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Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. 2004N-0454: Premarket Notification for  
New Dietary Ingredients**

To Whom It May Concern:

The American Botanical Council ("ABC") is submitting the following comments to the Food and Drug Administration ("FDA") in response to the agency's public notice published in the *Federal Register* on October 20, 2004 (Volume 69, Number 202: "Dietary Supplements; Premarket Notification for New Dietary Ingredient Notifications; Public Meeting").

ABC is a tax-exempt, non-profit research and education organization under section 501(c)(3) of the IRS tax code. ABC is a member-based research and education organization, with over 3000 non-voting members from various areas of interest in the fields of herbs and medicinal plant products, including research on their agronomics, chemistry, pharmacology, toxicology, and clinical applications, as well as their production, marketing and promotion, and their utilization. ABC members include consumers, healthcare practitioners, academic and industrial scientists, botanical gardens and arboreta, libraries, members of industry, government scientists and officials, journalists, and more. ABC publishes numerous educational materials, including *HerbalGram*, a quarterly, peer-reviewed journal, and *HerbClip*, a bi-weekly publication containing summaries and critical reviews of recent clinical research and other papers published about herbs and phytomedicines from the scientific, medical, and related literature. ABC licenses numerous electronic databases of back issues of *HerbalGram* all *HerbClips*, and two of ABC's books for health professionals and researchers to various commercial and noncommercial licensees for educational purposes, including the Food and Drug Administration for posting on FDA's intranet site for use as a research resource by FDA's employees.

ABC has had a long interest in issues relating to the safety of herbs and related botanically-based preparations in the United States, including the issue of New Dietary Ingredients (NDIs). ABC is grateful for the opportunity to comment on the questions posed by FDA in its *Federal Register* notice of October 20, 2004 (FDA, 2004a).

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ABC commends FDA for its ongoing efforts to ensure the safety of new ingredients used in dietary supplements and other areas of the food supply. ABC also appreciates the FDA's recent initiatives to further enforce the provisions of Dietary Supplement Health and Education Act of 1994 (DSHEA) by offering draft guidelines for substantiation of structure-function claims under DSHEA, as published in November 2004 (FDA, 2004b). ABC urges FDA to continue to work within the legal framework established by DSHEA to promote a rational system for the evaluation of the relative safety of botanical and other related materials that are intended to be used as ingredients in dietary supplements.

For several years ABC has been concerned that industry, media, health professionals and other areas of the general public have not adequately understood or appreciated the significance of Section 8 of DSHEA, the New Dietary Ingredient provision (codified at 21 USC § 350b). For this reason ABC published an article on NDIs in *HerbalGram* in 2004 in which the NDI provision of DSHEA and various aspects related to Section 8 were explained (Noonan and Noonan, 2004). ABC has also distributed in its HerbClip Educational Mailing Service another significant article on the subject of NDIs that was published in the past year (McGuffin and Young, 2004).

ABC appreciates FDA's recent attention to NDIs and the agency's apparent willingness to provide meaningful guidance in this area. ABC believes that a robust, rational enforcement program by FDA coupled with effective self-regulatory programs established by the responsible elements of the dietary supplement industry can help reach the goal of providing the public with quality herbal dietary supplements that are reasonably expected to be safe under recommended (or ordinary) conditions of use, provide health benefits that are documented by existing knowledge of traditional use and scientific/medical research, and are marketed with truthful and not misleading claims concerning beneficial effects on bodily structure and function.

### **Defining "Grandfathered" or Old Dietary Ingredients (ODIs) and Official Recognition of Lists of ODIs**

One of the primary reasons DSHEA was passed was Congress's response to the public's demands for continued *access to* dietary supplements as well as *information on the benefits* of these supplements. Thus, satisfying the public's demand for continued public access to supplement ingredients was a primary consideration in the minds of Congressional sponsors of the Act as well as Congressional leaders when Congress passed DSHEA in October, 1994. Thus, DSHEA provided protections to dietary supplement ingredients that had been marketed in the U.S. prior to October 15, 1994 to permit continued access to such dietary ingredients. For these ingredients, no FDA premarket review or approval is required. Such ingredients are commonly referred to as "old dietary ingredients" (ODIs) or "grandfathered" ingredients, although these terms do not appear in DSHEA. On the other hand, the DSHEA established a mechanism by which certain "new dietary ingredients" are subject to premarket review and acceptance by FDA. Section 413 of the Federal Food, Drug, and Cosmetic Act, as amended by DSHEA,

states that the term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994. (21 USC § 350b(c)).

During the intervening decade since DSHEA was passed, there has been some confusion in the marketplace – at least with respect to some herbs and botanically-derived ingredients -- as to which dietary ingredients are ODIs and which are NDIs. ABC believes it would be most constructive for industry as well as for the research and regulatory communities if the FDA were to officially recognize a positive list of ODIs.

**Lists of ODIs or Grandfathered Ingredients.** In its *Federal Register* notice of October 20, 2004 the agency asks the following:

Is there an authoritative list of dietary ingredients that were marketed prior to October 15, 1994, and therefore are not NDIs? If not, should there be? Who should compile such a list and what criteria should be considered for placement of the dietary ingredient on such a list? (FDA, 2004b)

As the Agency is aware, the American Herbal Products Association, the leading trade association representing the herb growing, importing, and manufacturing industry, published a list of approximately 1,500 plants (2,048 separate species) with the proposed standardized common names of herbal products sold in the U.S. that were *presumably* sold in the U.S. prior to the passage of DSHEA. This list, compiled as a book titled *The American Herbal Products Association Herbs of Commerce, 2d edition* (McGuffin et al., 2000), comprises an excellent self-regulatory mechanism initiated by industry to standardize the common names of herbs sold in the U.S. and provide corresponding Latin binomials according to the most recent conventions in modern botanical taxonomy. ABC commends the Agency for its wise and appropriate recognition of this self-regulatory publication as official nomenclature of common names for herbal ingredients in dietary supplements (FDA, 2003).

As the Agency is aware, according to AHPA this list was based on invitations to its member companies and to industry experts to submit names of plants that the companies either sold and/or the companies or the experts knew were sold in the U.S. prior to the passage of DSHEA:

This work represents a compilation of submissions from companies involved in the trade of products containing botanicals and from experts in this class of trade. These were in response to written requests from AHPA that specifically stated that only dietary ingredients marketed prior to October 15, 1994 should be included in such submissions. In addition, the editors [of the AHPA publication] included species that were thought to have been overlooked in this process. To the best of our knowledge, only plants marketed prior to this date are included herein, though neither AHPA nor the editors have expended any effort in independent verification of this assumption. The listing of a particular species of plant in this work is not, therefore, in and of itself, evidence that such species was marketed in the United States prior to October 15, 1994. (McGuffin et al., 2004, p. xx).

It should be noted that while the AHPA list constitutes a *comprehensive* list of plant species putatively sold in the United States prior to October 15, 1994, the list is not proposed as *exhaustive*; it is possible that it overlooked plants that could be recognized subsequently as ODIs, presuming evidence of marketing exists to support such a classification. The AHPA authors write:

Similarly, the exclusion of a particular plant should not be seen as proof of or an indication that such plant was not marketed in the United States prior to October 15, 1994. Although every effort was made to broadly distribute the written requests referred to above, no evaluation has been made of the thoroughness of this process in identifying all such botanical ingredients. (McGuffin et al., 2004, p. xx).

The FDA declined to recognize the AHPA list in *Herbs of Commerce 2d edition* as having any official status as a positive list of botanical dietary supplements for ODI status when the Agency officially recognized the AHPA list as an official nomenclatural guide for the common names of herbs sold in U.S. commerce. (FDA, 2003).

In addition to the AHPA list, both the Council for Responsible Nutrition (CRN) and the Utah Natural Products Alliance (UNPA), both trade associations representing various members of the dietary supplement industry, have compiled comprehensive list of ODIs that is comprised of herbal/botanical ingredients plus conventional nutritional ingredients and related compounds (CRN, 1998; UNPA, 1999).

The CRN list, published in September, 1998, is based on a list compiled previously by the National Nutritional Foods Association (NNFA), another trade association in the dietary supplement and natural foods industry. CRN members added more items to the basic list prepared by NNFA.

The UNPA list was initially compiled in September 1997, a relatively short period of time after the passage of DSHEA. This list reflects the combined conventional wisdom and the best efforts of the dietary supplement industry and other experts regarding which dietary ingredients were sold in U.S. commerce prior to October 15, 1994. It is based on UNPA's own research from its various members, plus it is the subsequent addition of ingredients found in similarly-developed lists from other industry groups, i.e., AHPA, CRN and NNFA. The UNPA list contains the names of over 2800 dietary ingredients (and their various synonyms) and is probably the most comprehensive list of putative ODIs available in one source.

These lists do not contain information about the types of preparations, who they were prepared (e.g., mode of processing, extraction, concentration, etc.). Instead, these lists are a baseline of recognition by the industry of the ingredients that were sold in dietary supplements prior to October 15, 1994.

ABC asks FDA to reconsider its previous withholding of official recognition of the AHPA *Herbs of Commerce* list as an official list of botanical ODIs. ABC respectfully requests that the FDA adopt the AHPA, CRN and the UNPA lists as official registers of ODIs and that the FDA recognize these lists as legitimate positive lists of botanical ODIs,

at least insofar as recognizing the possibility that any plant species and other dietary ingredient included on these lists is presumably an ODI, so long as these ingredients meet other criteria for an ODI, e.g., a dietary ingredient derived from the plant species consists of either crude botanical material (whole or cut or powdered herb) or a concentrate, metabolite, constituent, extract or any combination of these ingredients (including gums, essential oils, etc.).

ABC appreciates the FDA's questions that imply a preference for an "authoritative" list of ODIs in which the marketing history of all ingredients can be positively documented with clear evidence of sale. However, so far as ABC is aware, there are no provisions of DSHEA and/or any other applicable federal legislation that impose an affirmative duty on the seller of an ODI to show evidence of marketing prior to October 15, 1994 to confirm the ODI status of that ingredient, i.e., that a dietary ingredient is not an NDI.

Further, in response to FDA's question about the development of an "authoritative" list, while ABC understands that such a list might be able to be constructed by a formal review of each herb and/or other dietary ingredient that members of industry and other qualified experts believe are ODIs and then requiring the type of evidence that FDA would want to confirm such status (e.g., an invoice, bill of lading, listing in a catalog, an advertisement, etc.), the amount of time, resources, and expense involved in the attempts to recreate such a thoroughly documented affirmative list would be, in ABC's view, a misallocation of resources on the part of industry and/or the Agency and/or nonprofit organizations that may be involved in such an undertaking. This is especially true for an undertaking of this magnitude more than a decade after the passage of DSHEA in October 1994. Understandably, few companies will have retained records of invoices, bills of lading, catalogs and/or other types of evidence that the Agency would consider adequate proof of sale of a purported ODI prior to October 15, 1994. In hindsight, ABC would have preferred that the Agency had taken the leadership to suggest such an undertaking a decade ago, or some reasonable time after the passage of DSHEA; that is, the Agency had what appears to be ample opportunity to work with industry associations to compile such an "authoritative" list but apparently declined to do so. ABC does not believe that the initiation of such a project is in any of the stakeholders' best interests, including consumers of dietary supplement products containing these ODIs. Furthermore, in consideration of the express language of the DSHEA, ABC does not believe that FDA would have the requisite statutory authority to institute such requirement.

ABC believes that the currently available ODI lists from AHPA, CRN, and UNPA that have been put forth as de facto lists of pre-DSHEA grandfathered ODIs should be recognized by FDA as official lists of "grandfathered" ingredients, and that all ingredients based on the botanical species on these lists should formally recognized as ODIs, unless FDA has credible evidence to the contrary, or FDA becomes aware of such evidence.

Further, ABC emphasizes that the recognition of such a list should not be exclusive. That is, other ingredients might be subsequently determined to be ODIs; lack of inclusion of a

particular ingredient on an officially recognized list of ODIs should not exclude that ingredient's being recognized as having ODI status by the agency.

**“Lawfully” Marketed.** The section of DSHEA that defines an NDI (as set forth above at 350b(c) of the USC), requires initial “marketing” of the ingredient in the U.S. after October 15, 1994. ABC is aware that in some of FDA’s recent warning letters, FDA has asserted that to qualify for ODI status, an ingredient must have been “lawfully marketed” (e.g., Satchell, 2001). ABC respectfully disagrees with FDA’s apparent interpretation of this provision of the law and maintains that FDA is in error. Indeed, prior to the passage of DSHEA, FDA asserted that numerous substances, including botanicals preparations such as evening primrose oil (from the seeds *Oenothera biennis*) and black currant seed oil (*Ribes nigrum*), were unlawful food additives. Notwithstanding the agency’s previous assertions, such ingredients are clearly within the scope of ingredients that are ODIs within the meaning of the law. ABC notes that the term “lawful” does not appear in this section of the DSHEA. If Congress had wished to impose this requirement, it could have included the term “lawfully” to qualify “marketed.” ABC’s position is that, according to the plain language of the statute, “marketed” would mean simply that an ingredient was “sold or offered for sale.” It should also be noted that an ingredient need not have been marketed as a “dietary supplement” ingredient in order to qualify as an ODI. ABC believes that it is reasonable to interpret this provision to mean marketed for oral consumption or for use as a food substance.

As the Agency is well aware, one of the primary motivations for the passage of DSHEA was the concern among a significant portion of the population that, prior to DSHEA, FDA’s interpretation of the law and the agency’s enforcement policy with respect to the sale and marketing of substances for which no Daily Reference Values had been established was not legally supportable (and/or was overly hostile). Moreover, the law and FDA regulations in effect prior to 1994, (including FDA regulations being promulgated pursuant to the Nutrition Labeling and Education Act of 1990) were in fact inadequate to appropriately address this class of products. Therefore, it is at least theoretically possible that an ingredient may not have been “lawfully sold” according to FDA – i.e., the ingredient may not have been GRAS or an approved food additive. Notwithstanding, such ingredients may be safe for their intended use, i.e., as an ingredient in a dietary supplement. In other words, the fact that a dietary ingredient may have been sold prior to passage of DSHEA on October 15, 1994 in a manner that was not “lawful” in the eyes of FDA under the inadequate regulatory framework of the times should not invalidate its status (and safety) as an ODI in today’s regulatory system.

### **Defining a New Dietary Ingredient (NDI)**

As ABC understands the relevant provisions of federal law, there are two types of NDIs: one requires FDA notification and one does not. The law states (21 USC § 350b) that a dietary supplement shall be deemed adulterated under section 402(f) (the “significant or unreasonable risk” safety standard), unless it meets one of the following requirements:

(1) the dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered, or

(2) there is history of use or other evidence establishing that the dietary ingredient when used under the conditions of use suggested in labeling will reasonably be expected to be safe and notification and information forming the basis of the safety determination is provided to FDA at least 75 days in advance of marketing.

In paragraph #5 of the "Statement of Agreement" constituting the entire legislative history of DSHEA, and accompanying S. 784 (the Senate version of the bill that was enacted as DSHEA), the term "chemically altered" for purposes of section 413(a)(1) does not include the following physical modifications: minor loss of volatile components, dehydration, lyophilization (freeze-drying), milling, tincture or solution in water, slurry, powder, or solid in suspension. [Congressional "Statement of Agreement" on DSHEA (Oct. 7, 1994); Senate Report (Labor and Human Resources Committee) No. 103-410, Oct. 8, 1994 to accompany S. 784].

ABC interprets this to mean that not all NDIs require FDA notification and premarket review. An NDI that is a component of food that has been present in the food supply may be freely marketed so long as the food in which the ingredient is found has not been chemically altered, as described above. This means that substances found in the food supply, at any level and regardless of their prior safety evaluation, would be excluded from the 75-day premarket notification requirement.

As is well known, Section 3 of DSHEA amends Section 201 of the Food, Drug and Cosmetic Act (FDC Act), by adding section ff, defining the term "dietary supplement" as "(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)..." (DSHEA, Section 3) (21 USC § 321 (ff)(1)(A)-(E)).

ABC is concerned that the Agency may be attempting to narrowly interpret the universe of ODIs, including those consisting of or derived from herbs or other botanicals, in contravention of the FDC Act, as amended by DSHEA. In particular, ABC is concerned that FDA may try to broadly interpret the "chemically altered" language included in the "Statement of Agreement" for purposes of section 413(a)(1), and apply it to section 413(a)(2), to attempt to limit the sale and availability of certain dietary ingredients by asserting "new dietary ingredient" status requiring FDA premarket notification.

ABC maintains that dietary ingredients derived from "old" or "grandfathered" herbs and botanicals that have been processed beyond the processes mentioned in the Statement of Agreement, referencing 413(a)(1) above, are properly considered ODIs.

ABC's position is that the process of producing standardized extracts in which some of the components of the extract are either concentrated beyond the naturally-occurring levels of said components, or even isolated from their original botanical matrix – would produce ODIs, assuming the plant from which they are produced is recognized as an ODI. ABC believes that such concentrated extracts and/or isolates are not NDIs *per se* if they were not themselves articles of commerce prior to October 15, 1994, since DSHEA states that any ingredient in the form described in section (F) above is a dietary supplement. Thus, a dietary supplement that qualifies as an ODI by virtue of the plant's identity and nomenclature should not be considered an NDI when it is extracted in such a manner as to be viewed as a concentrate, metabolite, constituent, extract, or any combination, including isolated concentrates, metabolites, constituents, or extracts. Indeed, the definition of dietary supplement in Section 3 of DSHEA (subsections fFC and fFF, per above) includes "herb or other botanical" and "extract, concentrate, metabolite or constituent."

ABC believes that any narrow interpretation of the provisions of DSHEA would, in effect, potentially limit consumer access to dietary ingredients that have been sold in one form or another as ODIs, but, have been either concentrated through a process of standardization (or chemical adjustment or normalization, as the process is sometimes called). ABC believes that this would be contrary to the intent of Congress in the passage of DSHEA.

Further, ABC notes that there are safety provisions in DSHEA to protect consumers. A manufacturer or distributor of a dietary supplement or dietary supplement ingredients has a duty to ensure that its products are not adulterated and would not present a "significant or unreasonable risk of illness or injury." ABC emphasizes that the provisions in Section 8 have limited applicability to NDIs but *all* dietary ingredients – old or new -- must comply with the safety standards of 21 USC 342(a);(f).

ABC believes that when Congress wrote the term "chemically altered", Congress presumably intended to mean a true modification or alteration of the *structure* of the chemistry of a particular ingredient, but not the *concentration* of that ingredient in its natural botanical matrix.

An example of a potentially erroneous interpretation of the "chemically altered" provision might be the increasingly popular supplement lycopene, a carotenoid complex found in tomatoes and other fruits and vegetables (e.g. pink grapefruit *et al.*). ABC does not believe that the concentration of lycopene in extract of tomato paste or the actual isolation of lycopene from tomatoes as a dietary ingredient constitutes an NDI under the terms of DSHEA.

**Criteria for Determining Safety of an NDI.** There has been some discussion as to whether the Agency is considering requiring a higher level of evidence for the determination of the relative safety of an NDI in the 75-day notifications for NDIs. In the article on NDIs published in *HerbalGram* (Noonan and Noonan, 2003), the authors distinguish between the levels of evidence that can render an ingredient to be "reasonably

expected to be safe” versus a more strict standard for food additives that the Agency appears to have been requiring from sellers who submit the 75-day notifications.

Another notable difference in the legal requirements between a food additive petition and an NDI submission is in the scientific validation needed for the new food additive ingredient. A new food additive petition must include full reports of investigations made with respect to safety of the food additive, and those reports must include detailed data from animal and other toxicology tests. In contrast, an NDI submission must include a history of use or other evidence of safety that the ingredient will be reasonably expected to be safe, including citations to published articles. While seemingly less stringent for an NDI, it is in this area that FDA apparently is expecting more studies and clinical information to show a reasonable basis for safety of a dietary ingredient. This is not found in any published FDA guidance but is discernable from the comments made by FDA for NDI submissions in which “no reasonable basis of safety” was cited as the reason for rejection. It is an FDA bias that results from the agency’s understanding of acceptable science for other food ingredients found to be GRAS or subject to a food additive regulation. (Noonan and Noonan, 2004)

While ABC supports and is deeply committed to efforts that help to ensure the safety of all dietary ingredients and other substances in the food supply, ABC believes that the standards that are employed in the determination of such safety for the purposes of allowing entry of an NDI to the market must meet the criteria intended by Congress when DSHEA was passed, i.e., to the extent that such standards were either defined or implied, and not the standards that are applied to determine the safety of food additives or GRAS substances.

**Plant Part.** In response to FDA’s questions about the information that should be included in the 75-day NDI notification, ABC suggests that the notification should include the part of the plant used; this information is apparently not presently required in 21 CFR § 190.6. Insofar as differing parts of the same plant usually contain different chemistry and thus differing nutritional benefits and/or biological activity and since the identity of plant parts is required in all labeling of dietary supplements under DSHEA, ABC believes that stipulating to which plant part the information in a 75-day notification pertains would be logical and appropriate.

**History of Use.** The language of DSHEA states that the traditional use history of an ingredient can be useful as a criterion for assessing that an NDI can be reasonably expected to be safe within its intended use. ABC believes that data on the traditional use of an ingredient in a foreign country and/or any epidemiological data on current use are reasonable and acceptable criteria to consider in evaluating the relative safety of an ingredient in an NDI notification.

**Detailed Information for Inclusion in Notification.** ABC believes that it would probably be most constructive to those who would file an NDI notification if the list of questions posed by FDA in its October 20, 2004 notice (pp. 61682-61683) were part of an expanded guidance document on NDI notifications to be issued by FDA for industry. This includes questions about the “Chemical Identification of the NDI” (IV.B. in the notice), “Establishing a Reasonable Expectation of Safety” (IV.D. in the notice).

Depending on the ingredient in question, some of the specificity regarding the ingredient as detailed in the questions posed by FDA in the notice may or may not apply to any particular ingredient. Thus, the posting of these questions, or possibly an expanded version thereof, could provide a party filing a notification with proper and adequate guidance on what type of information to include with the notification to support the safety of the NDI.

**Guidance Document v. Regulation.** ABC believes that the publication of a guidance document from FDA that clarifies the agency's current thinking on the quality and quantity of data required to establish reasonable expectation of safety of NDIs in the 75-day notifications would be preferable to the issuance of new regulations.

**Safety: Risks and Benefits.** ABC recognizes that in general the vast majority of herbal ingredients used in dietary supplements have an excellent record of safety when used responsibly and in accordance with labeling directions. At the same time, however, ABC also recognizes that herbal dietary ingredients often contain naturally-occurring pharmacologically active compounds, which, individually, additively, and/or synergistically can produce potentially adverse effects, particularly when used by persons with specific medical conditions and/or by certain persons who may also be using conventional prescription and/or nonprescription medications. ABC understands that such information, when available and when applicable to an NDI, should be considered during the FDA's evaluation of an NDI notification, but that this safety data needs to be assessed within the context of the proposed quantities of use of the NDI and the ingredient's potential benefit, expressed as how ingredient most probably will affect the structure or function of the body of prospective users. ABC also acknowledges that under the current regulatory system for herbs, related botanical products and other dietary ingredients, there is no rational mechanism available for the evaluation and official recognition of benefits for this class of substances. Accordingly, ABC is concerned that the Agency may employ a process to evaluate the potential risk of an ingredient that is the subject of an NDI notification without considering the potential risk in relation to a potentially countervailing benefit.

Further, as part of its ongoing public education efforts, ABC has developed its Safety Assessment Program in which ABC employs a peer-review process to evaluate the relative safety of herbal dietary ingredients for use by manufacturers of herbal dietary supplements in the development of directions for use, warnings, and other pertinent information for dietary supplement labels, company Internet sites, and other appropriate means of communication. To date, ABC has evaluated about two dozen herbs for their safety as dietary supplements, with recognition of their potential risks as well as proposed warnings for herbal dietary supplement product labels, as provided by Section 10 of DSHEA. This information is licensed by ABC to various companies for their further use.

ABC is grateful for the opportunity to file these comments and looks forward to the possibility of working with the FDA and all other interested parties towards ensuring the

safety of dietary supplement ingredients by establishing a meaningful and rational standard of regulation for NDIs.

Sincerely,



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