

Consumer Healthcare Products Association

Representing manufacturers and distributors of quality dietary supplements and nonprescription medicines

Founded 1881

Pregnancy/Nursing Statements for Dietary Supplements CHPA Voluntary Labeling Program

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SLIDE: Good morning. I am Dr. Bill Soller, Senior Vice President and Director of Science & Technology for the Consumer Healthcare Products Association, known as CHPA.

SLIDE: CHPA is the 118-year-old trade organization representing the manufacturers and distributors of national and store brand dietary supplements and nonprescription medicines. CHPA's membership includes over 200 companies involved in the manufacture and distribution of these self-care products and their affiliated services (e.g., raw material suppliers, research testing companies, contract manufacturing companies, advertising agencies, etc.).

Thank you for the opportunity to convey our perspective on how to address the issue of dietary supplement use by pregnant and lactating women in the context of the structure/function rule and specifically on our recent announcement of a voluntary industry labeling program to address concerns in this area.

SLIDE: To address the issues set forth by the agency in its February 24th *Federal Register* announcement of this meeting, I will make brief background remarks, elaborate the points to consider on the safety and benefits of dietary supplements, explain the rationale for our recently adopted voluntary program and the program itself, and make brief concluding remarks.

SLIDE: By way of background, FDA issued its final rule on structure/function claims for dietary supplements, and quite appropriately made a distinction between diseases, such as heart disease, and natural states, such as simple noncystic acne, simple constipation, the menstrual period and others. I emphasize, it was unexpected to many in industry that FDA included symptoms like edema associated with pregnancy as a potential condition that would be amenable to structure/function claims.

In response, CHPA undertook a situation analysis, looking at the safety of dietary supplements in pregnancy as well as the uses of dietary supplements in pregnancy. Let's take each in its turn.

SLIDE: First, it is important to recall in any potential safety or efficacy issue that FDA has a long-standing policy that label statements must be “scientifically documented, clinically significant, and important to the safe and effective use of the product by the consumer” [e.g., Final Rule Regarding Label Warning for Pregnant or Nursing Women; Delegations of Authority and Organization. 47 *Federal Register* 54750-58 (12/3/82)]. This policy has stood up very well as a framework for working through public health issues relating to the labeling of self-care products. It is a three part standard, with credible scientific documentation as the first hurdle. Without adequate scientific documentation there is no need to determine whether the effect under scrutiny has clinical significance, let alone importance to the consumer use situation.

Second, unlike an ingredient-specific safety issue that is scientifically documented, this issue relating to pregnancy/nursing is a unique situation relative to FDA’s long-standing policy, since the potential dangers of specific dietary supplement use in pregnancy are not uniformly documented scientifically. While a number of self-care products, such as prenatal dietary supplements, have good safety profiles for use in pregnancy, there are also a number of these self-care products for which the scientific documentation for use in pregnancy/nursing may not be fully developed.

Hence, any approach would be based on an absence of scientific documentation. This is the uniqueness of the situation.

Further, pregnancy and nursing are particularly vulnerable periods for the unborn, with unknowns making this a unique situation relative to ingredient-specific safety issues in adults.

I can not overemphasize this point, that pregnancy/nursing are unique as regulatory matters. We typically make label decisions based on scientific data and their adequate documentation. Yet here we have little published documentation across the many dietary supplement products, and we have a particularly vulnerable population under consideration. Hence, this situation should be viewed as it was when pregnancy/nursing statements were placed on OTC drug products in December, 1982 – i.e., as unique.

Therefore, in other situations involving possible labeling changes to dietary supplement ingredients, we expect that FDA’s longstanding policy would remain intact.

SLIDE: A third point that we considered in our situation analysis was the finding that many of our members already include a pregnancy/nursing statement on their product labels.

As a final point relating to our assessment of the safety aspects of the current situation is the fact that under the Dietary Supplement Health and Education Act of 1994 -- for dietary supplements as for other foods -- it is the manufacturer’s responsibility to ensure that dietary supplement products are safe and properly labeled prior to marketing. As stated earlier, we feel very strongly about the fact that the uniqueness of the pregnancy /nursing issue, and our response to it, should not be seen as a signal of erosion of our

commitment to DSHEA or in our members' confidence in the safety of their products, nor an erosion of our support for the substantial enforcement powers that FDA and the Federal Trade Commission already have over dietary supplements. Indeed, to support our view, I quote FDA Commissioner Dr. Jane Henney: "FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the FD&C Act, as amended by DSHEA." (This statement was made on March 25, 1999 by Food and Drug Administration Commissioner Jane E. Henney, M.D. before the House Committee on Government Reform.)

Thus, in developing our response to FDA's ruling that conditions associated with pregnancy may be areas of structure/function claims, we considered current FDA policy, finding pregnancy/nursing to be unique among potential labeling issues, determined many of our members had already stepped forward with specific labeling in this regard, and recalled the fundamental premise of the law that it is the manufacturers' responsibility to ensure dietary supplements are safe and properly labeled prior to marketing. All these points had to be a part of our response to this issue.

SLIDE: Now as part of our situation analysis we also considered how dietary supplements are intended to be used. Some are intended for use by pregnant and nursing women, while some are not.

A balanced diet and adequate intake of essential nutrients is important for full term normal pregnancies. Adequate intake of such micronutrients as folate, zinc, iron and other ingredients are important in the prenatal period. For example,

- Supplementation with iron is generally recommended during pregnancy to meet the energy demands of both mother and rapidly growing fetus.¹
- Inadequate intake of zinc or folate or both potentially leads to impaired cell division and alterations in protein synthesis; such alterations are most notable and have the greatest potential to do harm during periods of rapid tissue growth, such as pregnancy; folate is of course the subject of an authorized health claim for the prevention of neural tube defects;¹

Thus, if certain dietary supplements are important for use in pregnancy, and if there is no concern about their safety in such situations, there would seem to be little need for a statement to consult an health professional before use of the product. Such a statement might even frighten a potential user away.

On the other hand, certain dietary supplements are intended for use in populations not likely to become pregnant, including young children, postmenopausal women and men. Here, a pregnancy/nursing statement would not be logical.

SLIDE: Therefore, from our situation analysis, looking at safety and matters pertaining to intended uses, our approach was to create a workable program that would:

- Be consistent with the law (DSHEA);

- Be logical (i.e., does not call pregnancy as disease, even for the purposes of the final rule);
- Be consistent with past rulings in this area (e.g., OTCs);
- Encompasses past scientific determinations in this area (e.g., compendial negative lists);
- Be medically appropriate;
- Recognize and not interfere with important benefits of certain DSs in pregnancy and nursing;
- Place important information in the hands of consumers;
- Be reasonably flexible in its wording to encompass current labeling.

SLIDE: I would like to now briefly describe our voluntary pregnancy/nursing labeling program for dietary supplements (see attachment for full text of program).

The basic “stem” statement is: “If pregnant or nursing, ask a health professional” (or, alternative wording that is substantially equivalent).

We include following exemptions that are based on the considerations of our situation analysis:

- (a.) Dietary supplements with recognized nutrient value that have adult recommended daily intake values (RDIs) and are labeled at or below the RDI, subject to 2.c. below;
- (b.) Dietary supplements with recognized nutrient values which are intended for prenatal use and/or for use during nursing and which solely contain vitamins and minerals with RDIs at levels safe for these intended uses;
- (c.) Dietary supplements that may be used during pregnancy and/or by nursing mothers based on recognized compendia and/or based on determinations or pending recommendations of other authoritative bodies such as the National Academy of Sciences and United States Pharmacopeia or others and/or based on company-generated research, or information, etc.;
- (d.) Dietary supplements that are labeled exclusively for pediatric use;
- (e.) Dietary supplements that are labeled exclusively for postmenopausal women;
- (f.) Dietary supplements that are labeled exclusively for use by men.

In addition, the program stays use of edema associated with pregnancy from being a structure/function claim during pregnancy. We are unaware of any dietary supplements making such claims in pregnancy.

CHPA’s program was adopted March 22, 2000, with a compliance date of the next label printing, but no later than April 2, 2001. Note that this one year compliance date is similar to the one year date given in the final rule for pregnancy/nursing label statements for OTC drugs.²

SLIDE: Furthermore, we plan to soon petition the agency to adopt our voluntary program into regulation. CHPA has had a long history of highly successful voluntary labeling programs that have been supported by FDA, even including FDA's urging that all manufacturers adopt our programs as we have promulgated them.

Further, many of our programs have been adopted into regulation by FDA in the form that maintains virtually all of the essential elements of our program, including

- Packaging and labeling of pre-natal iron-containing vitamin/mineral products to help reduce accidental childhood poisoning;
- Solid OTC dosage form identification;
- Many ingredient-specific labeling recommendations for OTC drug products.

SLIDE: In conclusion, CHPA's approach addresses FDA's questions relating to safety, acknowledges the benefits of certain dietary supplements in pregnancy and nursing, is a rapid response by responsible manufacturers, is consistent with past consumer products in this area, and ultimately – indeed primarily – meets consumers needs.

Thank you. I would be pleased to answer any questions you may have.

NOTE: The CHPA Voluntary Pregnancy/Nursing labeling Program follows as an attachment. Endnotes follow the voluntary program.

Attachment**Voluntary Labeling Program for Dietary Supplements
Proposed Pregnancy/Nursing Label Statement**

Members of the Consumer Healthcare Products Association (CHPA)¹ which market dietary supplements formally initiated a voluntary labeling program on March 22, 2000 which relates to the use of the following label statement on dietary supplement products:

If you are pregnant or nursing a baby, ask
a health professional.

This statement (or its reasonably substantial equivalent; see 2.b.), when included in the labeling of dietary supplement products defined by the voluntary program, will be prominent and conspicuous and may appear in one of a number of alternative forms which convey essentially the same information intended by the label statement cited above (see below re: Alternative Statements). Certain dietary supplements logically do not need such a label statement because, for example, their intended uses are not for women of child-bearing age, or because they have recognized uses for women of child-bearing age (e.g., prenatal vitamins and minerals) or have data to support the use of the product by women who are pregnant and/or nursing a baby. Types of products that fall in these categories are listed below under "Exemptions."

The implementation time for this program is at the next label printing, but no later than April 2, 2001.

1. **Voluntary Pregnancy/Nursing Statement:** If you are pregnant or nursing a baby, ask a health professional.
2. **Provisions:** The following provisions apply to the voluntary use of this label information statement by CHPA members marketing dietary supplements:
 - a. **Scope:** This label information statement is intended for use on dietary supplements defined by the Dietary Supplement Health and Education Act (DSHEA), with certain exemptions:
 - (1.) **DSHEA Definition of Dietary Supplements:** "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 daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients."
 - (2.) **Exemptions:**
 - (a.) Dietary supplements with recognized nutrient value that have adult recommended daily intake values (RDIs) and are labeled at or below the RDI, subject to 2.c. below;
 - (b.) Dietary supplements with recognized nutrient values which are intended for prenatal use and/or for use during nursing and which solely contain vitamins and minerals with RDIs at levels safe for these intended uses;

¹ CHPA, founded in 1881, represents manufacturers and distributors of dietary supplements. CHPA has over 200 members across the manufacturing, distributing, supply, research testing and advertising sectors of the self-care industry.

- (c.) Dietary supplements that may be used during pregnancy and/or by nursing mothers based on recognized compendia and/or based on determinations or pending recommendations of other authoritative bodies such as the National Academy of Sciences and United States Pharmacopeia or others and/or based on company-generated research, or information, etc.;
 - (d.) Dietary supplements that are labeled exclusively for pediatric use;
 - (e.) Dietary supplements that are labeled exclusively for postmenopausal women;
 - (f.) Dietary supplements that are labeled exclusively for use by men.
- (3.) **Stay of Use of Structure/Function Claims for Certain Conditions Associated with Pregnancy:** Under this voluntary program, member companies would not make claims relating to edema associated with pregnancy.
- b. **Alternate Statements:** As with other CHPA voluntary label statements, this proposed pregnancy/nursing statement may be used in reasonably substantially equivalent wording, such as:
- consult (or, *ask*; or *contact*)² a (or, *your*) doctor (or, *health professional*; or, *health practitioner*) if you are pregnant or nursing (or, *breast feeding*) a baby;
 - before using (or, *before using this product*) consult (or, *ask*; or *contact*) a (or, *your*) doctor (or, *health professional*; or, *health care practitioner*) if you are pregnant or nursing a baby (or, *lactating*; or, *breast feeding*);
 - ask (or, *consult*; or *contact*) a (or, *your*) doctor (or, *health professional*; or, *health care practitioner*; or, *doctor or other health professional*) before using (or, *before using this product*) if you are pregnant or nursing a baby;
 - if you are pregnant or nursing a baby, ask (or, *consult*; or, *contact*) a (or, *your*) doctor (or, *health professional*; or *doctor or other health professional*; or, *health care practitioner*);
 - not for use during pregnancy and lactation, unless directed by a health care practitioner (or, *doctor*; or, *doctor or other health professional*);
 - Or other substantially equivalent statements.
- c. **Combination of the Voluntary Pregnancy/Nursing Label Statement with Other Similar Voluntary Label Statements:** The voluntary pregnancy/nursing label statement may be combined with other voluntary labeling statements provided the combined language creates a logical construct (e.g., If you are taking a prescription medicine, or, if you are pregnant or nursing a baby, ask a doctor).
- d. **Implementation Date:** At the next label printing, but not later than April 2, 2001.

- xx -

² Words in italics represent examples of reasonably equivalent wording, and are not to be considered inclusive of all possible reasonably equivalent statements.

Endnotes of Presentation Text

- ¹ Institute of Medicine, National Academy of Sciences. Nutrition during pregnancy. Washington, DC: National Academy of Sciences Press, 1990.
Department of Health: Folic acid and the prevention of disease. Report of the Committee on Medical Aspects of Food and Nutrition Policy, January, 2000.
- ² Final Rule Regarding Label Warning for Pregnant or Nursing Women; Delegations of Authority and Organization. Federal Register 47: 54750-58, December 3, 1982.

- xx -