

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**DIETARY SUPPLEMENT LABELS:
KEY ELEMENTS**



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EXECUTIVE SUMMARY

OBJECTIVE

To identify key elements that can increase the potential for dietary supplement labels to help consumers make informed and appropriate choices about supplement use.

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 also 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. Given the limited requirements governing dietary supplement labels, FDA officials have expressed an interest in our presenting a vision for the kind of label that could better assist consumers in making informed and appropriate choices about supplement use. Thus, we consulted a wide variety of stakeholders, reviewed the pertinent literature, and then developed a template of key label elements.

The template uses the existing requirements for dietary supplement labels as a starting framework (see the primer on page 4). We then incorporated the feedback we heard from 76 interviews with key stakeholders, such as regulators, industry representatives, and consumer groups, and from 7 focus groups with consumers and health professionals. We also took into account data from industry groups and independent research organizations, and conducted a comprehensive literature review on dietary supplement use and labels, including congressional testimony and national survey data.

The template also serves as the framework for a companion report, *Dietary Supplement Labels: An Assessment* (OEI-01-01-00121).

KEY ELEMENTS OF A DIETARY SUPPLEMENT LABEL

Below, we present our template of key elements of a dietary supplement label that can help consumers make informed and appropriate choices about supplement use.

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.** It would contain language and visual cues that are 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 by pointing consumers to alternative sources of information.

CONCLUSION

This template sets forth a vision of key elements that can increase the potential of dietary supplement labels to help consumers make informed and appropriate choices about supplement use. It is a vision that appears to have considerable support among the wide range of stakeholders whom we interviewed. We recognize that this template is general and that it leaves out many important details concerning specific expectations or requirements for supplement labels. It does, however, put forth 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.

For an assessment of the extent to which existing dietary supplement labels reflect the elements identified in this template, see our companion report, *Dietary Supplement Labels: An Assessment* (OEI-01-01-00121).

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INTRODUCTION

OBJECTIVE

To identify key elements that can increase the potential for dietary supplement labels to help consumers make informed and appropriate choices about supplement use.

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 regulatory framework for dietary supplements and expanded the information that could be placed on labels. 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 2001.¹ 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. FDA estimates that about 29,000 dietary supplements are on the market.² Dietary supplements are nearly a \$17 billion industry.³

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 reporting 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 (see Appendix A for a fuller description of the advertisements).

Concerns about Dietary Supplement Labels

Our 2001 study 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 (GAO) cited similar problems with dietary supplement labels.⁴ 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.⁵

Methodology

Given the limited requirements governing dietary supplement labels, FDA officials have expressed an interest in our presenting a vision for the kind of label that could better assist consumers in making informed and appropriate choices about supplement use. Thus, we consulted a wide variety of stakeholders, reviewed the pertinent literature, and then developed a template of key label elements. The template we developed can provide FDA with a starting point for a mechanism to communicate critical information and useful strategies about dietary supplements to consumers.

The template uses the existing requirements for dietary supplement labels as a starting framework (see the primer on page 4). We then incorporated the feedback we heard from 76 interviews with key stakeholders, such as regulators, industry representatives, and consumer groups, and from 7 focus groups with consumers and health professionals. We also took into account data from industry groups and independent research organizations, and conducted a comprehensive literature review on dietary supplement use and labels, including congressional testimony and national survey data.

Throughout the course of our inquiry, we refined and adjusted the template to incorporate the diversity of perspectives that we encountered. The template represents broad consensus among those we interviewed as to key label elements.

This Report and its Companion Report

This report identifies key elements that can increase the potential for dietary supplement labels to help consumers make informed and appropriate choices about supplement use, and organizes those elements into a template. The template draws on existing requirements for dietary supplement labels, feedback from interviews and focus groups, industry data, and the professional literature.

In our companion report, *Dietary Supplement Labels: An Assessment* (OEI-01-01-00121), we assess the extent to which current dietary supplement labels meet the potential expressed in the template outlined in this report. We also examine barriers that may prevent supplement manufacturers from developing labels that incorporate the elements of our template, and note potential consequences to consumers and health professionals of maintaining the current label requirements for dietary supplements.

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 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;
- 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.

KEY ELEMENTS OF A DIETARY SUPPLEMENT LABEL

We defined the key elements of a dietary supplement label to be those that can help consumers make informed and appropriate choices about supplement use. This definition comes from DSHEA, in which Congress called for labels to contain information, such that “consumers may make informed and appropriate health care choices for themselves and their families.” More recently, in announcing the FDA’s Consumer Health Information for Better Nutrition Initiative, the FDA Commissioner and the Secretary of Health and Human Services have reinforced the important role that labels can play in helping consumers make informed choices about the products they buy.

The label on a dietary supplement can fulfill this role by facilitating consumers’ choice of a supplement, guiding their use of it, and communicating any safety information associated with it.

Consumers who have decided to purchase a supplement are often faced with a wide array of choices. The label can play a role in helping consumers to select an appropriate supplement by providing information about the purposes of the supplement, the conditions for which the supplement should be taken, and factual information about the contents and manufacture of the supplement.

Roles of the supplement label:

- ✓ Facilitates product choice
- ✓ Guides use
- ✓ Communicates safety information

Furthermore, by providing information on possible side effects and potential interactions, the label can play an important role in helping consumers to appreciate any risks associated with using the supplement. After a consumer selects an appropriate supplement, correct administration and dosing are essential. By providing such information, the label can guide consumers in the appropriate use of a supplement. Should a consumer experience adverse symptoms, the label can play an important advisory role by informing consumers when to stop taking a supplement and whom to contact.

The notion that a label can help consumers make informed and appropriate choices takes on heightened significance, given that dietary supplements are self-care products. According to a recent national study, consumers would often rather treat their own health conditions than go to a doctor.⁶ While dietary supplements are not approved as a way to treat health conditions, close to one-quarter of the population (26 percent) say they have used dietary supplements for a health problem.⁷ According to another national study, 22 percent of adults report using vitamins and minerals to treat and prevent serious illnesses, and 14 percent report using herbal remedies for this reason.⁸ Some consumers even use supplements to treat life-threatening conditions, such as cancer.⁹

Given the limited requirements governing dietary supplement labels, FDA officials have expressed an interest in our presenting a vision for the kind of label that could better assist consumers in making informed and appropriate choices about supplement use. Thus, we consulted a wide variety of stakeholders, reviewed the pertinent literature, and then developed a template of key label elements.

The template uses the existing requirements for dietary supplement labels as a starting framework (see the primer on page 4). We then incorporated the feedback we heard from 76 interviews with key stakeholders, such as regulators, industry representatives, and consumer groups, and from 7 focus groups with consumers and health professionals. We also took into account data from industry groups and independent research organizations, and conducted a comprehensive literature review on dietary supplement use and labels, including congressional testimony and national survey data.

The template sets forth key elements of a dietary supplement label in terms of essential information and precepts for presenting that information (see page 7). The template is meant to be a general framework that can apply to all types of supplements. The template may serve as a mechanism to enhance the potential of the supplement label to communicate information and strategies about dietary supplements to consumers.

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.** It would contain language and visual cues that are 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.

Scope of the Template

The template can serve as a general label framework that has applications to all types of dietary supplements, including vitamins and minerals, herbals and botanicals, and specialty supplements. Where we determined that label information was relevant to only one type of dietary supplement, we note it in the text.

LABEL CONTENT

The first five elements of the template delineate the major categories of information that our analysis found to be key in a dietary supplement label. A label may not be able to help consumers make informed and appropriate choices about supplement use, if it does not adequately address ingredients, intended use, safety information, directions for use,

and product information. While the vast majority of stakeholders we spoke with agreed that these five categories of information are critical, there were differences of opinion in how best to incorporate each element into the label. The label is of limited size, and while all of these elements ought to be included on the label, we recognize that there may be trade-offs in terms of the extent of information that can be presented about any single element.

Ingredient Information

The label would fully disclose the ingredients contained in a supplement. The ingredient declaration would accurately reflect the amount of each ingredient included in the supplement.

A dietary supplement label that meets our template would not only disclose the net quantity of ingredients, but would also provide information about the quantity and percent of each active ingredient. This would be especially relevant to supplements containing multiple ingredients and to supplements that are available in different forms and from different sources. The active ingredients would have unique names so that consumers would be able to readily recognize them. Furthermore, the active ingredients would be easily distinguishable from the inactive ones. If a supplement's bioavailability (extent of absorption into the bloodstream) were known, this would be noted on the label.

An accurate declaration of ingredients is key to maintaining consumer confidence in dietary supplements. Consumers would be made aware of any efforts toward standardizing, certifying, or producing a dietary supplement according to good manufacturing practices. Because of the wide variety of standardization programs currently in use, information would be available to consumers about the methods used to standardize or certify a supplement. This information need not be on the label itself, but would be available either in a package insert or through a toll-free number or website.

Some stakeholders we interviewed, particularly herbalists and health care providers, stated that the labels of herbal supplements ought to contain additional information pertaining to ingredient origins and product preparation, because the growing conditions and production processes have a direct effect on the level of active ingredient(s) in a dietary supplement. Herbs harvested in different parts of the world can contain disparate levels of active ingredients. In addition to stating the plant part and species of herb, they would like to see supplements state the country in which the ingredient was harvested. Several interviewees told us that they would like tinctures to contain information about the extraction process, because the type of solvent used to extract an herb can have a substantial impact on the supplement's potency. Others have cautioned, however, that while such information is important, it may be of limited use to the vast majority of consumers.

Intended Use

The label 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.

To meet our template, statements about intended use would address the primary functions and purposes of the supplement, a description of how the supplement would result in a health benefit, and the conditions and symptoms for which the supplement is intended. FDA currently requires benefit statements to be expressed as claims (such as structure/function claims or health claims), but that need not be the only format for expressing intended use. Whatever mechanism is used to convey intended use, the statements would be specific enough to be useful to consumers.

Intended use statements could go further by helping consumers to understand the roles of key active ingredients. Information on the supplement's purposes could be presented in such a way that consumers could associate active ingredients with the primary purposes of the supplement. Other self-care products, such as over-the-counter drugs, are required by regulation to present active ingredients immediately adjacent and to the left of the purpose statement.

Ideally, statements of intended use would be based upon accepted scientific evidence. Acceptable scientific evidence would be clearly defined, and this definition would be widely accepted and adhered to by manufacturers. The definition would delineate the extent and the conditions under which intended use claims could be extrapolated from existing research. Furthermore, equivalency would be required between the dose supporting an intended use claim and the dose administered during the clinical trial. The public would have access to the citations for any secondary research upon which the claims are based. Such information could be made available through a package insert, website, or toll-free number.

If labels could express intended use in more than one way, some delineation would exist, such that consumers would be able to understand the extent and nature of the federal oversight for each. Furthermore, consumers would be able to distinguish among the various types of claims used on supplements. Should disclaimers be associated with statements of intended use, these disclaimers would be easily recognized and understood by consumers.

Our stakeholders debated the appropriate place for intended use statements. Some industry representatives told us that the basic function of a dietary supplement and types of circumstances in which supplements should be consumed could not be conveyed on the label because of size limitations. They noted that, instead, such information ought to be conveyed through accompanying literature. Other interviewees, including consumers, health professionals, and herbal practitioners, believed that intended use statements were not only essential but also were feasible to include on supplement labels.

According to recent FDA focus groups, any mention of possible health benefits on a supplement label was considered desirable because it told consumers what the supplement was for.¹⁰ The American Association of Retired Persons (AARP) also found, in its recent survey, that information on the label about a supplement's purposes is very important to consumers.¹¹

Safety Information

The label would provide consumers with known safety information. This would include interactions, contraindications, and possible side effects and adverse reactions.

Safety information on a label that meets our template would include potentially harmful interactions between the supplement and prescription drugs, over-the-counter medicines, other supplements, and foods; contraindications for certain populations and medical conditions; possible side effects and adverse reactions; and a statement telling consumers to stop taking the supplement if they experience adverse symptoms. Focus groups conducted by FDA found that supplement users are keenly interested in safety information.¹² A recent study by AARP confirmed this on a national scale.¹³ Other groups have also called for the inclusion of safety information on labels.¹⁴

While most stakeholders we interviewed agreed on the concept of safety information and many of the particulars noted above, they disagreed over the extent of safety information necessary on a supplement label. Some industry representatives believed that only in very specific circumstances should warnings appear on supplements (for example, on supplements containing Ephedra and St. John's Wort, which have been associated with adverse reactions, or precautionary statements pertaining to pregnant or lactating women); otherwise it would be impractical to list all interactions. Their preferred approach would be to call upon doctors or pharmacists to alert consumers to potential interactions. Others believed that safety information ought not be included on the label, unless the risks were well-documented in research studies or through adverse events.

Others, particularly consumer advocates, believed that labels ought to list all possible interactions. They expressed concerns that health professionals may lack sufficient knowledge about supplements to adequately inform consumers of potential interactions or adverse effects. Finally, some would like safety information to go even further by including information on adverse event reporting. The State of Texas has begun requiring all Ephedra products to contain the toll-free number of the FDA's Medwatch medical product reporting program. Others, however, have raised concerns that by including the FDA Medwatch number on a supplement label, consumers may perceive it as an implied endorsement of the safety of the supplement and may assume an incorrect level of FDA oversight.

The majority of consumers and health professionals in our focus groups told us that they were more comfortable with an explicit warning label, rather than a vague statement, such

as “if you have a health condition, please discuss with your doctor.” Our interviewees tended to prefer warnings that mentioned specific medical conditions and that were written in simple language. For example, most people liked the Ephedra warning because of its completeness. It addresses topics such as contraindications, interactions, maximum dosage, and adverse effects.¹⁵ A few people, however, told us that having too much information, or too many specific references, might either scare consumers or lead them to ignore the warning.

Stakeholders were split over the need for labels to carry a statement calling for the consumer to consult with a health professional before using the supplement. Since supplements are technically not considered drugs, some industry representatives believed that carrying a precautionary note to discuss usage with a health provider is unnecessary. Others, particularly consumer and health providers, believed that labels ought to encourage consumers to discuss supplement usage with their health providers, especially if they are taking other medications. A recent survey by *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 over-the-counter product.¹⁶

Despite disagreements about the level of information that ought to be included on supplements, all interviewees stated that there ought to be consistency among the warning labels for similar supplements. Warnings pertaining to supplement-drug interactions ought to convey similar information separately on the drug and the supplement. Furthermore, stakeholders believed that requirements for warning statements ought to be harmonized across federal and state regulatory agencies.

Directions for Use

The label would provide consumers with adequate directions for use. The directions would include guidance on proper doses, if the information is available.

Directions for use on a label that meets our template would cover a range of important information, including a recommended daily dose, minimum duration of time for which a supplement should be taken in order to see results, maximum dose or extent of time for which a supplement can be safely taken, and information about how to consume the supplement (e.g., with or without food and liquid). Some groups, including the Commission on Dietary Supplement Labels, would also like to see labels direct consumers to use the supplements only as recommended on the label.

Consumer studies have shown that dosage information on labels is of the utmost importance to consumers. For example, in a recent survey by *Prevention Magazine*, consumers reported that, of all the information on the label, they are most likely to look for information pertaining to recommended dose.¹⁷ Consumers in our focus groups told us that when they use a dietary supplement, the most important questions to which they

seek answers are: How much of the supplement do they need to take to get the result they are looking for? How much is too much?

Ideally, dose per use and duration of use would be based on the amount of supplement necessary to meet the label claims. Consumers would be able to achieve the benefits suggested on label claims based on the number of pills in the supplement; if this is not the case, the label would clearly indicate the amount of supplement needed to achieve that benefit. Dosage information might vary depending on the condition or indication for which the supplement is being taken. It might also vary, based on the age of the consumer. Whatever dose is stated on the bottle would be clear to consumers; any distinctions between the recommended serving size and the recommended daily intake would be obvious. Furthermore, dosage recommendations would be standardized across supplements so that identical supplements with similar claims would call for equivalent doses.

To meet our template, the label would also contain any special storage instructions, including expiration dates for herbals and other supplements with a finite shelf life. Such information can ensure that consumers do not attempt to ingest supplements whose ingredients can no longer deliver the desired benefit. According to surveys by *Prevention Magazine* and AARP, consumers consider the expiration date to be a valuable component of the label.¹⁸

Product Information

The label would identify the manufacturer, production source and batch, and information about the net quantity of contents found in the supplement.

Product information can assist consumers in identifying key attributes about the contents, production, and manufacture of a supplement. A label that meets our template would contain the name, address, and contact information for the manufacturer. Such information could be helpful to consumers, should they have a question about a supplement. Contact information is helpful to consumers when it contains a toll-free number or website address through which consumers can easily reach the manufacturer. A second important piece of information is the net quantity of contents in the bottle or package, expressed in either weight, measure, or number. This type of information can help consumers comparison shop among supplement brands. Finally, the label would contain a lot number to identify the production source and batch. In the case of a product recall, lot numbers could help consumers and manufacturers easily identify and track those supplements.

LABEL PRESENTATION

The second five elements of the template deal with the way in which information is presented on a supplement label. While it is key for labels to adequately address ingredient information, intended use, safety information, directions for use, and product

information, it is equally important that the information be presented to consumers in a clear and meaningful way. In this section we address five general precepts that are key to label design.

Standardized Format

The label would present similar types of information across supplements in a similar order. The label would use widely accepted terminology, headings, and titles.

A standardized label would serve as a “system” for consumers, helping them to interpret important information on the label and also assisting them in comparing that information across supplements. Furthermore, a standardized label structure would improve consumers’ ability to process label information. In both the food and drug areas, stakeholders told us that the standardizing of labels has proven to be enormously helpful.

A standardized dietary supplement label that meets our template would reflect several elements. First, it would require that all labels contain similar types of information. Second, it would require that information be conveyed across supplements in a consistent manner. The order and flow of information, and the format in which that information is displayed, would be consistent across supplements. Finally, the language on supplements would also be standardized. Important terminology, such as the name of a supplement, would be similar across supplements. Headings, which would alert consumers to information, such as product safety and recommended dose, would be uniform across supplements.

The standardized format would need to be well understood by consumers. Because there is a limit to how much information consumers can hold in their memory at one time, it is key that the amount of information required on labels be congruent with consumers’ ability to retrieve and process information. Research suggests that consumers are most likely to engage in a behavior, such as reading a label, if they believe they can successfully complete the task.¹⁹ Thus, consumers would have to find the format easy to use, navigate, and comprehend.

A standardized label need not mean that there is only one way of presenting information. Required information could be presented in one of several standardized formats, depending on the type and size of the supplement. For example, FDA’s Center for Drug Evaluation and Research has authorized a range of different formats for over-the-counter (OTC) labels, depending on the type and size of product.

While the vast majority of stakeholders we spoke with liked the idea of a standardized label, a few dissented. Some pointed out that manufacturers are already hard-pressed to get information on labels, and raised concern that requiring yet more information could lead to overcrowding on the label. Others pointed out that a standardized format might

encroach upon a manufacturer's ability to use the label as a marketing tool, because it would greatly limit the discretionary space on labels.

Distinct Product Features

The label would have a unique design, format, or specific language that would assist consumers in distinguishing supplements from other self-care products.

A label that meets our template would contain distinct product features so that consumers could distinguish dietary supplements from other types of self-care products. The ability to distinguish one type of product from another is key to a consumer's ability to select appropriate supplements. To achieve such a distinction, the dietary supplement label would need to look significantly different from other self-care products, such as over-the-counter drugs and homeopathic products. For example, supplement labels could have a unique design, shape, language, color, or product feature, such as a symbol on the bottle cap. An important factor in choosing a distinct product feature for a dietary supplement is that it be one that consumers would readily associate with supplements.

In distinguishing a supplement from other types of products, the label would also carry language that clearly communicates to consumers important features about supplement regulation. For example, the label could make clear through a disclaimer or some other mechanism that supplements are not subject to premarket approval or that FDA has not evaluated their safety and effectiveness. We recognize that such statements could call for trade-offs in label information. Such a statement, which would need to be in a large enough font and in simple language, may come at the expense of other critical information, such as safety information.

Readability

The label would contain language that is easily understood by a broad group of consumers.

A label that meets our template would be easily understood by consumers. To that end, the language must be clear and concise, with a reading level that is suitable for a broad group of consumers. The language must be simple enough that it could be understood by lay persons. An important component of readability is font size, which needs to be sufficient for a broad group of consumers. To increase readability, labels could contain symbols or other visual cues to focus the consumer's attention to important information. Some of our interviewees believed that symbols or visual cues, such as a danger sign or red box, could effectively alert consumers to safety information. However, others believed that symbols could be problematic, pointing out that cues can have different meanings to different people. Thus, were symbols to be incorporated into labels, the label redesign would have to be accompanied by public education.

Changes in consumer information needs must be taken into account in assessing how best to ensure that labels are read and understood by a broad group of consumers. With continued advances in nutrition, medicine, and the study of herbal medicine, labels will have to communicate increasingly sophisticated messages on topics, such as directions for use and safety information. Changes in American demographics will also have an impact on consumer information needs. The elderly, who are large users of supplements, are becoming a larger proportion of the population.²⁰ They may have greater difficulty reading a label because of poor vision. Finally, as the number and percentage of United States residents, who do not speak English as their primary language, increases, labels that can be understood by a wide variety of language speakers will become increasingly important.²¹

Balance

The label 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.

A label that meets our template would present a balance between competing types of information. For example, the label would give fair treatment to information about a supplement's benefits as well as its risks. The label would include an appropriate balance between factual information, as required by FDA label regulations, and marketing information, which could include claims, company logo, designs, and images. Finally, space would be balanced between claims and disclaimers. This balance would need to be determined on a case-by-case basis. In some instances, balance would entail equal space being devoted to both kinds of information. In other cases, the amount of space would depend on the level of science and knowledge in a particular area. Finally, the placement of information on a label may have implications for the extent to which labels accomplish balance. The balance of information is key to the informed and appropriate use of any self-care product, and is required in the advertising for OTC drugs.

Constructive Use of Label Space

The label would seek to expand the limited label space through creative packaging and pointing consumers to alternative sources of information.

While the size of a label is an inherently limiting factor to the amount of information that can be placed on the label, the placement of that information need not be limited to the primary display panel. A label that meets our template would seek to expand the limited space through creative packaging.

Expanded labels hold particular promise for information that is important but not so critical that it needs to be on the package label. For example, the following types of information could be effectively placed on an expanded label: information about the

scientific legacy of the supplement, including information about the clinical trials; key mechanism of action for the active ingredients; additional information about the processing and manufacture of a supplement; and the full text of a disclaimer, should a truncated version be used on the label.²² In our review of labels, we identified four options for expanding the information contained on a dietary supplement label. Below we discuss the options, identifying both benefits and potential concerns.

- ▶ *Innovations to existing label space.* Label space can be expanded through innovations, such as a “twist-n-turn” label, in which the outer part of the label twists around an inner band of information; an “accordian” label, in which the label folds out to be several times its size; and a “neck strap” label, in which a tag is attached to the bottle neck. However, these labels may get torn off, lost, or malfunction. Consumers may also be overwhelmed by the different label forms, resulting in increased confusion and a decreased ability to compare supplement labels.
- ▶ *Inclusion of a package insert.* By physically increasing the size of the label or adding a package insert, more space can be made available. Yet, in some cases a larger label may be impossible, especially for small packages. Some interviewees also cautioned that consumers and health providers might not read package inserts.
- ▶ *Use of outer packaging.* By enclosing supplements in boxes or another type of outer package, manufacturers can greatly enhance the label space available because the outer package becomes an extension of the label. Yet, a large box, which might be necessary to carry all the necessary label information, could mislead consumers into thinking that the quantity contained in the accompanying bottle is greater than in fact it is. Manufacturers also told us that the use of boxes could lead to increased production costs.
- ▶ *Alternative sources of information.* Alternative sources of information could include a toll-free number or website. These would be listed on the label and would essentially serve as a continuation of the label. Both options hold great promise because they allow for potentially unlimited space where manufacturers could disclose pertinent information, such as safety precautions. However, consumers must take an additional step on their own initiative to get further information. Not all consumers have access to the Internet. Even for those who have access to a telephone, some concern exists about bias, because company employees would be fielding the calls. Consumers and health professionals told us that it would be most helpful for labels to point consumers to a toll-free number staffed by a neutral party, such as the National Institutes of Health. Finally, including a website or toll-free number on the label raises a host of regulatory oversight issues, as it potentially expands the definition of a label.

CONCLUSION

This template sets forth a vision of key elements that can increase the potential of dietary supplement labels to help consumers make informed and appropriate choices about supplement use. It is a vision that appears to have considerable support among the wide range of stakeholders whom we interviewed. We recognize that this template is general and leaves out many important details concerning specific expectations or requirements for supplement labels. It does, however, put forth 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.

For an assessment of the extent to which existing dietary supplement labels reflect the elements identified in this template, see our companion report, *Dietary Supplement Labels: An Assessment* (OEI-01-01-00121).

ADVERTISEMENTS FOR DIETARY SUPPLEMENTS

We discovered these advertisements, which are regulated by the Federal Trade Commission, during our review of magazines and newspapers. Supplement A is for a joint health product and Supplement B is for a weight loss product. In each case, we were struck by the messages and claims conveyed to consumers. We do not disclose the names of the supplements, or the individuals who endorse them. Each of the following boxes highlights excerpts from the advertisements:

Supplement A

“...For 20 years, severe bone/joint problems put Celebrity #1 through living hell. But three days after he discovered a new breakthrough in natural relief from joint problems, the crippling pain was gone. Not diminished - gone!

What was this ‘miracle’ that finally got rid of Celebrity #1’s bone/joint agony after 20 years of trying countless medications and treatments?
Supplement A”

Supplement B

“...Teacher loses 70 pounds in only 8 weeks easily ... without being hungry... after everything else fails her!

This has become the #1 choice of famous TV and movie stars to lose weight ... and the public ... with over 1 million people using it to lose 10 million pounds.

Supplement B includes 100 percent natural fat-busting, energizing natural nutrients that give your body no choice but to make fat and inches disappear like magic.”

METHODOLOGY

Development of the Template

Our template represents a synthesis of the feedback we heard during 76 interviews, 7 focus groups, and a review of literature pertaining to important characteristics of supplement labels. We continuously added to and refined the elements of the template to reflect the diversity of perspectives, which we encountered, and particularly notable areas of agreement or disagreement. We also shared the template with key stakeholders at various stages of its evolution to confirm that it could be a useful and useable construct for them.

Interviews and Focus Groups

We conducted 76 interviews with key stakeholders. We spoke with each of the 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 conducted 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 from 1999 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

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.
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). (Memorandum re: questions concerning dietary supplement labeling, June 13, 2001)
3. NBJ's Annual Overview of the Nutrition Industry VI, *Nutrition Business Journal* (2001), 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. Roper Starch Worldwide, *Self-Care in the New Millennium*, 2001,10. According to this study, 73 percent of people prefer to treat conditions themselves, rather than go to a doctor; furthermore, 59 percent say that they are more likely to treat their own conditions than 12 months ago. In other cases, consumers are seeing a health care practitioner but not reporting their use of dietary supplements. For example, another survey revealed that 30 percent of those who reported taking supplements regularly had not shared this information with their physician. Robert Blendon et al, Americans' Views on the Use and Regulation of Dietary Supplements, *Archives of Internal Medicine* (March 26, 2001), 161: 805-810.
7. Roper Starch Worldwide, *Self-Care in the New Millennium*, 2001,19.
8. *Prevention Magazine*, "National Survey of Consumer Use of Dietary Supplements," Rodale, Inc., 1999, 32.
9. *Ibid.*, 35-37.
10. Alan Levy and Brenda Derby, Consumer Studies Team. *FDA Report on Dietary Supplement Labeling Focus Groups*, September 30, 1999.
11. Seventy-six percent of consumers thought it would be very important for information to appear on a supplement label about "what a supplement does, for example, helps you sleep, boosts the immune system." AARP Public Policy Institute, *Dietary Supplements and Older Consumers*, Data Digest 66,

7.

12. Alan Levy and Brenda Derby, Consumer Studies Team. *FDA Report on Dietary Supplement Labeling Focus Groups*, September 30, 1999.

13. Respondents thought it would be important to have the following information appear on dietary supplement labels: information on possible side effects or adverse reactions (82 percent); information on interactions with prescription and over-the-counter medicines (80 percent); the maximum amount that is safe to take (81 percent); expiration date (82 percent); and information on whom to contact in case of an adverse reaction (76 percent). AARP Public Policy Institute, *Dietary Supplements and Older Consumers*, Data Digest 66, 3.

14. The Food Committee of the Association of Food and Drug Officials has called for the mandatory label disclosure of the following items: information regarding any side effects or adverse reactions; contraindications to warn those consumers who may be adversely affected because of their age, existing health problems, and risks posed, if pregnant or nursing; if there is a risk of adverse drug and dietary supplement interaction; and cautionary language to seek health practitioner guidance, if there are health concerns present. Association of Food and Drug Officials, Resolution Concerning: Safety and Marketing of Dietary Supplements. June 17, 2001.

The Commission on Dietary Supplement labels recommended that, “Ensuring the safety of supplements includes the need to provide adequate information and warnings to consumers. The Commission strongly suggests that dietary supplement manufacturers include appropriate warnings in product information, where necessary, as specifically permitted by DSHEA. In addition, manufacturers should recognize the need to advise women who are pregnant or breast-feeding to consult a health professional about supplement use during pre-and postnatal periods.” Commission on Dietary Supplement Labels, *Report of the Commission on Dietary Supplement Labels*, November 1997, vii.

15. The warning on the Ephedra supplement we used during our focus groups contained the following language: “Not for use by or sale to persons under age 18. Do not use if pregnant or nursing. Consult a physician or licensed qualified health care professional (“physician”) before product use if you have, or have a family history of, heart or thyroid disease, diabetes, high blood pressure, recurrent headaches, depression, any psychiatric condition, glaucoma, difficulty urinating, enlarged prostate, seizure disorder, if you are using a monoamine oxidase inhibitor (MOAI) or any other dietary supplement, prescription drug or over-the-counter drug containing ephedrine, pseudoephedrine or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold, and weight control products), or if you intend on taking to reduce weight. Under Ohio law, the maximum recommended dosage of ephedrine for a healthy adult is 100 mg in a 24-hour period for not more than 12 weeks. Exceeding recommended serving may cause serious adverse health effects including heart attack and stroke. Discontinue use and call a physician immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath or other similar symptoms. Individuals who consume caffeine with this product may experience

serious adverse health effects. Keep out of reach of children.”

16. *Prevention Magazine*, “National Survey of Consumer Use of Dietary Supplements,” Rodale, Inc., 1999, 37-39.

17. *Prevention Magazine*, “National Survey of Consumer Use of Dietary Supplements,” Rodale, Inc., 1999, 59-63. The recommended dosage is the most widely read item on a supplement label. Consumers reported to *Prevention Magazine* that they look for recommended dosage “always or most of the time” for vitamins and mineral (89 percent), and for herbal remedies (90 percent).

The AARP also found that “the amount [one] should take” is a very important element that should appear on dietary supplement labels. Eighty-one percent of their survey respondents stated that it would be very important to appear on the label. AARP Public Policy Institute, *Dietary Supplements and Older Consumers*, Data Digest 66, 7.

18. *Prevention Magazine*, “National Survey of Consumer Use of Dietary Supplements,” Rodale, Inc., 1999, 59-63. The expiration date is the second most widely read item on a supplement label. Consumers told *Prevention Magazine* that they look for expiration date “always or most of the time” for vitamins and mineral (74 percent), for herbal remedies (77 percent).

The AARP also found that the “expiration date, that is, the date after which a supplement is no longer effective” is a very important element that should appear on dietary supplement labels. Eighty-two percent of their survey respondents stated that the expiration date would be very important to appear on the label. AARP Public Policy Institute, *Dietary Supplements and Older Consumers*, Data Digest 66, 7.

19. Center for Drug Evaluation and Research, FDA, *Summary of Study A and B (untitled document)*. Provided to OIG by the Center for Drug Evaluation and Research in 2001.

20. Department of Commerce, Census Bureau, *National Population Projections (Population Pyramids)*. Retrieved from http://www.census.gov/population/www/projections/np_p5.gif, March 26, 2002.

21. The Census data from 2000 show that almost 45 million people speak a language other than English at home, and over 19 million of those speak English less than “very well.” By contrast, in 1990 almost 32 million people spoke a language other than English at home, and 14 million of those spoke English less than “very well.” Census 2000 Supplementary Survey Summary Table QT-03: Profile of Selected Social Characteristics: 2000; 1990 Summary Tape File 3 (STF 3) - Sample data – Table DP-2: Social Characteristics: 1990. Retrieved from <http://factfinder.census.gov>, May 17, 2002.

22. Alan Levy and Brenda Derby, Consumer Studies Team. *FDA Report on Dietary Supplement Labeling Focus Groups*, September 30, 1999.

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