



Consumer Healthcare
Products Association

February 1, 2005

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

Re: Docket No. 2004N-0454, Solicitation of Written Comments on the Premarket Notification for New Dietary Ingredient Notifications. 69 Fed. Reg. 61680-61684 (October 20, 2004)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to provide comments on the premarket notification for new dietary ingredient (NDI) notifications for dietary supplements (69 Fed. Reg. 61680-61684, October 20, 2004). CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplements and over-the-counter drug products.

The Food and Drug Administration (FDA) has requested information on several questions posed in the *Federal Register* notice in efforts to determine how best to assist industry with submissions for NDI notifications. FDA clarification of the statutory requirements for NDI submissions will assist companies by ensuring that they submit the information needed for proper evaluation. Industry welcomes the efforts of the FDA to obtain public input as it moves forward on this issue and agrees that clarification on the current requirements for NDI submissions will be useful.

The sections below correspond with the sections in the *Federal Register* notice.

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Section A: Status of a Substance as a “New Dietary Ingredient”

The members of CHPA strongly believe that the definition of a dietary ingredient as stated under sections 201(ff)(A) through (F) in the Dietary Supplement Health and Education Act of 1994 (DSHEA) should not be altered. The definition clearly states which substances can or cannot be considered as dietary ingredients. CHPA members would oppose any attempts to limit the current scope of the definition for dietary ingredients.

CHPA member companies know of no all-inclusive, authoritative list of dietary ingredients marketed before October 15, 1994. Development of an authoritative list of dietary ingredients marketed before October 15, 1994, may be difficult to accomplish. Several books, lists, and other references published by different trade organizations and other interested parties are useful resources but should not be considered exhaustive or exclusive. If a company can provide legitimate documentation that a dietary ingredient was marketed prior to October 15, 1994, then that dietary ingredient should be grandfathered, regardless of its omission from current dietary ingredient publications. This is made clear by DSHEA section 413(c)'s exclusion from the new dietary ingredient provision for dietary ingredients marketed prior to October 15, 1994.

CHPA members are opposed to the Agency developing a standard checklist used to determine when a change in the condition of use would warrant the need for a separate NDI notification. The need for a NDI submission based on a change in the condition of use should depend on the initial condition of use stated for the dietary ingredient. If the initial NDI submission covered a range of use conditions (e.g., up to 10 mg/day), then no additional notification would be needed if the new use was within the range specified. However, if the new condition of use (e.g., 10 mg/day) differs from the condition of use in the original NDI submission (e.g., 5 mg/day), a NDI notification would be justified.

Section B: Chemical Identification of the NDI

CHPA members support inclusion of such chemistry information as chemical name, Chemical Abstract Service registry number (if available), empirical and structural formulas, quantitative composition, and chemical characterization and specifications as suggested by FDA in the *Federal Register* notice. Due to the extensively broad range of dietary ingredients, it would be difficult to formulate a single list of required data related to other types of chemistry or botanical information that would apply to all NDI submissions. While certain specific types of information presented for consideration in the *Federal Register* notice may be important for some dietary ingredients, our members do not feel all information is pertinent to every dietary ingredient. A listing of information to be considered for inclusion (rather than a list of required

information) would be more valuable as a guideline for individual NDI submitters preparing their notification for filing. If FDA finds critical information has been omitted, the company should be contacted to resolve the matter as quickly as possible. Similarly, reasonably thorough information regarding methods of extraction should be included in NDI notifications on botanical extracts. Extraction information is not relevant for all dietary ingredients and therefore would not be appropriate for inclusion in all NDI notices.

Section C: Information about the Dietary Supplement

FDA requests comments related to the types of information about the dietary supplement product label and formulation that should be included in the NDI notification. Currently, the regulations for an NDI require a written description of the dietary supplement that includes the new dietary ingredient in the notification. That description includes the level of the new dietary ingredient in the product and the conditions of use that would be recommended in the dietary supplement labeling. Inclusion of this description is important for establishing that the dietary supplement product can reasonably be expected to be safe, since a dietary ingredient may be safe only at a specific level and/or under certain conditions.

Because in many cases the label and other labeling information are not complete at the time of the NDI notification submission, members of CHPA advocate allowing submission of the pertinent information in a text format instead of a copy of the proposed label. A written description of the dietary supplement should be adequate at the notification stage. As the final label is unlikely to be available at the time of notification, especially if a supplier or manufacturer submits the notification several months before marketing the product, a copy of the proposed or final product label should not be required as part of the notification. Additionally, labeling requirements for dietary supplement products are already standardized and detailed in DSHEA.

In regard to the composition/formulation of the dietary supplement product, information needed for establishing a reasonable expectation of safety, such as characterization of the dietary ingredient and a description of relevant manufacturing processes, are provided for in the NDI notification. Detailed information on the final composition or formulation of the dietary supplement product, which would most likely be proprietary and confidential, is not necessary for demonstrating safety and therefore should not be required in a NDI notification. Manufacturers would be responsible for ensuring the safety of the final product.

Section D: Establishing a Reasonable Expectation of Safety

FDA seeks industry recommendations about establishing a reasonable expectation of safety for dietary ingredients. CHPA members advocate using a model similar to that of “generally recognized as safe” (GRAS) for establishing a reasonable expectation of safety for dietary ingredients. A company’s panel of outside, qualified experts or opinions from other authorities should be sufficient to determine the safety of the dietary ingredient. A dietary ingredient should be deemed “reasonably expected to be safe” if qualified scientific experts have concluded it to be so after review of sufficient data generated from appropriate scientific procedures. Because the types of scientific data necessary to evaluate safety vary depending on the specific dietary ingredient, there should be flexibility in the types of evidence submitted for expert review.

Additionally, a dietary ingredient would meet the requirements under DSHEA section 413(a)(2) for historical use if it has been used by a relevant population. The time and extent of reasonably safe use of the dietary ingredient by an appropriate population should be sufficient to establish a reasonable expectation of safety. Documentation of the information used to corroborate the history and conditions of use would be readily available for review by interested, qualified experts in the United States and the country of historical use.

Section E: The Role of Definitions in Evaluating NDIs

CHPA members propose that the terms listed in the *Federal Register* notice be interpreted broadly under the spirit of DSHEA. Restrictive definitions are not needed.

Section F: Is There a Need for Guidance or Amendment of Current Requirements?

CHPA members welcome the development of a guidance document to facilitate a more transparent process for NDI submissions but see no need to amend the current requirements. Dietary supplement manufacturers appreciate the efforts of FDA to include the perspectives of interested parties, including industry, as it grapples with this difficult issue. CHPA members would be happy to provide continued input should the opportunity arise (e.g., establishment of a joint task force comprised of FDA, industry, and other interested parties) and welcome ongoing dialogue as the guidance is developed.

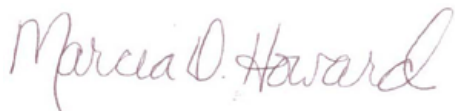
Additional Points for Consideration

CHPA members believe a company that has submitted an NDI notice to FDA should be permitted to withdraw the notice without prejudice. The option to withdraw the submission should be available anytime before the Agency issues its response. FDA would be able to better use its limited resources by eliminating unnecessary reviews of NDI submissions withdrawn by the applicant.

To encourage continued research into the safety of dietary ingredients and supplements, FDA should search for ways to provide market exclusivity to companies that undertake these expensive and time-consuming scientific studies. A January 12, 2005, Institute of Medicine press release urged Congress to create incentives for research on the efficacy of complementary and alternative therapies, which include dietary supplements. Under the current system, firms who submit safety data for NDI notifications have no real opportunity to recover the cost of their substantial investment. Although an easy method to implement this program is unlikely to be found, FDA, industry, and other interested parties should have an open dialogue on realistic ways to reward companies who invest in safety studies.

CHPA member companies thank the Agency for the opportunity to provide comments about its premarket notification program and strongly urge FDA to consider the industry perspective as it moves forward in clarifying the statutory requirements of this program. Furthermore, our members welcome continued dialogue with FDA to achieve a notification program for new dietary ingredients that places no unreasonable burden on industry yet provides safe dietary ingredients and supplements to the general population.

On behalf of the CHPA Dietary Supplements Committee,

A handwritten signature in red ink that reads "Marcia D. Howard". The signature is written in a cursive, flowing style.

Marcia D. Howard, Ph.D.
Associate Director of Scientific Affairs