

BEFORE

THE UNITED STATES OF AMERICA

NATIONAL INSTITUTES OF HEALTH

OFFICE OF DIETARY SUPPLEMENTS

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE

DIETARY SUPPLEMENT LABEL DATABASE

December 30, 2015

TABLE OF CONTENTS

Prefatory remarks1

1. DSLD disclaimer.....2

2. Sources of DSLD information4

3. Foreign products in the DSLD.....7

4. Direct submission of labels by supplement marketers9

5. Organization and content10

6. Current contractor’s use of data14

Conclusions15

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products, including herbal dietary supplements. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

The Dietary Supplement Label Database (DSLDB) is a joint project of the Office of Dietary Supplements (ODS) and the National Library of Medicine (NLM) of the National Institutes of Health (NIH). The DSLDB is an online database described as containing “the full label contents from a sample of dietary supplement products marketed in the U.S.” and all information is reported as “obtained from the manufacturers’ labels.”¹ The DSLDB provides images of included supplement product labels, presents information about the listed products in numerous fields, and is searchable by a number of these fields.

On October 29, 2015 ODS issued a Federal Register notice (the October 29 notice) in which it requested public comment to solicit ideas and suggestions for how the DSLDB might evolve and what features might be added, improved, or enhanced that would make the DSLDB a more valuable tool for users. 80 FR 66549. In making this request ODS identified as examples of such features attention to capabilities related to search, sorting, organization, and downloading of information. According to the October 29 notice, the DSLDB currently contains 50,000 labels, and is expected to grow rapidly over the next three years to include most of the estimated 75,000+ dietary supplement products sold to American consumers. The October 29 notice also states the DSLDB is updated regularly to include any formulation changes and label information in a product,² and includes the labels of products that have been discontinued and are no longer sold.

¹ <http://www.dsldb.nlm.nih.gov/dsldb/index.jsp>, accessed December 20, 2015.

² AHPA understands that updates to labels for products already in the DSLDB will include formulation changes, if any, reflected in the updated label for the product, and that there are no other mechanisms whereby the DSLDB would “update ... formulation changes.”

Numerous AHPA members market herbs and herbal products in or as dietary supplements, which products may currently be listed in the DSLD or may come to be listed therein. In addition, in May 2015 AHPA announced that its Board of Trustees had acted to encourage members that market dietary supplement products under their own brands to submit labels for inclusion in the DSLD, and to also recommended that improvements be made to the accuracy of entries in the database and that the database be redesigned to provide only currently marketed labels through public access. AHPA and its members thus have an interest in the DSLD, in its current content and functionality, and in its possible additions, improvements and enhancements. These comments are therefore submitted on behalf of AHPA and its members.

The focus of these comments is limited to certain specific details of the DSLD of interest to AHPA and its members; absence of comments regarding any other element of the DSLD does not represent AHPA's endorsement of any element not addressed herein.

1. DSLD disclaimer

Each exhibited webpage of the DSLD website bears a disclaimer that reads as follows:

Disclaimer: All information contained in the Dietary Supplement Label Database comes from dietary supplement labels. The dietary supplement label may not have met the then current nor meet current U.S. Food and Drug Administration (FDA) regulations. The presentation of dietary supplement label information is not an endorsement or guarantee of accuracy by the Office of Dietary Supplements or the National Library of Medicine, both part of the National Institutes of Health, U.S. Department of Health & Human Services.³

AHPA understands that a disclaimer is standard for websites that present information not prepared or controlled by the website operator, and AHPA recognizes the legitimacy of disclaiming in such a forum the website operator's responsibility for the accuracy of the underlying information and endorsement of the represented products. AHPA, however, views the second sentence of the disclaimer on the DSLD website (i.e., "The dietary supplement label may not have met the then current nor meet current U.S. Food and Drug Administration (FDA)

³ <http://www.dsld.nlm.nih.gov/dsld/index.jsp>; accessed December 23, 2015.

regulations.”) as unnecessarily calling into question regulatory compliance of labels included in the DSLD.

AHPA is aware of the *FDA Online Label Repository*,⁴ a website maintained by the U.S. Food and Drug Administration (FDA) on which labels for FDA regulated products are made available to the public. A disclaimer presented on this website includes the following statements:

- Drug labels: “The drug labels and other drug-specific information on this Web site represent the most recent drug listing information companies have submitted to ... FDA. ... The drug labeling and other information has been reformatted to make it easier to read but its content has neither been altered nor verified by FDA. The drug labeling on this Web site may not be the labeling on currently distributed products or identical to the labeling that is approved.”
- OTC drugs: “Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies described in monographs. Drugs marked ‘OTC monograph final’ or ‘OTC monograph not final’ are not checked for conformance to the monograph.”
- Medical devices: “The device labeling and other device-specific information on this website have been voluntarily submitted to the FDA by device manufacturers. FDA has not reviewed this information prior to posting on this website. The device labeling has been reformatted to make it easier to read but its content has not been altered nor verified by FDA. The device labeling on this website may not be the labeling on currently distributed products.”
- Unapproved products: “Drugs marked ‘unapproved medical gas’, ‘unapproved homeopathic’ or ‘unapproved drug other’ on this Web site have not been evaluated by FDA for safety and efficacy and their labeling has not been approved. In addition, FDA is not aware of scientific evidence to support homeopathy as effective.”

In each of the above cited statements, FDA conveys that it has not “verified,” “checked for conformance,” or “approved” the labels and label information available on the site, and acknowledges that the labels on the website may not be the most current. But these disclaimers do not make any statement to the effect that the labels “may not have met the then current nor meet current” FDA regulations.

⁴ Available at www.labels.fda.gov; accessed December 23, 2015.

To address just the issues discussed above,⁵ AHPA requests the disclaimer on the DSLD website be changed to one of the following alternative options, where the struck through language is proposed to be removed and the bolded language is proposed to be added:

- Disclaimer: All information contained in the Dietary Supplement Label Database comes from dietary supplement labels. ~~The dietary supplement label may not have met the then current nor meet current U.S. Food and Drug Administration (FDA) regulations.~~ The presentation of dietary supplement label information is not an endorsement or guarantee of accuracy by the Office of Dietary Supplements or the National Library of Medicine, both part of the National Institutes of Health, U.S. Department of Health & Human Services.
- Disclaimer: All information contained in the Dietary Supplement Label Database comes from dietary supplement labels. **The labeling and other information has been reformatted to make it easier to read but its content has not been altered nor verified.** ~~The dietary supplement label may not have met the then current nor meet current U.S. Food and Drug Administration (FDA) regulations.~~ The presentation of dietary supplement label information is not an endorsement or guarantee of accuracy by the Office of Dietary Supplements or the National Library of Medicine, both part of the National Institutes of Health, U.S. Department of Health & Human Services.

2. Sources of DSLD information

The DSLD homepage as well as each DSLD product page includes a statement that all information contained therein “comes from dietary supplement labels.”⁶ Additionally, each product page identifies the information as “a complete representation of the manufacturer’s

⁵ AHPA has raised additional points below that may require further revision to this disclaimer. For example, AHPA has found numerous examples in which the information provided about listed products was derived from sources other than labels, so the first sentence of the disclaimer may also need to be revised.

⁶ <http://www.dsld.nlm.nih.gov/dsld/index.jsp>; accessed December 23, 2015.

label contents on the date that the data was entered” and “includes all information available on the product label.”⁷

AHPA has identified, however, several DSLD products webpages that provide an image at the “View Label” link on the page that are not images of actual product labels but appear instead to be images or screenshots of Internet sites on which products were offered for sale or otherwise presented. Examples include the following; the access date for all identified links was December 23, 2015:

- 21 Super-Vita; posted at <http://www.dsld.nlm.nih.gov/dsld/docs/13537.pdf>. The image presented is a page identified as “Appendix for NIH Proposal: ‘Paying for Performance’” and bears several hand-written notes, including a number that is the same as the information presented for this products as its “NHANES ID.” The source, origin or Internet location (URL and date accessed) of this image is not identified in this DSLD listing.
- Pharbestusa Oyster Shell Calcium – 500 mg + D; posted at <http://www.dsld.nlm.nih.gov/dsld/docs/13928.pdf>. The image presented is apparently a page from an online catalogue of products identified as “Neutraceutical [sic] Products” marketed by this brand and bears a hand-written asterisk to indicate the particular products and a hand-written number that is the same as the information presented for this products as its “NHANES ID.” The source, origin or Internet location (URL and date accessed) of this image is not identified in this DSLD listing.
- Sunshine Naturals Vitamin B-6 Pyridoxine HCl 50 mg (100 tablets); posted at <http://www.dsld.nlm.nih.gov/dsld/docs/34612.pdf>. The image presented is apparently from a website that offered this product for sale at the time this was posted at the DSLD as it includes a small “Add to Cart” icon. The image bears hand-written marking that crosses out information in a pictured Supplement Facts panel (“Vitamin B-12 500 mcg”) and indicates apparent substitute information (“Vitamin B-6 50 mg”). The source, origin or Internet location (URL and date accessed) of this image is not identified in this DSLD listing.

⁷ See, for example, the webpage listing the products identified as Bayer HealthCare – ONE A DAY(R) Maximum (<http://www.dsld.nlm.nih.gov/dsld/prdInfo.jsp?id=9735>; accessed December 23, 2015). In the course of preparing these comments AHPA staff has reviewed numerous product webpages and finds the same description on each such page.

AHPA has not performed an exhaustive review of all dietary supplement labels included in the DSLD. The above examples are therefore merely representative of the use of non-label sources for DSLD information and AHPA is uncertain as to the extent of this practice.

A search of the DSLD database for only those records identified as in the NHANES database returns 903 such records,⁸ some of which are accompanied by images of actual labels, others with photographs of products, and still others with documents similar to those described for the three above-cited examples.

AHPA understands there may a specific NHANES-related function for some users of the DSLD, such that the information included for some listed products do not come from product labels but from other information sources. Against that background, AHPA recommends the DSLD be modified to implement either of the following:

1. Establish as a practice for the DSLD that only an actual product label be used as the source of information about a dietary supplement product listed in the database and therefore remove all current listing for which product information was obtained from other sources and retain the current statements on the site that identify product labels as the sole source of DSLD product information; or
2. If label information and the associated label image for some DSLD-listed products will continue to be obtained from sources other than an actual product label in situations where the actual product label is not reasonably available:
 - a. Provide text throughout the site that accurately describes that the source of listed product information may come from various sources; and
 - b. Add a field for each listed product to clearly disclose whether the information for that product was obtained from an actual product label, a website description of the products, or such other source as was used to obtain the information; and
 - c. Provide exact information about the origin or Internet location (URL and date accessed) of non-label information sources; and
 - d. Establish robust security and review measures to assure any such non-label information accurately represents the information about each listed product

⁸ Search performed on December 24, 2015 as an “Advanced Search” with all “ingredient categories” selected and only “NHANES” selected as a “Database” under “Product Information.”

prepared by the company that owns the product (hereinafter “the brand owner”) in accordance with relevant labeling regulations.

Of the two above options AHPA considers the first greatly preferable. Users of the DSLD will assume the information presented for each listed dietary supplement product to be accurate and may even assume the brand owner provided the DSLD label information or reviewed the information for accuracy. When information in the DSLD is derived from sources outside the supplement brand owner’s control, such as third-party Internet resellers, it may be difficult or impossible to ensure that DSLD information accurately reflects the information the brand owner placed on its actual product labels.

Note also that AHPA is proposing elsewhere in these comments that consideration be given to creating additional fields to record information that does not appear on a supplement’s label. For example, AHPA proposes elsewhere in these comments that additional fields be created in the DSLD to accurately record the source of information for each listed dietary supplement and to record additional non-label information provided by a supplement’s brand owner.

3. Foreign products in the DSLD

According to the DSLD homepage the database contains the label content from a sample of “dietary supplement products marketed in the U.S.”⁹ It is AHPA’s understanding that this statement is intended to both inform users as to the identity of the contained information and to limit DSLD information to only products labeled for marketing in the United States as dietary supplements under U.S. law.

AHPA has identified, however, several DSLD-listed products that provide labels in the “View Label” link on the relevant pages to products not labeled for marketing in the U.S. Examples include the following; the access date for all identified links was December 23, 2015:

- SimplyBest VitaMen Plus; posted at <http://www.dsld.nlm.nih.gov/dsld/docs/22587.pdf>. The product is labeled in English, provides an address and a website in the U.K. and identifies the parent company as Simply Supplements. The label does not include the

⁹ <http://www.dsld.nlm.nih.gov/dsld/index.jsp>; accessed December 23, 2015.

following label details as required for a dietary supplement: a U.S. domestic address or phone number; the word “supplement” on the principal display panel; or a Supplement Facts box. There are a total of sixteen products listed in the DSLD under the brand “SimplyBest” and an additional 104 (one hundred four) under the brand “Simply Supplements” with the same U.K. address. While AHPA has not reviewed all of these labels, those that were reviewed have the same label details as identified above for the apparently representative product marketed by this company, and so do not appear to be labeled for marketing as dietary supplements in the U.S.

- Quest Preventative My Little Sunshine 50 mL; posted at <http://www.dsld.nlm.nih.gov/dsld/docs/24043.pdf>. The product is labeled in English and French, identifies the company as SunOpta, Inc. (“a proud Canadian company”), provides an address in Canada, and displays an NPN (Natural Product Number), as is required for natural health products sold in Canada. However the label does not include the following label details as required for a dietary supplement: a U.S. domestic address or phone number; the word “supplement” on the principal display panel; or a Supplement Facts box. There are a total of 74 (seventy-four) products listed in the DSLD under the brand “Quest.” While AHPA has not reviewed all of these labels, those that were reviewed have the same label details as identified above for the apparently representative product marketed by this company, and so do not appear to be labeled for marketing as dietary supplements in the U.S.

As noted previously, AHPA has not performed an exhaustive review of all labels included in the DSLD. The examples presented above are therefore presented as merely representative of the issue of inclusion of foreign products in the DSLD and AHPA has no knowledge as to the extent of this practice. Irrespective of the extent of such practice, AHPA recommends the DSLD be modified to implement either of the following:

1. Refrain from listing products in the DSLD that are not dietary supplements labeled for marketing in the U.S. and retain the current statements on the site that state all listed products are dietary supplements; or
2. If products that are not labeled for marketing in the U.S. will continue to be included in the DSLD:
 - a. Provide text throughout the DSLD that accurately describes that the database contains information about both dietary supplements and other products sold in

other countries that are similar in nature but not, in fact, labeled for marketing as dietary supplements in the U.S; and

- b. Add a field for each listed product to disclose, when known or obvious to DSLD, if a product is one that is not labeled for marketing in the U.S.

4. Direct submission of labels by supplement marketers

As noted in the prefatory remarks in these comments, AHPA announced earlier this year that its Board of Trustees had acted to encourage AHPA's member companies that market dietary supplement products under their own brands to submit labels for inclusion in the DSLD. AHPA has been informed that numerous of its member companies have submitted labels to the DSLD, including some who had done so prior to this action by the AHPA board. Several of these companies have communicated that their purpose for submission of labels was to correct listings of their products that were outdated or simply erroneous.

AHPA believes that a supplement label submitted to the DSLD by the brand owner will necessarily be most accurate and most able to provide current information that may be of interest to users of the DSLD. AHPA therefore believes that the DSLD should include a field where the source of the label is identified, e.g., "brand owner supplied;" "purchased at retail" with the specific retail location and date of purchase identified; "purchased online," with the specific online location, including URL, and date of purchase identified; "label provided by [named party]," with the specific name of the individual or institution that provided the label specified along with the relevant date; "website screenshot," with the specific online location, including URL, and date of recording identified; etc. Such information, even though it would not "come from dietary supplement labels," would already be available to DSLD, would provide accurate information about the source of information for each listed product, and may be of importance to DSLD users.

AHPA also recommends the DSLD implement effective mechanisms to identify and maintain the currency of contained information for labels submitted directly by the brand owner. AHPA recommends that when a brand owner submits a label that it identifies as the most current version of a DSLD-listed label, that label be the one entered and maintained for that product and any previously posted label be removed or archived.

Dietary supplement brand owners that submit labels to the DSLD may want to provide additional information about their products other than that which appears on their products' labels. Such information may be useful to DSLD's users, and AHPA therefore recommends new fields be created in the DSLD to record such information, which may include, for example, membership in one or another trade association or other organization; certifications obtained by the brand owner, for example for its manufacturing facility; registration or marketing of the same product in other countries; publication of research on its listed product or ingredients therein; etc. Each product entry in the DSLD currently includes a statement to the effect that the information provided is that present on a label "on the date that the data was entered on [date recorded]" ¹⁰ and some similar statement could be provided to ensure users know that such extra-label information was accurate on the date submitted by the brand user.

5. Organization and content

AHPA offers the following specific suggestions to ensure that DSLD content is readily searchable and the information contained for each listed dietary supplement is of greatest benefit to users.

5.1. Inclusion of off-market products. The DSLD currently includes both labels of dietary supplements that are believed to represent currently marketed products ("DSLID On Market products") and labels for products that are no longer available for purchase in the U.S. ("DSLID Off Market products").

AHPA understands ODS considers the inclusion of off-market labels to be of potential value to users that want to match research on consumer supplement use practices to actual products marketed at the time such research is conducted and the ingredients contained in those products at that time. But several AHPA members have communicated their experience in submitting labels to the DSLD database to provide the most up-to-date information, to correct errors in earlier listings, or to remove extraneous and unauthorized information provided by,

¹⁰ See, for example, the webpage listing the products identified as Bayer HealthCare – ONE A DAY(R) Maximum (<http://www.dslid.nlm.nih.gov/dslid/prdInfo.jsp?id=9735>; accessed December 23, 2015). In the course of preparing these comments AHPA staff has reviewed numerous product webpages and finds the same description on each such page.

for example, online third-party resellers. Under the current DSLD system these earlier erroneous labels and extraneous information would still be available as “DSLID Off Market” products¹¹ and readily located with searches of the database.

AHPA therefore suggests that information about “DSLID Off Market products,” if accurate at the time of posting, be moved to a separate archival section of the DSLD to avoid confusion with “DSLID On Market products,” and that access to such old labels be available only through requests submitted to the operator of the DSLD.

5.2. Removal of inaccurate information. AHPA further recommends that any labels or label information in the DSLD that is identified by the brand owner as erroneous or unauthorized extraneous information be completely removed from the database at the brand owner’s request. AHPA sees no value in retaining erroneous information on the DSLD and believes continued inclusion of such inaccurate information is likely to mislead users and thereby undermine the usefulness of the DLSD and be actively counterproductive to the DLSD’s stated purpose. If such information cannot be deleted from the DLSD then at a minimum it should be prominently flagged as having been identified as inaccurate by the brand owner.

5.3. Precision of information on intended users. The “Product Information” tab on each product page includes among other information a field in which the product’s “intended target group(s)” is identified. There are four options for this field: adults and children 4 and more years of age; children less than 4 years of age; infants; and pregnant and lactating women.¹²

A similarly named field, “Attributes, including intended target groups,” is found on some but not all products’ “Label Statements” tab. This field is apparently only visible and populated if a product is labeled with one or another phrase, such as “Not intended for use by persons under the age of 18,” that is intended to limit the product to adult use.

¹¹ AHPA is aware of numerous instances of off-market products represented as “DSLID On Market” and believes this to be due to lack of currency of information about these products.

¹² AHPA understands this field uses LanguaL coding language (used for food research purposes) but believes this “structured” and “controlled” vocabulary limits the data field options and renders the search options inaccurate or confusing for most users.

For the listing of such an adult use-labeled product the following information will be available to users of the DSLD:

- An image of the actual label including the statement, “Not intended for use by persons under the age of 18”;
- The following information in the “Intended target group(s)” field in the “Product Information” tab: “Human consumer, four years and above”;
- The following information in the “Attributes, including intended target groups” in the “Label Statements” tab: “Adult (18 – 50 years);” note this reference to “50 years” need not appear on the product label in order to be included in this statement, and in fact AHPA has not been able to locate a single supplement label that instructs against use after the age of 50 years.

Presentation of these three separate age-related details for the same product is likely to confuse DSLD users. Similarly, the four basic options given under “intended target group(s),” are likely to confuse and/or mislead DSLD users, since the categories do not accurately correspond to the target populations identified on the actual product labels.

AHPA therefore recommends the DSLD data fields be revised to remove any such possible confusion. AHPA strongly recommends that in making such revisions precedence be given to presenting the exact information provided on a product label on presentation of age-related information. AHPA notes that such an approach would be consistent with the stated policy of having all information about listed products “come from dietary supplement labels.”

5.4. Product certification. The “Label Statements” tab includes a field identified as “Seals/Symbols.” Information placed in this field includes, for example, “USDA Organic,” “USP Verified,” “NSF Certified for Sport,” “Kosher,” “Halal,” “Certified Vegan,” etc. Many of these label statements may require certification by a private or government-authorized organization in order for the related seal to be present on product labels.

AHPA believes the word “certification” is more communicative to DSLD users than the words “seals” or “symbols” and therefore recommends this field be renamed to include the word “certifications.” As a further possible improvement for communication of pertinent certification information, AHPA alternately recommends creation of two or more separate fields. One field

could, for example, identify label markings that require or indicate certification by some third party (for example, “Third-Party Certifications”) and another could be used for markings that indicate the brand owner’s assertion of a particular quality (e.g., “Other Seals/Symbols”). Furthermore, the information presented through label seals and symbols could be organized into conceptual categories, such as, for example, “Manufacturing Seals and Certifications;” “Religious Seals and Certifications;” “Dietary Seals and Certifications;” etc.

AHPA also notes the description provided on the DSLD site for its current “Seals/Symbols” is not entirely accurate. This description states, in part, “The presence of such a seal does not have to be approved by any government agencies nor are any assertions that accompany such a seal necessarily verified by a government agency.” While this may be accurate for most of the seals and symbols now identified in this field, it is inaccurate for any supplement that is labeled as “USDA Organic” or “Made with Organic Ingredients,” since the USDA National Organic Program (NOP) regulates all such labeling, including on dietary supplements, under Title 7, Part 205 of the Code of Federal Regulations. AHPA therefore recommends that either the DSLD description of the “Seals/Symbols” field be revised or that NOP-compliant organic labeling be identified in a separate field.¹³

5.5. Product forms. AHPA notes that searches conducted of the DSLD for a commonly used ingredient may return very large numbers of records. Some users may be most interested in only obtaining records for supplement products that contain the target ingredient in one particular product form, such as tablet, capsule, soft gel, gummy, powder, or liquid. AHPA therefore suggests that the DSLD have a simple and readily accessible mechanism to indicate the product form when conducting a search of the labels included in the database.¹⁴

5.6. Listings of several SKUs of the same product. AHPA notes that searches of the DSLD return multiple records for the same dietary supplement if the same product is available in several

¹³ Furthermore, if foreign products continue to be listed in the DLSD, then the “Seals/Symbols” field similarly should not disclaim any foreign government-verified seals, such as the “blue S” symbol for approval by the P.R.C. government’s General Administration of Quality Supervision Inspection and Quarantine which appears on certain Chinese-made dietary supplement-type products, or the “NHP-number” symbol required by the Canadian government for Natural Health Products.

¹⁴ AHPA recognizes that it is, to a limited extent, possible to search the DSLD by product form using the advanced search option, but believes the options there are insufficiently detailed and are too difficult to find and use for the average user.

package sizes (i.e., SKUs or shelf-keeping units). A user may therefore find two or three or more listings for the same product where the only difference is in the package size. AHPA therefore requests that the DSLD search function be modified to have searches return a single listing to indicate a unique product and provide separate links within that listing to the labels of the various product package sizes.

6. Current contractor's use of data

AHPA is aware that the current third-party contractor that manages the DSLD uses the information in the site, including the information provided voluntarily by brand owners, to support the content of certain of its privately-owned for-profit products which are made available to customers on a fee basis. AHPA suggests that if this practice is allowed to continue brand owners be explicitly informed of this extra-DSLD use prior to their submission of labels or other information for inclusion in the DSLD.

Conclusions

As previously noted, AHPA members have a strong interest in the DSLD functioning effectively to provide users with accurate labels and other information about dietary supplements. AHPA has publicly encouraged its members that market dietary supplement products under their own brands to submit labels for inclusion in the DSLD.

AHPA has also publicly recommended that improvements be made to the accuracy of DSLD entries. The present opportunity to submit comments to ODS has provided AHPA a forum to present specific recommendations for some such improvements and restate its view that the DSLD be redesigned to provide only currently marketed labels through public access.

AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,



Michael McGuffin
President, American Herbal Products Association
8630 Fenton Street, Suite 918
Silver Spring, MD 20910
(301) 588-1171 x201
mmcguffin@ahpa.org



Anthony L. Young
General Counsel, American Herbal Products Association
Kleinfeld, Kaplan and Becker, LLP
1850 M Street, N.W., Suite 900
Washington, DC 20036
(202) 223-5120
ayoung@kkblaw.com