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## Using the Dietary Supplement Label Database to Identify Potentially Harmful Dietary Supplement Ingredients

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### Abstract

Over half of young adults, athletes, and Military Service Members self-report using at least one dietary supplement (DS) 1 or more times per week. DS may be consumed to improve health, provide more energy, increase muscle strength, and/or enhance performance. The United States Food and Drug Administration (FDA) has raised concerns regarding adulteration, safety, and adverse events associated with DS marketed for brain health and bodybuilding. Some DS products may compromise health as well as lead to a serious adverse event. The National Institutes of Health (NIH) Dietary Supplement Label Database (DSLD), available at <https://dslid.nlm.nih.gov/>, can be freely accessed and used by researchers, providers, and consumers alike to screen for potentially harmful DS. It was developed to serve the research community and as a resource for health care providers and the public. Herein we provide two examples of how the database can be used to identify DS ingredients of concern in products marketed for brain health and bodybuilding. The search for DS marketed for brain health returned 49 unique DS, and the search on DS marketed for bodybuilding returned 18 unique DS. Search results were cross-referenced with the Operation Supplement Safety High-Risk Supplement List, the FDA Tainted Products Marketed as Dietary Supplements list, the Natural Medicines database, and NIH Office of Dietary Supplements Fact Sheets. Three ingredients found in DS marketed for brain health and two ingredients in DS

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marketed for bodybuilding were identified as “of concern”. Educational tools, including the DSLD, can help consumers and providers make informed decisions regarding DS.

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## Introduction

More than half of young adults (66%), athletes (55–64%), and Military Service Members (55–74%) self-report using dietary supplements (DS).<sup>1–3</sup> Individuals report using DS for any number of reasons including to improve health, provide more energy, increase muscle strength, and/or enhance performance.<sup>1–3</sup> Compared with nonusers, DS users are more likely to participate in physical activity to increase muscle mass.<sup>3,4</sup> Since 2007, the United States (US) Food and Drug Administration (FDA) has found that over 800 DS products, especially those marketed for weight loss, bodybuilding, and sexual enhancement, contain undeclared drug ingredients, steroids, steroid-like ingredients, and/or stimulants.<sup>5</sup> Such DS may compromise not only health and performance, but also may lead to a serious adverse event and/or produce unwanted urinalysis test results for athletes, Military Service Members, or individuals in public safety related occupations (e.g. law enforcement, truck driving). **A new tool that can be used by researchers and providers to identify potentially harmful DS products is the National Institutes of Health’s (NIH) Dietary Supplement Label Database (DSLSD; <https://www.dsld.nlm.nih.gov/dsld/>).** The DSLSD is an open-access website that provides full label information for many DS marketed in the US in a searchable format.

## Searching DS on DSLSD

The FDA estimates that more than 85,000 DS are currently available on the market in the United States, of which approximately 76,000 are cataloged in the DSLSD. The end goal of the DSLSD is to consolidate information on all DS sold in the United States into a single web-based repository accessible to consumers and researchers at no charge. Consumers, including young adults, athletes, Military Service Members, and healthcare providers, can utilize several features on the DSLSD to risk stratify DS. The *Search* feature on the homepage allows users to search for any text on a DS label. Search results are sorted in alphabetical order based where the search term appears on the label under the following Label elements: Product(s), Ingredient(s), Brand(s), Manufacturers, distributors, or packagers, and Anywhere. Consumers can also cross-reference search results from the DSLSD with the Operation Supplement Safety High-Risk Supplement List (OPSS HRSL) and the FDA Tainted Products Marketed as Dietary Supplements list to identify DS of concern. Further, providers may utilize results from the *Search* function to identify DS ingredients that may interact with medications, laboratory results, and/or other DS. Researchers will likely find the *Advanced Search* feature more useful than the general *Search* function. The *Advanced Search* feature enables users to search keywords under the following six headings: Ingredients, Ingredient Category, Product Names, Category Codes (LanguageL™ Codes<sup>6</sup>), Label Statements or Health Claims, and Manufacturer, Distributor or Packager. With the exception of Ingredient Categories and Category Codes, up to five search fields may be included within each of the other headings. Search results can be downloaded as either a

Microsoft Excel data (.xls) or comma-separated value (CSV) file to aid in analysis. The DLSD offers many features that consumers can utilize to risk stratify DS.

The objective of the study was demonstrate the utility of the DSLD. This was accomplished by conducting two separate searches by using the DSLD to identify ingredients in DS that may pose a safety concern. The first search was conducted to identify DS products marketed for cognitive enhancement and brain health. The second search was conducted to identify DS products marketed for performance enhancement and bodybuilding. Subsequent search results were cross-referenced with the OPSS HRSL, FDA Tainted Products Marketed as Dietary Supplements list, Natural Medicines database, a commercial database that also includes assessments not only of safety but efficacy, and the NIH's Office of Dietary Supplements (ODS) Dietary Supplement Fact Sheets to identify ingredients that may pose a safety concern. The resources used to cross-reference the results were selected because they all provide evidence-based information regarding DS.

## Methods

### Search 1: DS products marketed for cognitive enhancement and brain health

We performed two separate searches in the DLSD (<https://www.dsld.nlm.nih.gov/dsld/>). The first search included terms commonly associated with cognitive enhancement and DS marketed for brain health. Terms were derived from an internet search on DS touted to improve cognitive health. Within the DSLD, the *Advanced Search* function is accessed by clicking *Search* on the menu bar located on the top left-hand side of the page. A drop-down menu will appear that allows users to search across a maximum of six search fields at one time: Table 1 provides an overview of the advanced search options. We started by clicking on *Search by Label Statement or Health Claims*. This yields a screen with two options: *Select* and *Label Statement or Health Claims contains* with the ability to add up to five different search terms. We sequentially typed in four search terms - neuro, brain, cognitive, and omega – into the *Label Statement or Health Claims contains* field, clicking add after each search term, with “must include,” for the first three *Select* options and “exclude” for omega. Finally we clicked “Search” on the bottom right-hand side of the webpage to obtain the results of our search. Table 2 presents the final search criteria.

### Search 2: DS products marketed for performance enhancement and bodybuilding

Before beginning a new search, click “Clear All” located on either the top or bottom right-hand side of the page. For our second search we used a slightly different approach. From the *Advanced Search* function we clicked on *Search by Ingredients*. For this search, under *Select* we chose “must include,” under *Ingredient Name* typed in “anabolic”, under *Location* chose “Supplement Facts Panel.” We clicked on “Add,” under *Select* chose “may include,” under *Ingredient Name* typed “prohormone,” and under *Location* chose “Supplement Facts Panel,” and clicked “Search.” This yielded 191 DS so we further refined by clicking on “Revise search parameters” located at the top left-hand side of the page. We added two additional terms, “iol” with “must include,” and “ione,” with “may include” with both on the “Supplement Facts Panel.” For all search terms, nothing was added under *Amount Per Serving*. Finally we clicked “Search” on the bottom right-hand side of the webpage to obtain

the results of our search. Terms were derived from an internet search on DS products marketed for bodybuilding. Table 3 displays the final search criteria for this approach.

## Identifying potentially harmful dietary supplement ingredients

Full label information for all DS was downloaded as a single .xls file and imported into Microsoft Excel for analysis. Search results were further cross-referenced with the OPSS HRSL (<http://www.opsshighrisksupplementlist.org/>), the FDA Tainted Products Marketed as Dietary Supplements list ([https://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted\\_supplements\\_cder](https://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder)), Natural Medicines database (<https://naturalmedicines.therapeuticresearch.com/>), and NIH's ODS Dietary Supplement Fact Sheets (<https://ods.od.nih.gov/factsheets/list-all/>) to identify ingredients that may pose a potential safety concern. The OPSS HRSL and FDA Tainted Products Marketed as Dietary Supplements list are tools to assist healthcare providers and consumers identify DS products that could pose a risk to health, both are open access. The OPSS HRSL and FDA Tainted Products Marketed as Dietary Supplements list also identify some DS products that have been found to contain undeclared DS ingredients, which can help healthcare providers identify possible adverse interactions. Natural Medicines database is a subscription-based website that provides evidence-based information on the safety and efficacy of DS ingredients and alternative therapies. As part of a collaboration between Natural Medicines database and OPSS, individuals with .mil/email address can sign up for free access to Natural Medicines database via <http://info.therapeuticresearch.com/dod>. NIH's ODS Dietary Supplement Fact Sheets are available free of charge and are available as a consumer version as well as more a detailed healthcare professional version and include a variety of DS ingredients.

## Results

### Cognitive enhancement and brain health

Initial search results for DS products marketed for cognitive enhancement and brain health yielded 63 products. Thirteen were removed due to multiple flavors of the same product or duplicate entries, and one product was removed because it did not contain complete label information, which left 49 unique DS. None of the 49 unique DS appeared on the OPSS HRSL or the FDA Tainted Products Marketed as Dietary Supplements list. Further analyses revealed five common ingredients including phosphatidylserine (20/49), ginkgo biloba (13/49), acetyl-L-carnitine (12/49), huperzine A (10/49), and vinpocetine (9/49). One or more of these ingredients were present in 63% (31/49) of the supplements. **Table 4** presents a brief overview of the five common ingredients. Each of the five were further cross-referenced with the Natural Medicines database and NIH's ODS Dietary Supplement Fact Sheets.

### Performance enhancement and bodybuilding

The second search focused on performance-enhancing and bodybuilding supplements. Initial search results yielded 191 DS products; however, after refinement, including the addition of 2 more search terms ("must include" *iol* and "may include" *ione*), 25 DS were identified.

Seven products were removed due to multiple flavors of the same DS, which resulted in 18 unique DS. None of the 18 unique products appeared on the OPSS HRSL or the FDA Tainted Products Marketed as Dietary Supplements list. Nearly all (17/18) supplements contained plant extracts claiming to be anabolic/prohormone products and included terms such as “Testosterone Support Complex,” “Male Performance Blend,” “Anabolic Blend,” “Anabol-5,” “Non-Steroidal Anabolic Stack,” “Muscle Stimulator Blend,” and other such blends or complexes (see **Table 5** for common plant derived ingredients reported on the labels for products marketed for performance enhancement and bodybuilding).

### Potential concerns stemming from the case studies

From the current searches DS ingredients of potential concern emerged. **With regard to cognitive enhancement and brain health products, three ingredients—vinpocetine, huperzine A, and picamilon—are potentially problematic.** According to the Natural Medicines database, vinpocetine and huperzine A “stretch the definition” of a DS because they are synthetic ingredients and have undergone extensive chemical purification with properties similar to purified drugs. Long-term studies (>12 wks) to evaluate the safety of these dietary ingredients are also lacking.<sup>7</sup> Subsequently, in 2016 the FDA tentatively concluded that vinpocetine does not meet the definition of a dietary ingredient, which would exclude it from being sold as a DS ingredient.<sup>8–10</sup> Picamilon is used as a prescription drug in Russia to treat a variety of neurological conditions; however it is not approved as a drug in the US. According to FDA, picamilon does not meet the statutory definition of a dietary supplement ingredient.<sup>11</sup> As a result, products containing picamilon and marketed as dietary supplements are considered misbranded.

According to the Natural Medicines database, **two ingredients identified in the bodybuilding and performance enhancement analysis, 1,3-dimethylamylamine (DMAA) and yohimbe, pose a safety concern.**<sup>7</sup> DMAA is a synthetically produced stimulant that has been linked to psychiatric disorders, cardiovascular problems, nervous system disorders, and death.<sup>12–14</sup> In 2013, FDA declared that dietary supplements containing DMAA are illegal.<sup>15</sup> Yohimbe has been associated with serious adverse effects including cardiac arrhythmia, agitation, myocardial infarction, and seizure.<sup>7</sup> For many of the other ingredients found in DS marketed for bodybuilding and performance enhancement, **little or no data are available on the safety and/or efficacy of these combinations of multiple ingredients.**<sup>7</sup> Further, FDA has urged consumers to avoid using DS marketed for bodybuilding or claiming to contain steroid and steroid-like substances due to the risk of serious liver injury and other adverse health consequences.<sup>16</sup> Based on previous work from our group and others, the label is not always accurate and any one of the products could have contained illegal anabolic steroid ingredients, drug analogs, and/or synthetic stimulants.<sup>17–19</sup> Such information would not be captured by the DSLD.

### Limitations of the DSLD

A limitation of the DSLD is a lack of integration with other databases. Currently, users must cross-reference search results with other databases to identify potential ingredients of concern. Also, it is not known what proportion of DS appearing on FDA Tainted Products

Marketed as Dietary Supplements list also appear in the DSLD. Although not a downloadable app, the 2008 DSLD was re-designed, re-engineered and re-released in 2017 with an improved graphical user interface, improved search functionality, and in a 'mobile friendly' format to better serve access from tablets and phones. Nevertheless, the DSLD fills a much needed gap for consumers, healthcare providers, and researchers to have free access to label derived information for nearly all DS sold in the US. Finally, many DS sold over the Internet marketed for brain health and bodybuilding are still not captured in the DSLD

## Conclusion

DS will continue to be popular with young adults, athletes, and Military Service Members, especially among those seeking to enhance their health and fitness. Our objective was to demonstrate how the DSLD could be used to identify potential DS ingredients that may pose a safety concern. We successfully utilized the DSLD to rapidly search approximately 76,000 DS labels and identified three ingredients that pose a safety concern in DS marketed for brain health and two ingredients in DS marketed for bodybuilding.

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**Table 1.**

Descriptors/Categories for “Advanced” Searching

Search by Ingredients
Search by Ingredient Category
Search by Product Names
Search by Category Codes (LanguaL)
Search by Label Statement or Health Claims
Search by Manufacturer, Distributor, or Packager



**Table 2.**

Search criteria used to identify dietary supplements marketed for cognitive enhancement and brain health under “Search by Label Statement or Health Claims.”

Select	Label Statement or Health Claims contains
Must include	neuro
Must include	brain
Must include	cognitive
Exclude	omega

**Table 3.**

Search criteria used to identify dietary supplements marketed for performance enhancement and bodybuilding under “Search by Ingredients.”

Select	Ingredient	Location	Amount Per Serving
Must include	anabolic	Supplement Facts Panel	Not Applicable
May include	prohormone	Supplement Facts Panel	Not Applicable
Must include	iol	Supplement Facts Panel	Not Applicable
May include	ione	Supplement Facts Panel	Not Applicable

**Table 4.**

Descriptions of the 5 common ingredients found in supplements marketed for cognitive enhancement and brain health.

Ingredient	Descriptions
Acetyl-L-Carnitine	A derivative of the amino acid, L-carnitine. L-carnitine transfers long-chain fatty acids into the mitochondria so they can be used to produce energy via beta-oxidation. Purportedly used to treat Alzheimer's disease, age-related cognitive impairment, and male infertility. <sup>7</sup>
<i>Ginkgo biloba</i>	A tree native to Asia. Leaf extracts are purportedly used to treat cognitive impairments, dementia, and memory loss. <sup>7</sup>
Huperzine A	An alkaloid derived from Chinese club moss, <i>Huperzia serrate</i> . Purportedly used to improve inflammation, swelling, mental illness, and cognitive deficit. <sup>7</sup>
Phosphatidylserine	Derived from plants and animals, it is a phospholipid consisting of a glycerol backbone with a serine attached through a phosphodiester linkage to the third carbon of the glycerol and 2 fatty acids attached to the first and second carbons. Highly concentrated in bovine brain cortex; due to risk of "bovine spongiform encephalopathy," is currently derived from soybeans or cabbage. Purportedly used to improve cognitive function and athletic performance and treat Alzheimer's disease, attention deficit-hyperactivity disorder, and depression. <sup>7</sup>
Vinpocetine	A synthetic compound derived from vincamine, <i>Vinca minor</i> L plant, or Voacanga seeds. Purportedly used to improve brain function, visual acuity, memory and focus, and weight loss and/or fat loss, and increase energy. <sup>7</sup>

**Table 5.**

Selected plant derived ingredients found in products marketed for performance enhancement and bodybuilding

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Chrysin
<i>Diindolylmethane</i> (DIM)
<i>Epimedium grandiflorum</i> (horny goat weed)
<i>Eurycoma longifolia</i> (Eurycoma)
Isoflavones
<i>Mucuna pruriens</i> (Cowhage)
<i>Prunus africana</i> (African plumb tree)
<i>Rhodiola rosea</i> (Roseroot)
<i>Tribulus terrestris</i> (Puncture vine)

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