarify its January 2000 rule on structure/function claims for small businesses and consumers.
- ▶ **Regulatory Guidebook for Industry.** The regulatory guidebook is being developed to provide manufacturers and distributors of dietary supplements a very basic introduction to the legal and regulatory requirements that must be met in order to market dietary supplements in the United States.

## Methodology

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### *Label Analysis*

We performed an original analysis of 100 labels of products that consumers would recognize as dietary supplements. We obtained these supplements from supermarkets, pharmacies, and natural foods stores in the greater Boston area and from samples distributed at industry conferences. Our sample was judgmental. Without the existence of an official registry of the number and types of supplements on the market, we could not conduct probability sampling.

We selected supplements that consumers commonly use, including some of the vitamin, mineral, and herbal supplements that account for the greatest proportion of sales (for example, vitamin C, calcium, ginseng, and soy).<sup>33</sup> Our sample attempted to reflect the variety in brands and in packaging currently on the market; our sample represents 36 manufacturers and 36 distributors. We also sought to select supplements that could serve as effective visual aids in our consumer focus groups and that could provide examples of the perspectives we heard during our interviews.

We tallied the number of labels that did not adhere to each of the key elements of our template. Two analysts independently reviewed the labels according to a detailed protocol reflecting the template's elements and recorded their observations in an Access database; a third analyst made final determinations. See Appendix A for the template and Appendix B for a summary of the findings of our analysis.

### *Interviews and Focus Groups*

We conducted 76 interviews with key stakeholders. We spoke with each of the major supplement industry trade groups, consumer advocacy groups, private quality oversight organizations, professional nutrition associations, academic researchers, marketers, and practicing herbalists. With each group, we discussed the role of a supplement label in the ideal and current label shortcomings, and solicited their recommendations for reform.

We also conducted interviews with federal and state regulators. We spoke with FDA officials at the Center for Food Safety and Applied Nutrition, the Center for Drug Evaluation and Research, and the Office of Regulatory Affairs, and National Institutes of Health officials in the Office of Dietary Supplements. In addition, we spoke with several state regulators who oversee food or supplement safety.

To learn more about specific concerns facing particular groups of supplement users, we conducted our own focus groups with consumers and with health care professionals, and

reviewed the findings of other focus groups. In cooperation with the Administration on Aging, we led five focus groups of elderly consumers who represented a diversity of cultural backgrounds, socioeconomic status, health condition, use of supplements, and use of prescription drugs. These focus groups took place in Massachusetts, Colorado, and California. We also, in partnership with the American Pharmaceutical Association and the American Geriatrics Society, conducted two focus groups of geriatricians and gerontologists and two groups of pharmacists with diverse geographic locations, practice settings, reliance on labels, and experience in advising patients. Finally, we reviewed the findings of FDA's consumer focus groups on dietary supplement labels.

### *Literature Review*

We reviewed relevant federal legislation, regulation, and program priority documents; position papers from consumer and industry groups; articles in peer-reviewed journals and trade press; transcripts from congressional hearings and FDA town meetings; and reports from Presidential commissions, federal evaluators, and government-sponsored colloquia on dietary supplements. We also reviewed consumer-oriented newsletters, books, advertisements, and Websites on supplement use.

We obtained existing data from nationwide surveys on consumer use of dietary supplements and supplement labels. We looked at both the raw data and the findings from *Prevention Magazine's* 1999 and 2000 surveys on dietary supplements, which were based on random samples of 2,000 people. In addition, we reviewed the findings of recent surveys from diverse federal, professional, academic, and private organizations.

We also reviewed existing data on the economic characteristics of the supplement industry. We obtained statistics from FDA-commissioned research reports and the *Nutrition Business Journal*.

## Endnotes

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1. Courtesy of *Nutrition Business Journal*. About 40 percent of the population uses supplements often, and 30 percent takes them infrequently. *Nutrition Business Journal* obtained these figures from a compilation of 13 consumer surveys. Individual consumer surveys, by groups, such as the Kaiser Family Foundation, Yankelovich Partners, the Dietary Supplement Education Alliance, and *Prevention* magazine, have found similar patterns in use over the past several years. The Center for Disease Control and Prevention's (CDC) third National Health and Nutrition Examination Survey (NHANES III), conducted between 1988 and 1994, found that 40 percent of the Americans surveyed had taken a dietary supplement in the month prior to the survey.
2. FDA estimated that the number of supplements on the market may range from 25,000 to 33,000 (29,000 is the midpoint of this range). Food and Drug Administration, *Memorandum Re: Questions Concerning Dietary Supplement Labeling*, June 13, 2001.
3. NBJ's Annual Overview of the Nutrition Industry VI, *Nutrition Business Journal* (2001) 5/6: 3, 7.
4. General Accounting Office, *Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods,"* GAO/RCED-00-156, July 11, 2000.
5. Food and Drug Administration, *Dietary Supplement Enforcement Report*. Retrieved from <http://www.fda.gov/oc/nutritioninitiative/report.html>, December 27, 2002.
6. Herbals/botanicals accounted for \$4,120,000 or 25 percent of supplement sales in 2000. NBJ's Annual Overview of the Nutrition Industry VI, *Nutrition Business Journal* (2001) 5/6: 7.
7. 21 C.F.R. sec. 104(h).
8. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Consumer Studies Team, *Dietary Supplement Labeling Focus Groups*, September 30, 1999.
9. *Prevention Magazine*, "National Survey of Consumer Use of Dietary Supplements," Rodale, Inc., 1999, 75. According to this study, 12 percent of consumers have experienced a side effect from taking an herbal product.

During the course of our research, we found examples of case reports, journal articles, and news stories documenting side effects and adverse reactions associated with supplements. Many of these articles also highlighted the importance of having adequate warnings on supplement labels:

- ▶ Victoria Stagg Elliott, "Code Green: Seeing the Side Effects of Alternative Supplements," *American Medical News*, March 5, 2001.

- ▶ Evenson, “Supplements Pose Danger in Combination with Heart Drugs,” *National Post/Chicago Sun-Times*, March 21, 2002.
- ▶ Jacqueline Stenson (2001) “The Herbal Frontier: The Promise and Peril of Supplements,” *MSNBC*, Retrieved from [wysiwyg://64/http://www.msnbc.com/news/522365](http://www.msnbc.com/news/522365), June 12, 2001 .
- ▶ Michael Ang-Lee et al., “Herbal Medicines and Perioperative Care,” *Journal of American Medical Association* 286 (July 11, 2001) 2: 208-216.
- ▶ Lisa Chavis, “Pharmacy-Based Consulting on Dietary Supplements,” *Journal of the American Pharmaceutical Association*, 41 (March/April 2001) 2: 186-187.

10. K.J. Rothman et al., “Teratogenicity of High Vitamin A Intake,” *New England Journal of Medicine*. 333 (November 1995) 21: 1369-73.

11. *Prevention Magazine*, “National Survey of Consumer Use of Dietary Supplements,” Rodale, Inc., 1999, 67. The survey found that 5 percent of users of vitamins and minerals, 5 percent of users of herbal remedies, and 9 percent of users of specialty products take more than the amount recommended on the label. The authors of the study then calculated the number of people in the U.S. population that these percentages represent. Twenty-eight percent of consumers who took vitamins and minerals to prevent a specific disease and 21 percent of consumers who took herbal remedies to treat a specific disease have taken more than the recommended dose in order to more effectively treat symptoms.

12. *Prevention Magazine*, “National Survey of Consumer Use of Dietary Supplements,” Rodale, Inc., 1999, 61-65. The survey indicated that 23 percent of consumers taking herbal products had difficulty finding information about possible interactions with prescription medicines; 20 percent had difficulty finding information about warnings about possible interactions with over-the-counter (OTC) products; and 21 percent had difficulty finding information on possible interactions with other supplements. Furthermore, 16 percent of consumers taking vitamins and minerals found it difficult to find warnings about possible interactions with prescription medicines, OTC medications, or herbal products.

13. *Prevention Magazine*, “National Survey of Consumer Use of Dietary Supplements,” Rodale, Inc., 1999, 37-39. *Prevention Magazine* found that 31 percent of consumers take dietary supplements in combination with a prescription medicine, and 30 percent of consumers take dietary supplements in combination with an OTC drug.

14. This quotation pertains to many of the supplements listed on the Dietary Supplement Information Bureau Website at [www.supplementinfo.org](http://www.supplementinfo.org). For example, we found this statement in the side effects section of the page pertaining to the supplement kava. Retrieved from <http://content.intramedicine.com/dse/consumer/monoAll-style.asp?objID=100070&ctype=ds&mty=1>, May 10, 2002.

15. *Prevention Magazine*, “National Survey of Consumer Use of Dietary Supplements,” Rodale, Inc., 1999, 74-77.

16. *Prevention Magazine*, “National Survey of Consumer Use of Dietary Supplements,” Rodale, Inc., 1999, 29. Prevention data shows that 66 percent of users of herbal supplements and 61 percent of users of specialty supplements will use these supplements for up to a month without results.

17. Dietary Supplement Education Alliance, “The Key to Consumer Confidence in Dietary Supplements,” *FDLI Update* (2001) 6: 14.

18. Food and Drug Administration, Center for Drug Evaluation and Research, *Consumer Comprehension and Preference for Variations in the Proposed Over-The-Counter Drug Labeling Format*, December 3, 1998, 2.

19. The FTC found these fraudulent websites through *Operation Cure.All*, a coordinated law enforcement and consumer education campaign between federal and state agencies. It targets Internet scams for herbal products, other supplements and devices that purport to cure diseases. For more detail on this effort, see: Federal Trade Commission, *Operation Cure.All Wages New Battle in Ongoing War Against Internet Health Fraud*, released June 14, 2001. Retrieved from <http://www.ftc.gov/opa/2001/06/cureall.com>, November 6, 2001.

20. Federal Trade Commission, *FTC Cracks Down on Marketers of Bogus Bioterrorism Defense Products*, released November 19, 2001. Retrieved from <http://www.ftc.gov/opa/2001/11/webwarn.htm>, January 30, 2002.

21. *Swindlers, Hucksters, and Snake Oil Salesmen: The Hype and Hope of Marketing Anti-Aging Products to Seniors Before the Senate Special Comm. on Aging*, 107<sup>th</sup> Cong., 1<sup>st</sup> Sess. 2 (September 10, 2001) (statement of Senators John Breaux and Larry Craig).

Also, in the spring of 1997, pharmacy students evaluated Internet information about 11 popular herbal products. They found that 45 percent of the claims were true, 6 percent were false, 2 percent were meaningless, and 47 percent undetermined when compared to peer-reviewed journals. When evaluated for substantiation, only 36 percent of the Internet claims were substantiated, of which only 40 percent were found to be true. See Deanne Nowak and Thomas Zlatic, “Herbal Products and the Internet: A Marriage of Convenience,” *Journal of the American Pharmaceutical Association*, Retrieved from [http://www.aphanet.org/PInfo/JaPha\\_Mar-Apr\\_99\\_Article.htm](http://www.aphanet.org/PInfo/JaPha_Mar-Apr_99_Article.htm), February 13, 2001.

22. The American Dietetic Association has cited examples of companies that present unpublished studies, animal data, and consumer testimonials as substantiating evidence for their claim. The State of Texas, which requests substantiation files for about 50 percent of the supplements that they regulate as drugs, has found that, in almost all cases, the manufacturer was not able to provide adequate

substantiation data.

23. 21 C.F.R, sec. 101 requires FDA to use the Association of Analytical Communities International's (AOAC) methods of analysis when available and applicable. AOAC has a compendium for vitamins and minerals based on validated methods, and FDA uses these methods in testing products. However, AOAC is still in the process of developing such methods for botanicals and other dietary supplements.

24. Judy Foreman, "St. John's Wort: Less than Meets the Eye. Globe Analysis Shows Popular Herbal Antidepressant Varies Widely in Content, Quality," *Boston Globe*, January 10, 2000, C1.

25. Joseph M. Betz, "Responsible Commerce and Self-Regulatory Initiatives," *American Herbal Products Association Report*, Spring 2001.

26. I. Scott Bass and Charles J. Raubicheck, *Marketing Dietary Supplements* (Washington, DC: FDLI, 2000), IV-19.

27. *Prevention Magazine*, "National Survey of Consumer Use of Dietary Supplements," Rodale, Inc., 1999, 57-58. Seventy-six percent of consumers taking vitamin and mineral supplements, and 79 percent of consumers taking herbal supplements always read the label the first time they buy supplements.

28. *Prevention Magazine*, "National Survey of Consumer Use of Dietary Supplements," Rodale, Inc., 1999, 59. The consumers in our focus groups listed these same components when we asked them what they consider the most important information on supplement labels.

29. *Ibid.*, 13 and 71.

30. *Ibid.*, 15. According to the *Prevention Magazine* survey, 26 percent of consumers turn to health professionals for information about dietary supplements. Moreover, a number of our focus group participants told us that they rely directly on the advice of physicians and pharmacists, and others said that they subscribe to newsletters and buy books on supplements, because "they are written by people we can trust...like physicians and pharmacists."

Also see, Sandra Levy, "Healthcare 2000 Reveals Consumer View on R.Ph.s," *Drug Topics*, October 4, 1999. Retrieved from [http://dt.pdr.net/be\\_core/d/index.jsp](http://dt.pdr.net/be_core/d/index.jsp), April 12, 2001.

31. Ziba Chang et al., "Pharmacists' Knowledge and Attitudes Toward Herbal Medicine," *The Annals of Pharmacotherapy*, 34 (June 2000): 710-715.

32. *Ibid.*, 711.

33. Dietary Supplement Education Alliance, *The Market for Dietary Supplements*. Retrieved from <http://www.supplementinfo.org/industry/marketplace.htm>. November 19, 2001 Also see NBJ's Annual Overview of the Nutrition Industry VI, *Nutrition Business Journal* (2001) 5/6.

# ACKNOWLEDGMENTS

This report was prepared under the direction of Mark R. Yessian, Ph.D., Regional Inspector General for Evaluation and Inspections in Boston and Joyce M. Greenleaf, MBA, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

Elizabeth Robboy, *Project Leader*  
Chaletta Clark, *Program Analyst*  
Sara Schulman, *Program Analyst*

Joseph Rutherford, *Program Specialist*  
Genevieve Nowolinski, *Program Specialist*

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